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Performance Audit Report

Essential List of Medicines

Prishtina, November 2018

The National Audit Office of the Republic of Kosovo is the highest institution of economic and financial control which, according to the Constitution and domestic laws, enjoys functional, financial and operational independence.

The National Audit Office undertakes regularity and performance audits and is accountable to the Assembly of Kosovo.

Our Mission is to contribute to sound financial management in public administration. We perform audits in line with internationally recognized public sector auditing standards and good European practices.

The reports of the National Audit Office directly promote accountability of public institutions as they provide a base for holding managers' of individual budget organisations to account. We are thus building confidence in the spending of public funds and playing an active role in securing taxpayers' and other stakeholders' interests in enhancing public accountability.

Performance audits undertaken by the National Audit Office are independent, objective and reliable reviews that assess whether government actions, systems, operations, programs, activities or organizations comply with the principles of economy[1], efficiency[2] and effectiveness[3] , and whether there is room for improvement.

Auditor General has decided in relation to this report "**Esential List of Medicines**" in consultation with Assistant Auditor General Vlora Spanca, who has supervised audit.

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1 Economy - The principle of economy connotes minimising the cost of resources. Resources used should be available on time, at the right quantity and quality and with best price

2 Efficiency - The principle of efficiency connotes securing the most out of available resources and has to do with the relationship between the resources mobilised, and results given in terms of quantity, quality and time

3 Effectiveness - The principle of effectiveness connotes achievement of established objectives and expected results.

TABLE OF CONTENT

Executive Summary 5

1 Introduction 7

2 The role of ELM, process and responsible authorities 10

3 Key findings 12

4 Conclusions 22

5 Recommendations 24

Annex 1. Audit Criteria, Methodology, Scope and Limitations 26

Annex 2. Unplanned medicines for 2015 31

Annex 3. Unplanned medicines for 2016-2017 32

Annex 4. Sample list of Medicines supplied outside ELM 34

Annex 5. List of Medicines without Contract for 2017 35

Annex 6. Sample of the reporting method for medicines and days of delay until the reporting date 36

List of Abbreviations

CPh	Central Pharmacy
ELM	Essential List of Medicines
EO	Economic Operators
GH	General Hospitals
HIF	Health Insurance Fund
HIs	Health Institutions
HUCSK	Hospital and University Clinical Service of Kosovo
MoH	Ministry of Health
UCCK	University Clinical Centre of Kosovo
WHO	World Health Organisation

Executive Summary

The National Audit Office has assessed the management process of Essential List of Medicines for secondary and tertiary level starting from planning, delivery and monitoring. Through this list, it is intended to ensure that all citizens of Kosovo are provided with important medicines to which they are entitled to as basic right guaranteed. The responsible institutions for managing the Essential List are the Ministry of Health, Health Insurance Fund and Hospital and University Clinical Service of Kosovo.

The audit results have revealed that the responsible Institutions have failed to fully meet the intended goals through the Essential List of Medicines. The list is not managed effectively and efficiently. The process of planning, distributing and monitoring of medicines both of secondary and tertiary level has been followed by shortcomings. Consequently, citizens do not take the medicines they are entitled to when they need them. There are several reasons that have led to the failure to meet the objectives intended through the Essential List of Medicines.

Firstly, the Essential List of Medicines has not been updated since 2013 to comply with patient needs and the development of medical and pharmaceutical trends. Only for 2016 and 2017 around 30% of medicines from essential list are not planned or requested by any Health Institution. On the other hand, there are important medicines that are constantly requested but are not included in the list at all. These medicines are purchased from the hospitals and the patients themselves.

For 2015-2017, the University Clinical Centre of Kosovo has spent around 3.5m euros on medicines and consumables outside the essential list. In addition to data obtained from health care institutions on medicine spending within and outside the essential list, there is no statistical data on the expenditures incurred by the patients. These are sufficient indicators that the list should be updated according to the needs.

Secondly, due to inadequate planning, hospitals do not have medicines when they need them. Annual planning of medicines up to the final approval changes according to the available budget, but these changes are not documented which medicine is prioritised. As a result, changes have also been made in vital medicines, the effect of which could be fatal to the patient. In 2016 there is a vital medicine that is reduced to 74% of the initial planned amount.

Another factor that has led to lack of medicines is the delay in their delivery process. The process of filing a request starts with an average of 10 days for every quarter, which is followed by an even greater delay by Economic Operators, up to 240 days. Days of reported delays are from Gjakova Hospital, while other hospitals have not thoroughly reported on this issue. This because the way their reporting is not regulated. In addition, MoH did not impose any fine against Economic Operators until April 2017.

Further on, a number of medicines cannot be ordered due to failure to contract them in time. There is a no follow-up process in place for contract validity which would contribute to better supply with medicines and at the same time it will lead to timely start of planning the procurement process.

Thirdly, the Ministry of Health and Health Institutions do not monitor the medicine planning and delivery process. Lack of monitoring led to failure to identify weaknesses throughout this process. The Health Insurance Fund does not prepare monitoring reports to present the amount distributed in each quarter, the validity of contracts for each medicine on a continuous basis and the situation in terms of stocks at the end of each year. Further on, the functioning of the Health Information System would play its role to preparing these reports that would contribute to the process from planning to delivery. According to the audit report published by the National Audit Office in 2017, this system is not fully functional.

Recommendations

In order to make the planning, delivery and monitoring of Essential List of Medicines in line with the needs, we recommend the Ministry of Health, the Health Insurance Fund and the Hospital and University Clinical Service of Kosovo to:

- Update the Essential List of Medicines;
- Established technical committee, continuously would follow world pharmaceutical trends. The task of this committee should also be the analysis of types of medicines that are not part of the Essential List and carry out cost-effective analysis for medicines which should be part of this List;
- Ensure that annual planning of medicines is done equally by all health institutions. This should be done by drafting a standard operating procedure which would include the available budget, medicines on the basis of priority, stocks and other issues related to effective planning; and
- Establish a regular monitoring system in all Health Institutions. This monitoring includes all phases: planning, delivery, stocks and contract implementation process.

The response of parties involved in the audit

Ministry of Health, Health Insurance Fund and Hospital and University Clinical Service of Kosovo have agreed with audit findings and recommendations. We encourage institutions involved in this audit to make all effort to address given recommendations.

1 Introduction

People need medicines and medical treatment, which are provided by public and private sector. Providing full access to healthcare and medicines at all levels and to citizens as well as fair delivery of healthcare resources is one of the main objectives of the Ministry of Health (MoH). The Ministry of Health has within its structure built-up the respective administrative structures responsible for monitoring of quality and management of institutions at all levels of public health sector.

The Health Insurance Fund (HIF) is an Executive Agency overseen by the Government, which enjoys the rights, obligations, responsibilities and authorisations related to negotiation and contracting out services from the list of healthcare services and the list of medicines and medical consumables named as Essential List of Medicines (ELM).

Through the Essential List of Medicines, the MoH is able to supply Health Institutions with cytostatic, medicines and medical consumables.

First level of healthcare includes services provided by Main Family Medicine Centres with the constituent units defined by the sub-legal act issued by the Ministry.

Second level of healthcare includes General and Special Hospitals with its constituent units, defined by the sub-legal act issued by the Ministry, specialist polyclinics, specialist out-patient cares, dental clinics, mental health centres with the House for Community Integration, blood transfusion centre, physical and climatic rehabilitation centre, sports medicine centre, the Occupational medicine centre, the regional health centre and the centre for hearing and speech rehabilitation.

Third level of health care includes University Clinical Centre, dental clinic, National Institute of Public Health, the National Centre for Occupational Medicine, the National Centre for Sports Medicine, the National Blood Transfusion Centre and the National Telemedicine Centre. While pharmacies are health institutions that function in all three levels of health care.

Despite objectives and engagement of health sector structures, previous regularity audit reports (MoH and Hospital and University Clinical Service of Kosovo) ascertained weaknesses related to supply with medicines, which include poor planning, delays to submit purchase orders and poor monitoring of supply and pharmaceutical stock[4].

[4] http://www.zka-rks.org/wp-content/uploads/2017/07/RaportiAuditimit.MSH.2016.Shqip.863039.pdf
http://www.zka-rks.org/wp-content/uploads/2017/07/RaportiAuditimit.SHSKUK.2016.Shqip.701623.pdf
http://www.zka-rks.org/wp-content/uploads/2017/06/RaportiAuditimit.SHSKUK.2015.Shqip.473749.pdf

Many of the patients who seek treatments at public hospitals are often not served with medicines not only due to financial difficulties but also due to ineffective management in in planning, delivery and monitoring in all three levels of the healthcare organisation.

The issue of supply with medicines has been a topic covered in many cases in the respective Parliamentary Committees within the Assembly of Kosovo, in the country's media and civil society organizations covering the health sector.

Beside findings from regularity audit reports, media have also reported on problems related to medicines.

- "University Clinical Centre of Kosovo lacks 50 per cent of medicines from the essential list[5] and 65 per cent of consumable material"[6].
- Dozens of essential list[7] products are lacking in UCCK, almost every clinic is left without any medicine[8];
- Lack of medicines from the essential list in public health institutions continues to be concerning both for patients and medical staff[9].

The above mentioned reasons have served as indicators for this area to be audited, as the timely delivery of medicines and for all citizens is of high public interest and has wide social impact.

Audit Objective and Questions

The objective of this performance audit is to assess whether the ELM is managed in line with the needs of the patients. The recommendations from this audit report aim to improve the overall management of medicines through planning, delivery and monitoring. The aim is to examine whether it is possible to improve supply with medicines given the resources available.

Key Audit Questions are the following:

- Is planning of the ELM effectively managed and monitored?, and
- Is the system for delivery and monitoring of medicines being efficiently implemented?

The subject of this audit is the MoH, HIF and HUCSK. We have also included the secondary and tertiary level, where case studies were taken from the University Clinical Centre of Kosovo, General

[5] Essential list is a list that contains the types of medicines (cytostatic, essential and non-essential medicines) for all three levels of health sector

[6] http://www.kosovapress.com/sq/shendetesi/mungese-barnash-ne-qkuk-73656/

[7] Essential list is a list that contains the types of medicines (cytostatic, essential and non-essential medicines) for all three levels of health sector.

[8] http://www.gazetaexpress.com/lajme/qkuk-se-i-mungojne-mbi-40-lloje-te-barnave-esenciale-233248?archive=1

[9] http://archive.koha.net/?id=27&l=116722

Hospital of Prizren, Gjakova and Gjilan. This audit covers the fiscal period 2015-2017 including the planning, delivery and monitoring of ELM.

Detailed audit methodology, audit criteria, scope and limitations are presented in the Annex to this report (Annex 1).

2 The role of ELM, process and responsible authorities

The Essential List of Medicines is prepared to satisfy the priority of healthcare towards the patients. Medicines are selected in a list such as ELM to ensure that all basic medicines which save life-threatening patients, provide health safety and are available at any time and free of charge by public health institutions. The Ministry of Health through its technical committee prepares the ELM containing medicines that are in line with the needs of the patients. World Health Organisation has a long list of medicines serving as model list which should be tailored to the epidemiological profile of the region, the skills of the medical staff and the possibility of referral to a higher-level health institution.

ELM is composed of three categories:

- General medicines (vital, essential and needed) containing 289 types of medicines;
- Medical consumable material – 473 types of products; and
- Cytostatic- containing 58 types of medicines

All these medicines and consumable material are aimed to serve hospitalised patients within University Clinical Centre of Kosovo and General Hospitals.

An appropriate ELM is developed by Technical Committee comprised of professional staff. The base for adequate ELM is the clinical pathways whose primary objective is to cure a patient of his disease and to minimise the impact of that disease on both the patient and those around him (such as the risk of transmission). The clinical pathways contain diagnoses for every disease and the required treatment, assisting professionals in standardising the evaluation, diagnosis, and care of patients aimed at achieving optimal outcomes.

ELM is classified into three types of medicines according to their importance: vital, essential and necessary. Vital medicines are important and required to save lives, therefore clinics such as Emergency, Intensive Care, Surgery Rooms, etc., should be fully supplied since those are places where the availability of medicines should not be questioned at any moment. The essential medicines are those that are not necessarily needed and the third category covers needed medicines so that if there is a budget available, they can be provided by the responsible authority but if no budget is available, they would not cause vital problems for the institution. On the other hand, medicines of vital category require increased attention when it comes to their management, such as minimum stock, security stock, date of expiry, medication records, but also key phases of medicine management such as selection, procurement, delivery and use. Therefore, an additional attention should be paid to the medicines of this category[10].

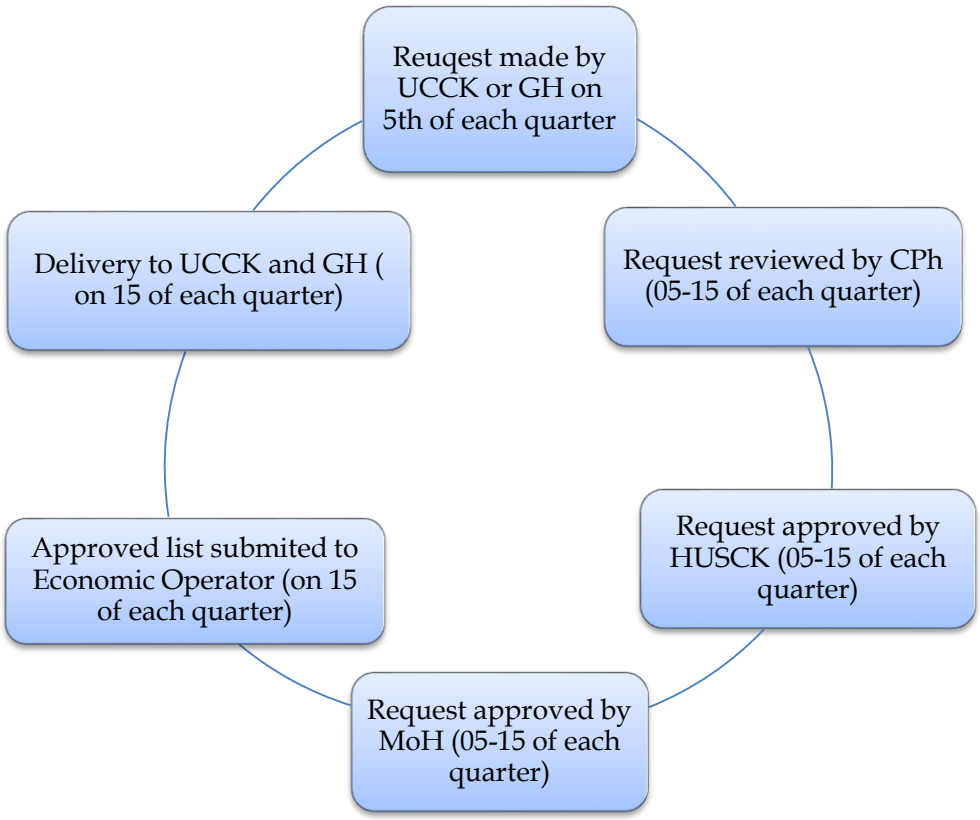
[10] EL Product Analysis for 2013 according to VEN and ABC Indicators, p10 (https://msh.rks-gov.net/wp-content/uploads/2013/11/Lista-Esenciale-sipas-VEN-dhe-ABC-Indikatoreve.pdf)

The ELM process is managed by HIF in close coordination with Hospital and University Clinical Service of Kosovo (HUCSK). An annual plan containing all the medicines and consumable material is prepared every year to be used during the coming year.

Chart 1. Process of Annual ELM Plan

The implementation process covering the annual plan consists of four quarters. The following chart introduces the process of each quarter based on the approved plan. Clinics within University Clinical Centre of Kosovo (UCCK) and General Hospitals (GHs) make a request for supply every quarter, including the calculation of stocks during these periods. Subsequently, the request is sent to the Central Pharmacy (CPh) who makes the review, and is sent to the HUCSK Director for approval. The request is then sent to the HIS which makes the final review and is then approved by the MoH. The list is sent to Economic Operators (EOs) who have 30 days to deliver all requested medicines.

Chart 2. ELM supply process



3 Key findings

This chapter covers the audit findings related to the management of the ELM in Public Health Institutions. Initially, findings on the management and updating of ELM and the prioritisation of medicines based on vital, essential and necessary categories are introduced. Findings regarding the annual planning process, delivery of medicines on a quarterly basis and their monitoring by responsible institutions are presented below.

3.1 Improper Management of Selecting Medicines and Failure to Update ELM

According to the World Health Organisation (WHO) and good practices, the Essential List of Medicines consists of medicines, cytostatics and consumables. The recommendation of WHO foresees that all states having such a health system should update this list at least every two years[11] in line with medical and pharmaceutical trends. Such a recommendation has not been implemented by responsible health institutions in Kosovo since ELM has not been updated since 2013.

[11] Selection of Essential Medicines, 2002 World Health Organization in Geneva http://apps.who.int/medicinedocs/pdf/s2296e/s2296e.pdf

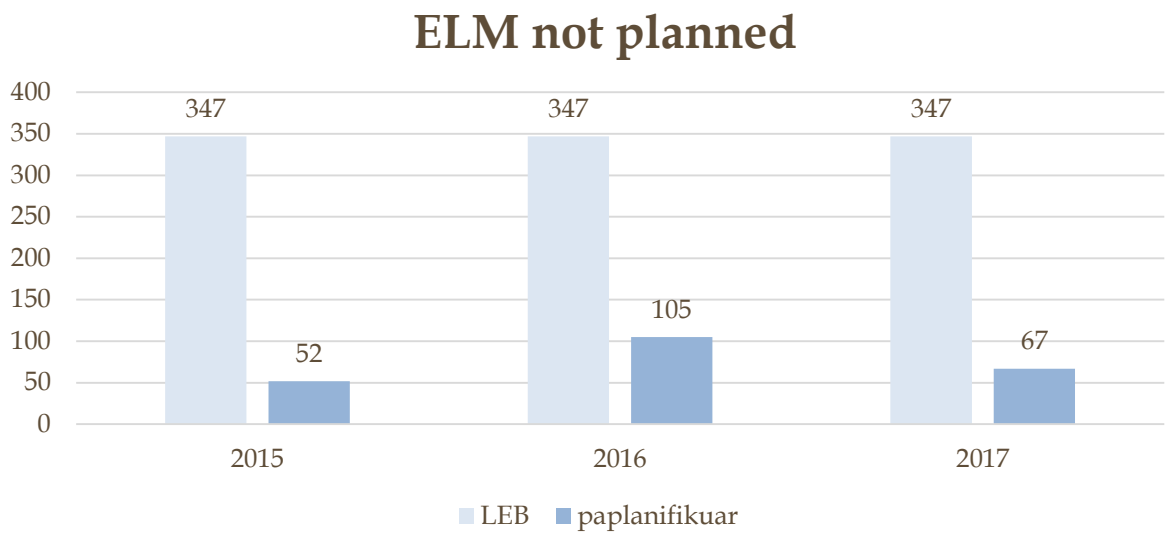
It is worth mentioning that an initiative was taken by the MoH, where a Technical Committee[12] was established for preparing a List of Medical Products and Consumable Materials, and a public call was initiated to the interested parties for providing a professional contribution to the revision of the essential list. This decision was taken in October 2018.

The ELM is the basis for good planning and resource allocation. It is therefore expected to correspond with current needs and aims to facilitate the process of providing essential medicines to hospitals and patients. However, the findings below indicate that ELM does not fully meet those objectives.

The update of ELM has proved to be more than necessary to meet the needs for treatment of patients. During the period 2015-2017 from the hospitals selected as sample, in average 30%[13] of medicines were not planned at all, which figure is a lower than expected (See Annexes 2 and 3).

The chart below provides an overview of medicines which are not included in the plan against the total.

Chart 3. The list of medicines not planned[14] by UCCK and GHs



Source: HSUCK, annual approved plans.

In addition to the number of medicines which were not planned over the years, this list is even more deficient due to the number of medicines requested but which have never been included by clinics and hospitals. From the interviews[15] in the field we understood that each ward within UCCK and GH has a list of important pharmaceutical products that have been prescribed to patients which are

12 Decision No. 45/18 on the Appointment of the Technical Committee, dated 04.10.2018
13 The percentage results from the average of unordered medicines over the years.
14 Unplanned implies also medicines that have not been requested over the years
15 interviews with Heads of Wards

not part of the ELM. Some of these medicines are purchased from budget of UCCK or GHs following separate procedures but there are cases where patients need to buy them using their own funds[16].

However, the evidence provided by the Central Pharmacy reveal that the request for review and update of ELM is sent year after year.

Based on the data provided, around 3.5 million euros were spent in UCCK for three audited years for medicines and medical consumables outside the essential list. During the interviews with doctors and chief technicians in wards of GHs[17] and UCCK clinics, we have understood that there are pharmaceutical products continuously purchased from their internal budget. Such lists have not been provided to us by other hospitals except UCCK (see Annex 4).

3.1.1 Lack of Clinical Pathways

Clinical pathways should be in use in order to have an ELM covering the needs of hospitalised patients which is defined as a process of systematic development that aims to facilitate medical staff on decisions for patient treatment and proper healthcare.

The Pathways are comprised of: clinical policies, procedures, protocols and guidance. These Pathways, in the furture should help the development of ELM which would include all diseases and its medical treatment using generic names by categorising its importance and alternative replacement. During 2018, MoH has published four Clinical Pathways[18] and four others are expected to be published by the end of 2018. These Pathways should be drafted for other diseases as well.

MoH did not establish a procedure which would facilitate in prioritising one medicine against another according to its importance in planning and did not document the process in line with available funds.

3.2 Difficulties of having a proper annual plan

Each year, the University Clinical Centre of Kosovo and General Hospitals draft plans for their annual needs. These plans aim to cover the needs of patients throughout the year. The process is organised and managed by HUCSK and the HIF and MoH.

The table below shows the budget allocated for medicines for the audited period and the budget changes for 2017.

Table 1. Budget for 2015-2017 period

[16] Interview with Head of Department at UCCK and GH, December 2017 up to February 2018

[17] Ibid.

[18] Prevalence and eclampsia management, Prevention and management of postpartal primary haemorrhage, Prevention and treatment of pre-cancerous cervical lesions, HIV testing services.

Budget for Supply with ELM (in €)			
	2015	2016	2017
Initial Budget	15,482,557	14,999,988	15,200,000
Final Budget	15,482,557	14,999,988	19,531,000

When the requests for medicines from the UCCK and the GHs are higher than the available budget, HUCSK and HIF request from relevant institutions (requesting units) to review these plans based on the allocated budget.

The plan, in some hospitals is prepared by the pharmaceutical department[19], while in some cases, the Director and the Head nurse[20] are the ones who draft the plan. No standards have been set to ensure common and rational planning by UCCK and GHs clinics.

In terms of calculating the needs, all hospitals have their own internal system, therefore, there is no integrated medicine registration system. Apart from the fact that there is no integrated system, the various systems found within HIs are not always used. The MoH has purchased a software application (Health Information System) that among others is intended to be used for registration of medicines, however this software application was not used in any of the clinics within UCCK, nor in two of the three audited GHs (only GH of Gjakova, has used it). According to the CPh and GHs, the software application does not provide opportunities to be used for the intended purposes, perhaps for planning of medicines for the following years, quantities delivered and stocks. A separate performance audit was carried out during 2017 covering software application to assess its condition[21], which according to the audit findings is not fully functional.

Therefore, every clinic in UCCK and GHs makes annual planning based on their knowledge and practice, while some also use the number of patients treated during the previous year, adding 10% (UCCK, GH Gjilan and GH Gjakova). The GH of Prizren uses another practice whereby annual planning is made using a statistical formula that included the standard deviation of the patients' calculations for the last ten years and the medical descriptions that were provided for the previous year as well as the stocks available.

The initial needs planned by these institutions do not coincide with the budget available. As a result, changes are made by the CPh in coordination with the clinic or hospital which makes the planning. According to the interviews conducted with all parties involved, we have been informed that changes and reduction is based on the importance of medicines, meaning that no vital medicine is reduced due to the importance. However, our analysis (Table 3) shows that when the plan was revised, this standard was not taken into account. As it can be seen in vital medicines (Vecuronium),

[19] Interviews with pharmacists in UCCK, GH of Gjilan, Gjakova and Prizren. December 2017 and January 2018

20 Interviews with Directors and Nurses of Clinics and Departments in UCCK, GH of Gjilan, Gjakova and Prizren. December 2017 and January 2018.

[21] http://www.zka-rks.org/wp-content/uploads/2017/12/Raporti_auditimit_-SISH_shq.pdf

the reduced percentage has reached up to 74% of the initially required quantity. Cases are presented in the table below.

Table 2. The revised plan in the UCCK and GH

2016					
Medicine	ELM/classification	Initial	Reviewed	Difference	Difference %
AMOXICILLIN + ACID CLAVULANIC	Essential	360	260	100	28
CEPHAZOLIN	Vital	173,720	138,720	35,000	20
CIPROFLOKSACIN	Vital	7,740	6,240	1,500	19
BENZYLPENICILLIN	Vital	54,950	50,450	4,500	8
GENTAMYCIN	Vital	129,704	108,704	21,000	16
AMPICILLIN	Vital	129,620	118,620	11,000	8
VECURONIUM	Vital	1,850	490	1,360	74
Total		497,944	423,484	74,460	15

For 2015, we were not provided with information on initial planning, which made it impossible to calculate the reductions of medicines, and for 2017, under the management decision of HUCSK, the planning was not revised but approved according to the needs and not the budget approved for ELM.

Although the final budget in relation to the initial budget has increased, we have once more noticed that the supply in hospitals was not according to the plan in any case. The reason for not supplying according to the plan was that the delivery was not timely or at all made or at by the EO, and the reason in some cases was the expiry of the contract.

3.2.1 Lack of Pathways for planning and prioritisation

No Pathways were drafted that would regulate the planning and prioritisation process for types of medicines which ensure that appropriate steps were taken during the annual planning. CPh has developed various procedures for management of medicines, but none of these relates to medicine planning process. Medicines that are part of the ELM that are categorised as vital by the World Health Organisation are Medicines that the need for them should be 100% due to their importance for human life, therefore there should be no cuts in this category.

In the CPh and pharmacies of General Hospitals, the responsible officials stressed out that the review of the plan was made based on the importance of the Medicines[22], but during our visit to UCCK clinics and various hospitals wards, the responsible officials confirmed that the same practice is not used when the annual plan was drafted. There are cases where the revision of the plan[23] has been rejected by hospitals and clinics, but in these cases the CPh has made changes/cuts in

[22] Interview with Head of Central Pharmacy in HUCSK, Doctors and Head Nurses in the Rheumatology, Emergency and Oncology Clinic, GH Heads in Prizren, Gjakova and Gjilan, December 2017 - February 2018

23 Interview with responsible officials at clinical pharmacies in UCCK, December 2017.

accordance with the budget. Reviewing plans without any guideline which would standardise the planning process may result in a lack of vital medicines that pose different risks to patients.

ELM also contains Medicines that for the three years covered by this audit were not contracted out by the MoH and hospitals were instructed not to include them in the plan. Some of these medicines for which MoH did not have a contract are vital to patients' life (See Annex 5).

3.2.2 Failure to standardise the process of submitting requests

The annual plan consists of four quarters, and the supply of medicines for each clinic in UCCK and GH is done on a quarterly basis. The timing and dates for starting the process according to the officials of the CPh are shown in the chart below.

Table 3. The timeframe of request initiation by UCCK and GH.

The figure above indicates the standard dates which according to CPh officials should be followed when initiating request per quarter but during the visits to GHs we have evidenced that the process is not initiated on these dates. The process starts only when the CPh informs all GHs and UCCK via electronic communication tools (email) for initiating the request for respective quarters. The request should ensure that the delivery time provides the patients with medicines when needed, but such a thing does not always happen. For example, for the second quarter, the deadline for receipt of requests should have been 15th of March, while the CPh itself has sent an email to initiate the requests on 16th of March, so the initiation of the requests started after the deadline has expired, which means at the beginning of initiation process, HIs are delayed by 15 days.

Based on the documents provided, the practice shows that the process of a request takes about ten days from its initiation up to the last approval in MoH. According to the contract, the economic operator is allowed a term of up to 40 days for each quarter in order for the medicines to be available to patients, and this does not include other delays that may occur. These delays occur in most cases especially when the stock is limited or there is no stocks at all.

Contribution to delays in the medicine delivery process has also been made by delays in entering into new contracts. The process of initiating procurement procedures is delayed and problems that may arise during the development of procedures were not anticipated.

3.3 Shortcomings in process of medicine delivery

Upon approval of the quarterly requests, the Procurement Department sends them to the EO to proceed with delivery to the requesting units[24]. The terms of the contracts include a deadline of 30-day deadline for the delivery of medicine from the EO, a period which in case of delayed approval of requests may result in delays in delivery of medicines to patients. Delays in approving requests or deliveries after the prescribed deadlines may lead to a shortage of medicines over several quarters, and having over-supply while in other quarters.

This implies that medicines are absent at the moment patients need them, and this leads patients to purchase medicines with their financial means.

We have noticed that the delivery process of pharmaceutical products in all healthcare institutions is done with many delays by EOs and in some cases those delays are reported by GHs and UCCK clinics. It is not that delays need any reporting standards, nevertheless each hospital reports in their own way. This causes difficulties in calculation of delays which is linked with penalties as foreseen in the contract.

As a consequence, we have identified delays up to 11 months where a number of medicines were not delivered to the requesting units, excluding the period allowed by the contract. The annual supply does not reach 100% and mainly due to the lack of timely delivery of the medicines by EO.

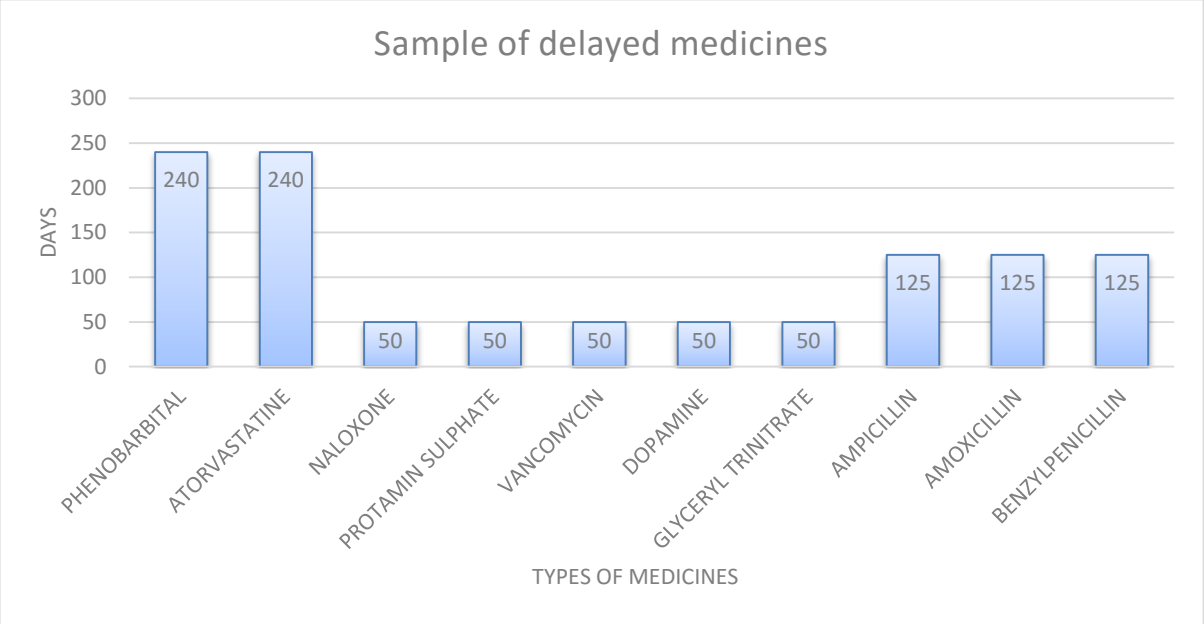
Although EOs have made partial supply or have not supplied medicines or medical consumables at all until April 2017, there is no evidence that these deviations have been analysed and adequate measures have been taken when imposing fines to EO in accordance with the contract. From the reports of delays received by the HIF we see that there are cases of delays of up to 240 days.

Furthermore, we have noticed that there is no reporting requirement for delays or non-deliveries. UCCK and GH of Prizren have regularly reported delays, but the reporting method used does not provide information on the days of delays. GH of Gjilan for three years reported delays only in one case. While the GH of Gjakova has provided more accurate information but still does not provide a complete picture allowing responsible institutions to take appropriate actions for these delays. All this occurred due to the lack of a request from HUCSK and HIF for reporting and failure to take any actions for reported delays.

The chart below shows the delays reported by GH of Gjakova, calculating the time from the request up to the delivery of medicines. (details are presented in Annex 6).

Chart 3. Delays of Medicines in GH of Gjakova

[24] Supply Contracts, Article 2/Delivery Terms



Source: data provided by GH of Gjakova.

Another factor that affects the delays in supplying medicines is the validity of contracts. There is no tracking process on contract that would identify in advance which contracts are on the verge of expiration[25].

In cases where MoH has failed to conclude new contracts or even follow the implementation of existing contracts with EO, the delivery of medicines and consumables has not been executed at all. Despite the fact that the requests in certain cases were urgent, they could not even contract the medicines in time to avoid delays.

We have not identified any good practice that the MoH and the HUCSK follow to manage the factors above that affect delays. A practice that has been told in the field work by all institutions is that there is an agreement between UCCK and GHs that in case there is a lack of medicines, they should supplement each other, borrowing whenever they are available.

3.4 Monitoring

Good monitoring means that the outcome on a regular basis is compared with plans, and this also means that there is a proper mechanism for monitoring the functionality of medicine cycle.

The table below presents the points where the HIF and HUCSK through monitoring ensure that the management of Essential List of Medicines is done properly.

Table 4. Points that monitoring should include

[25] Law on Health L no.04/125 obliges HIF to conclude and maintain contracts with economic operators, but this competence has not yet been transferred from MoH

Monitoring Process						
Initial Plan of Medicines	Plan Review	Plan Approval	Quarterly Requests	Medicine Delivery	Stock	Regular Reporting by Clinics and GH

Within the Central Pharmacy we have noticed controls in planning process, however there is no monitoring report in place on eventual changes[26] in planning. The process of requests and delivery is monitored through pharmacists' committee but also on ad-hoc basis[27]. Reports on the financial value, the stock verification and the execution of the requests per quarters are prepared from this monitoring. The abovementioned central pharmacy committees also prepare annual verification reports for clinic warehouses as needed[28].

According to the interviews with relevant officials[29] within the GHs, the registration and monitoring depends on wards, e.g. Emergency Wards carry out monitoring for the current supply based on the needs presented, while Dialysis Ward monitor the situation on a monthly basis. During the audit, we did not come across any monitoring reports which includes periodic financial, statistical or descriptive reports, documenting the progress of the process.

In the GH of Gjakova, for 2016 and 2017, it is reported according to quarters.[30] An analytical assessment report was prepared for 2015, which could also be considered as a monitoring report for planning, supply and consumption of medicines[31]. For 2015, a supplies report with percentages is also prepared[32]. However, this monitoring method was not applied for the next two years. It is worth mentioning that for 2016/17 the monitoring process has been transferred to the Quality Office which was established within the hospital for the purpose of monitoring and evaluation.

In GH of Prizren the annual reports are prepared in "Excel" and show the circulation of medicines, reconciling balances and annual supplies. These reports can also serve to monitor the situation. This reporting should be regular and on an annual basis in order to present the situation of medicines in all clinics and hospitals.

By the end of 2016, the responsibilities for medicine management have been transferred from the MoH to HIF. In order to have a clear and comprehensive overview of the course of the drug management process, HIF will need to carry out monitoring on all secondary and tertiary health institutions. During the audit in HIF, we came to a conclusion that they did not carry out any monitoring on medicine management nor were we provided with any evidence for such a process.

[26] Eventual changes imply as those in table no.3 of this report
[27] Verification reports financial values and dates of supply, 2015/16/17
[28] Reports for the verification of pharmaceutical stocks
[29] WP, Interview at Gjilan Regional Hospital, visits to pharmacy department 20-22.12.2017
[30] Quarterly reports of 2016/17
[31] Annual Report 2015, submitted to MoH on 08.01.2015
[32] Planning and supply in percent for 2015

The lack of an overall monitoring picture makes it impossible to have a realistic planning and management of the whole medicine process.

Lack of monitoring it is noticed also with delays of medicine deliveries. In continuity, SP and UCCK submitted complaints about delays of medicines, but due to lack of monitoring, until April 2017, no action ta has been taken by MoH and HUCSK to ensure that appropriate steps have been taken in order the supply is in compliance with requests.

Another obstacle that contributed to shortcomings in monitoring is the failure to fully put HIS into operation. This led to not having a clear picture of the course of the process in each stage and the medicine management process as a whole.

4 Conclusions

MoH, HIF and HUCSK do not manage this list well, resulting in a lack of medicines most of the time and as a result patients should purchase them themselves. Further on, key audit conclusions are the following:

- ELM has never been updated during last five years and as a result we have identified a large number of medicines part of this list that have not been ordered by any clinic within UCCK or GH (around 30%), and at the same time different types of medicines have been identified that are requested and purchased by hospitals but were not part of ELM.

- Life-saving vital medicines are reduced for budget reasons without any criteria in place. The planning process does not have a standard calculation form. Data during visits to the CPh indicate that medicine prioritisation in accordance with the budget has not been confirmed. If vital medicines are reduced during the review process, there is a risk that patients will be life threatened in absence of these medicines. Lack of standards on how this process should be organised will lead clinics and GHs towards making wrong prioritisation during planning, in case of budget constraints.

- Delays in delivery in many cases are a reason why medicines are not available in time for the patient. The process of requesting for medicines although allegedly organised at regular intervals, the information gathered during the audit indicates that these dates change and this affects the delivery. Under the contracts, EOs have a deadline up to 30 days to deliver medicines, but in practice there were delays in delivery for up to 240 days. For these delays, the MoH has not taken any action because a standard process is not in place where reporting for delays from ELM is required. Although there have been reports from some hospitals (the most frequent case is the case of GH of Gjakova), the MoH since April 2017 started taking measures.

- Due to the delivery with obstacles and continuous delays, a lack of medicines in all health institutions at long intervals has been evidenced. Neglecting the implementation of contracts by EO and failure to take measures by MoH and HUCSK respectively, the supply was incomplete and as a consequence the medicines needed to treat the patients were not available. This has also affected the pocket of the patient since in absence of medicines in hospitals, they were forced to buy medicines themselves;

- Further on, delays in initiating procurement procedures have resulted in lack of medicines. MoH and HIF did not start procurement procedures for contracts that expired and as a result supply with medicines for patients was not made in timely manner;

- In absence of monitoring it is impossible to know the situation of medicine supply process in real time. In addition to CPh of UCCK, all health institutions lack summarised monitoring reports. Health institutions do not provide summarised annual monitoring and assessment reports to compare the outcomes against the plan. PhD in HIF does not have access to stock information, but such reporting is only made when required; and

- Even though the Health Information System was programmed to include information on medicines such as: Planned quantities, approved quantities and stocks, this system is not functional. Such system would provide the information about parties and level of responsibilities within system

5 Recommendations

The recommendations given below are intended to ensure that the responsible entities, namely MoH, HIF and HUCSK establish appropriate and sustainable mechanisms for managing the planning, delivery and monitoring of ELM for secondary and tertiary levels.

While the scope of the audit covered 2015-2017 and the competencies in these years were not only the MoH or HUCSK and while by the law of health insurance competences in the future are transferred to the HIF then the recommendations are addressed to the responsible parties to be for each audited field. Therefore, we recommend to:

Ministry of Health

- Update the Essential List of Medicines as soon as possible;
- Continue developing clinical pathways for other illnesses as well and their treatment in cooperation with HUCSK professionals;
- Established technical committee continuously would follow world pharmaceutical trends. Among other things, the committee should make upcoming ELM updates in line with clinical pathways and cost-effective analyses; and
- Put the database into operation (Health Information System), which would include all the information on expenditures covered by the state budget and those by the patient.

Health Insurance Fund

- Ensure through HUCSK that the annual planning of medicines is done in the same way by all Health Institutions. Develop a standard operating procedure that includes the available budget, medicines of vital importance (vital, essential and necessary), stocks and other issues related to effective planning;
- Establish mechanisms for tracking contract expiration. To initiate procurement procedures in a timely manner, including the period of complaints, cancellations and re-tendering;
- Standardise the period of requests from healthcare institutions for supply in each quarter;
- Ensure that the reporting method for delays is mandatory for all health institutions and contain the same information based on contractual obligations;
- In case of delays from the EO, to take measures in line with the contractual obligations; and
- Establish a system for monitoring, supplying and delivering medicines. Further on, follow the implementation of the contracts by the EO and the expiration of these contracts.

Hospital and University Clinical Service of Kosovo

- Establish a monitoring system in all Health Institutions, where the status of requests, supply, delivery, stock and delays are monitored; and
- Require from all HIs to report on a regular basis about the status of supply, delivery delays and stocks

Annex 1. Audit Criteria, Methodology, Scope and Limitations

Audit criteria

In order to respond the questions in this audit we have set criteria that are based on International Best Practices as well as national practices with aim to ensure proper management of the ELM. Initially, the World Health Organisation on of the most recognised orgranisation in healthcare considers that essential medicines should be updated at least every second year. In order to do this, there are criteria that the responsible authority should comply with. Some of the important criteria are as follows:[33]

- There should be Clinical pathways in place (Clinical Protocol[34]) where the types of medicines for treatment of each disease are specifically[35] defined. Further on, based on good practices, ELM needs to be updated at least once every two years;
- Regularly update the list so that it reflects therapeutic advances and changes in cost, resistance patterns and public health relevance [36];
- The selection list should contain only the medicines for which there is accurate and adequate evidence of the efficiency of the type of disease being treated, which are in the market for supply[37];
- Each medicine selected must be available in a form in which adequate quality, including bioavailability, can be ensured; its stability under the anticipated conditions of storage and use must be determined.

The following criteria apply for management of planning, delivery and monitoring:

- To make an adequate planning, it is important to take into account available budget, priorities to be clear according to VEN categorisation and in case change in planning is made to be based and properly coordinated with hospitals, e.g., requiring to review the plan and

[33] Selection of Essential Medicine, http://apps.who.int/medicinedocs/pdf/s2296e/s2296e.pdf

[34] The Clinical Protocol contains a list of diseases and, among other things, types of therapies for treating the patient including the replacement /covering a medicine with another medicine

[35] Managing the selection of the list: https://www.msh.org/sites/msh.org/files/mds3-ch16-selection-mar2012.pdf f4 pika 16. 3
Clinical Guidelines by Medicines Sans Frontiers: http://refbooks.msf.org/msf_docs/en/clinical_guide/cg_en.pdf
https://medicalguidelines.msf.org/msf-books-hosting/14385582-English.pdf

[36] Ibid.

[37] Ibid.

changes in items/types of medicines are done according to importance. In terms of annual planning and possible changes they should beforehand rely on an official standard that includes all the steps and planning criteria. Deviations from the plan are analysed and acted appropriately. Based on the roles and duties of each responsible level to ensure that the requirements are in accordance with the plan or have the right justification. The roles and responsibilities clearly defined between all levels involved should facilitate the process of requests in accordance with the approved plan;

- In order to ensure that number of medicines are meeting the needs of the hospitalised patients, request should always be analysed by calculating stocks, available budget, including prioritisation of medicines and number of patients treated during the previous years;
- In order not to cause delays in the delivery of medicines to patients, the deadlines for initiating claims should be determined and enforced by calculating the time needed for each step in the process;
- Responsible institutions should take the necessary steps to ensure that economic operators (EOs) deliver medicines in time. In case of identifying delays in accordance with the contract signed, appropriate actions are taken. Such action may include the implementation of financial sanctions for the EO[38]. This will also affect the prevention of such actions in the future.
- Good monitoring means that outcome is on a regular basis compared with plans; it also means that there is a proper mechanism for monitoring the functionalization of medicine cycle;

In order to respond to the audit objective we have posed two main audit questions as follows:

1. Is planning of the ELM effectively managed and monitored?

    - Is ELM updated in line with international best practices in order to ensure adequate medicines in the list?
    - Is planning properly organised?
    - Are the requests and needs been appropriately managed?

2. Is the system for delivery and monitoring of medicines efficiently implemented?

    - Is the outcome against plans properly managed?
    - Are deviations of supplies properly analysed and whether appropriate measures have been taken?

3. Do the responsible authorities monitor the management of the medicines in all pharmacies?

[38] Contract signed with EO and MoH, p 9, article 14

Audit scope

This performance audit aim is to assess the management of medicines at secondary and tertiary level, specifically the planning and monitoring of the supply and delivery of medicines from "essential list" for these two health levels.

Our audit will focus on the Ministry of Health (MoH) and Health Insurance Fund (HIF), who is responsible for the management of essential list of medicines. In order to answer our audit questions has selected the secondary and tertiary level health care as case studies, namely University Clinical Centre of Kosovo (UCCK) and three General Hospitals (GHs) since they provide more services whereas the use and the need for of medicine is greater. Furthermore GHs serve patients of more than one Municipality, therefore the audit impact would be higher.

It was assessed whether the ELM is updated based on the global trends in the pharmaceutic sector, further on, how MoH manages the annual plan and the requests from UCCK and GHs. The audit covers the delivery of medicines in line with the planned quantity of medicine from the essential list to the requesting units (UCCK and GHs) and also the way MoH monitors this process.

Entities that will be part of this audit as case studies are selected based on their size by the number of employees and the number of departments within these entities. Furthermore, the reason why we have specifically selected these hospitals is because there patients are treated in more than one city including more complex diseases.

The selected entities that have been selected as case studies for this audit are:

- UCCK together with its subordinate units; and

The following three General Hospitals:

- General Hospital of Prizren;
- General Hospital of Gjilan; and
- General Hospital of Gjakova.

Audit Methodology

We have responded to audit questions through:

- Analysis of laws, regulations, standard procedures and relevant strategies;
- Analysis of relevant statistics, documents and reports by the responsible authorities involved;
- Interviews with officials from responsible authorities involved as well as experts and stakeholders in this field; and

- Relevant studies and research from different countries and relevant institutions. Specifically, we have reviewed the documents related to planning of medicines for the last three years, we interviewed key officials who were responsible and involved in the planning process.

We have reviewed all documents relating to the essential list of medicines for the secondary and tertiary level from drafting the plan, request, delivery and monitoring.

Role of the involved parties through the process

UCCK and GH

Each clinic within UCCK and Regional Hospitals carries out annual planning (Action Plan) for medicines and medicine consumables for the following year. The plan is made based on number patients treated during the previous years, stocks and available budget.

As noted above, the quarters are based on the annual plan and it is the pharmaceutical department within the clinic or hospital that organises the quarter request, this is done in close coordination with directors in each department.

In case the list is considered to be revised Clinics and hospitals based on Lists division (VEN) revise of the initial action plan. This revision is based on disease/medicine priority.

Another step the pharmacies, doctors and nurses are involved are the supply phase. The pharmaceutical unit receives the medicines and consumable material from contracted companies which are registered in the system and after distribute to the departments within clinic or hospital.

Health institutions report on stock status on a 3-month basis (as needed). The volume of the stock are calculated at the end of the year serves as basis of the plan and for the quartile requests, the base of the calculation is also the stock remaining from quarter to quarter.

The Central Pharmacy

Pharmacists and technical staff are employed in the Central Pharmacy who among other tasks are responsible to review the annual plan and request sent by the Clinics in the UCCK and GH to ensure the requests are in line with annual plan as well as stock register.

In addition, to review by CPh, pharmacists from CPh monitor the planning process to ensure that all the important elements in the process are taken into account such as stock, drug importance, analytical statistics of the hospital

In the case of new requests made by the requesting units (hospital clinics/pharmacies), the CPh ensures that the requests are in accordance with the current action plan and budget. When delivering medicines, the CPh monitors the process of delivering the goods from the EO.

The Head of CPh, time to time, established the ad-hoc committees to inspect and monitor the stocks in the clinics and hospitals.

Directorate of the HUCSK

After review of the annual plan by CPh, the Director of the HUCSK is recommended to approve the plan. Same situation is with each quarter, the CPh provides assurance to the Director that the requests are addresed to HUCSK (Coordinator within HUCSK) who returns plans to clinics and hospitals for review in coordination with the budget

Ministry of Health and Heath Insurance Fund

MoH is responsible to set professional committee to ensure the ELM is in line with current development in pharmaceutics. The committee updates the ELM on required periods so the list

contains the required medicines. Since this committee is established by Minister, they report to minister for updates of the list during the set periods.

Furthermore, the MoH organises the procurement procedures for ELM, while HIF is responsible for analysing, planning and managing contracts for medicines and medical consumables for all three levels.

Plans reviewed by CPh and approved by Director of HUCSK are processed at the in HIF. The role of HIF is to compare plan with the current budget and in cases where planning is higher than budget, these plans are returned to UCCK or GHs with required instructions for further corrections.

In regard to quarter request, when request are approved by responsible authorities, the procurement department within MoH will proceed the required list to the EO so the delivery is done for the UCCK and GH. In the case of medicines in a period not later than 30 days or 45 days respectively.

The HIF in coordination with Procurement Department does the verification and comparison of the requests against the delivery and then proceeds to finances for payment.

For the last three years there were more than one party responsible in this process. During 2015, the budget, procurement procedures and supply were the competence of HUCSK. In 2016, the budget was returned under the competence of the Ministry of Health, whereby the procurement procedures were conducted by MoH, whereas the delivery was done directly by the EO to the requesting units. During 2017, at the beginning of the year, the competencies were the same as in 2016, and then the budget went to the HIF, procurement procedures are still developed by the MoH and the delivery continues from the EO to the requesting units for GHs and UCCK for CPh. This applies to secondary and tertiary levels. This situation was during the time while were in the audit.

Annex 2. Unplanned medicines for 2015

Lista e barnave te pa planifikuar dhe porositura per vitin 2015			
Nr	**Lloji**	**Formati**	**Specifikimi**
1	REINFORCED TRACHEAL TUBE WITH CUFF	2.5	
2	REINFORCED TRACHEAL TUBE WITH CUFF	3	
3	SET DOUBLE LUMEN ENDOBRONCHEAL TUBE	39 i djathte	with Conector
4	SET DOUBLE LUMEN ENDOBRONCHEAL TUBE	39 i majte	with Conector
5	SET DOUBLE LUMEN ENDOBRONCHEAL TUBE	41 i djathte	with Conector
6	SET DOUBLE LUMEN ENDOBRONCHEAL TUBE	41 i majte	with Conector
7	SUTURE ABSORBABLE POLYGLACTINE	USP 1	50mm 75cm 1/2 RB
8	MONOFILAMENT POLYGLYCONATE SYNTHETIC ABSORBABLE	USP 0	are prepared from a copolymer of glycolic acid and trimethylene carbonate, should be sterile, inert noncollagenos and nonantigenic, should fullfill USP and EP for synthetic adsorbable
9	MONOFILAMENT POLYGLYCONATE SYNTHETIC ABSORBABLE	USP 1	are prepared from a copolymer of glycolic acid and trimethylene carbonate, should be sterile, inert noncollagenos and nonantigenic, should fullfill USP and EP for synthetic adsorbable
10	I.V. PLACEMENT UNIT, SHORT , LUER TYPE DISPOSABLE	14 G, 2.1 x 70 mm	
11	DISPOSABLE NEONATE BREATHING CIRCUITS		Φ = 10 mm (complete, consisting of two hoses with water traps , Y- piece and elbow) length (from 160 to 180 cm), Latex free
12	ANTIBACTERIAL FILTER FOR NEONATE BREATHING CIRCUITS		with Luer lock port.
13	ELECTRONIC DEVICES FOR HEARING		sipas nevojes
14	X RAY FILM	31 x 41 mm	
15	JV WIRE		150cm
16	EXTENSION TUBE FOR VENTRICULOGRAPHY		
17	CORONARY STENT STAINLESS STEEL		(8mm-38mm diapazan I diametrit 2.5mm)
18	CATHETER BALLOON		per mikrokateterizim dhe hemodinamike
19	LEAD INTRADUCER FOR DEFIBRILATOR		
20	PACEMAKER		CRT
21	CAPILLARY DIALYSERS PAED POLYSULFONE DIALYSERS		Effective Surface area (m2) 0.2 Ultrafiltration Coeff (ml/h - mmHg) 7 Priming Volume (ml) :
22	DOUBLE LUMEN LONG TERM HEMODIALYSIS CATHETER FOR ADULT		14,5 F x 28 cm
23	DOUBLE LUMEN LONG TERM HAEMODYALISES CATHETER FOR ADULT		14,5 F x 32 cm
24	SILICONE DOUBLE LUMEN LONG TERM CATHETER WITH CUFF FOR CHILD		8F x 18 cm
25	SILICONE DOUBLE LUMEN LONG TERM CATHETER WITH CUT FOR CHILD		8F x 24 cm
26	STRAIGHT PEDIATRIC TENCKHOFF CATHETER , TWO FIXED CUFFS		Internal diameter 2.6mm, external diameter 4.9mm, length 25cm
Citostatiket			
1	ASPARAGINASE	sol per inj	10MIU, 10ml
2	CHLORAMBUCIL	tbl	2mg
3	CITARABIN	sol per inj	100mg/ml, 1ml
4	DAUNORUBICIN	plv per inj	20mg
5	DOCETAXEL	konc. dhe tretes per sol per inf	40mg/ml, 2ml
6	DOXORUBICIN	plv per inj	10mg
7	FLUDARABIN	plv per sol per inj	50 mg
8	5 FLUOURACIL	sol per inj	50 mg/ml, 5ml
9	HYDROXICARBAMIDE	caps	500mg
10	6 MERCAPTOPURIN	tbl	50mg
11	MELFALAN	tbl	2mg
12	METHOTREXAT	tbl	2.5mg
13	PROCARBAZINE	tbl	50mg
14	SODIUM CLODRONAT	caps	800 mg
15	SODIUM CLODRONAT	konc.per sol per inf	60mg/ml, 5ml
16	TIOGUANINE	tbl	40mg

Annex 3. Unplanned medicines for 2016-2017

Lista e barnave te pa planifikuar per vitin 2016 dhe 2017				
Nr	**Emri Gjenerik**	**Forma farmaceutike**	**oza & Vellir**	**Aplikimi**
1	FENTANYL patch	patch	50mcg	
2	FENTANYL sublingual	tbl	300mcg	sublingual
3	PARACETAMOL	tbl	500mg	oral
4	DESLORATIDINE	sir	mg/ml, 60-20	oral
5	LORATADINE	tbl	10 mg	oral
6	CARBAMAZEPINE	sir	0mg/5ml, 100	oral
7	PHENOBARBITAL	tbl	100mg	oral
8	PHENOBARBITAL	tbl	15mg	oral
9	SODIUM VALPROATE	tbl	500mg	oral
10	SODIUM VALPROATE	susp	g/5ml, 100-2	oral
11	GRANISETRON	sol per inj	mg/ml, 1-3m	i.v
12	PALONOSETRON	sol per inj	0mcg/ml, 5m	i.v
13	AMPICILIN+CLOKSACILIN+LACTOBACIL	susp.	5mg/5ml, 100	oral
14	AMOXICILLIN	plv per susp	0mg/5ml, 100	oral
15	BACITRACIN + NEOMYCIN SULPHATE	pulv	DIU+3300IU	extern
16	CEFTRIAXONE	plv per sol per inj	250 mg	i.m&i.v
17	CIPROFLOKSACIN	sol per inf	mg/100ml, 10	i.v
18	COLISTIN	sol per inj	1MIU	i.v
19	ERTAPENEM	plv per sol	1g	i.v
20	ERYTHROMICIN	sol per inj.	500mg	i.m&i.v
21	FLUCONAZOLE	plv per susp	50mg/5ml	oral
22	PEGINTERFERON ALFA 2a	shiringe e mbushur /sol per inj	180 mcg	s.c
23	PEGINTERFERON ALFA 2b	shiringe e mbushur/plv & sol per inj	150 mcg/ml	s.c
24	SULFAMETHOXAZOLE + TRIMETHOPRIM	susp	40mg/5ml, 50	oral
25	CAPREOMYCIN	plv per inj	1g	i.m & i.v
26	CYCLOSERIN	caps	250 mg	oral
27	ETIONAMID	tbl	250 mg	oral
28	IZONIAZID	tbl/thyeshme	100mg	oral
29	PYRAZINAMID	tbl/thyeshme	150mg	oral
30	RIFAMPICIN + IZONIAZID	tbl	0 mg + 30 m	oral
31	RIFAMPICIN + IZONIAZID	tbl	0 mg + 60 m	oral
32	RIFAMPICIN + IZONIAZID + PYRAZINAMID	tbl	g + 30 mg + 1	oral
33	TRI-HEXYPHENIDYL	tbl	2mg	oral
34	ACENOCOUMAROL	tbl	4mg	oral
35	ENALAPRIL	tbl	10mg	oral
36	LOSARTAN	tbl	50mg	oral
37	RETEPLASE	plv dhe sol per inf	10 U	i.v
38	VARFARINE	tbl	3 mg	oral
39	HYDROCHLOROTHIAZIDE	tbl	25mg	Oral
40	MANITOL	sol per inf	10%	i.v
41	IMIGLUCERASE	plv per inf.	500IU	i.v
42	INFLIXIMAB	plv per inf.	100mg	i.v
43	MESALAZINE	tbl	400mg	oral
44	PANCREALIPAZE	caps	25000 UI	oral
45	LACTULOSE	susp	10g/15ml	oral
46	LEVOTHYROXINE	tbl	100mcg	oral
47	OCTREOTID	plv per inj	0.1mg	s.c &i.m
48	OCTREOTID	plv per inj	10mg	s.c &i.m
49	OCTREOTID	plv per inj	20mg	s.c &i.m
50	PROPYLTHIOURACIL	tbl	50mg	oral
51	HYDROCORTISONE	tbl	20mg	oral
52	DIDROGESTERONE	tbl	10 mg	oral
53	METRONIDAZOLE	tbl vag	400mg	vaginal
54	MISOPROSTOL	tbl	100 mcg	oral

56	BETAMETHAZON	sol	0.2% - 5 ml	per sy
57	BETAXALOL	sol	0.25% - 5ml	per sy
58	PROXYMETACAINE HYDROCHLORIDE	sol	0.5% , 10 ml	per sy
59	CIPROFLOXACIN	sol	0.3% - 5ml	per sy
60	INTERFERON BETA -1 b	shiringe e mbushur/plv per sol	250mcg/ml	sc.&im.
61	LORAZEPAM	sol per inj	4mg/ml	i.m/i.v.
62	SALBUTAMOL	sol	mg/5ml, 100-200u	oral
63	ACID IBANDRONIK	tbl	150mg	oral
64	HYDROXOCOBALAMIN	sol per inj	000mcg/ml, 1u	i.m
65	ZINC SULPHATE	sol	25mg/ml	oral
66	RABIES VAKSINA	plv and sol per inj.	250 IU/ml	i.m
67	VAKSINA KUNDER ETHEVE TE VERDHA	susp i stabilizuar i virusit 17D	00LD_50/0.5	i.m &s.c
68	VAKSINA KUNDER ETHEVE TIFOIDE	antigj. polisacarid te salmonella tifi	25mcg/0.5 ml	i.m
69	VAKSINA KUNDER MENINGJITIT	antigjen korp. i ACW136 Y	50mcg/0.5 ml	i.m & s.c
70	VAKSINA KUNDER GRIPIT	A(H3N2),A(H1N1) dhe B	0.5 ml	i.m
71	VAKSINA KUNDER GRIPIT (PEDIATRI)	A(H3N2),A(H1N1) dhe B	0.25 ml	i.m
72	VAKSINE E KONJUGUAR KUNDER PNEUMOKOKUT (PCV)	1,4,5,6B,7F,9V,14,18C,19F, 23F	0.5 ml	i.m
73	VAKSINA BCG	sipas kalendarit te imunizimit	sipas nevojes	i.d
74	VAKSINA DTP	sipas kalendarit te imunizimit	sipas nevojes	i.m
75	VAKSINA DaPT -Hib-IPV	sipas kalendarit te imunizimit	sipas nevojes	i.m
76	VAKSINA KUNDER HEPATITIT	sipas kalendarit te imunizimit	sipas nevojes	i.m
77	VAKSINA DT	sipas kalendarit te imunizimit	sipas nevojes	i.m
78	VAKSINA OPV	sipas kalendarit te imunizimit	sipas nevojes	orale
79	VAKSINA Td	sipas kalendarit te imunizimit	sipas nevojes	i.m
80	VAKSINA MMR	sipas kalendarit te imunizimit	sipas nevojes	s.c
81	VAKSINA TT	sipas kalendarit te imunizimit	sipas nevojes	i.m
82	NEVIRAPINE	tbl	200 mg	oral
83	SULPHATE ABACAVIR	tbl	300 mg	oral
84	KONCENTRAT PLUHUR I ACIDIT Dry Acid Concentrates Composition of ready-to-use dialysis fluid: Na mmol/L = 140.00 , K mmol/L = 3.00 , Ca mmol/L =1.50 , Mg mmol/L = 1.00 , Cl mmol/L = 110.00 , HCO3 mmol/L =32.00 , Acetate mmol/L = 6.00 ,Glucose g/L = 1	konc. Pluhur Composition of ready-to-use dialysis fluid	s of conc/box	hemod.
85	SOLUCION PER DIALIZE PERITONEALE Solution for peritoneal dialysis, single use doble bag system made of non-PVC material for all system components, central control switch to regulate all treatment steps, Composition: 1.75 mmol Calcium and 4.25% glucose	sol. per dialize peritoneale	2000ml	d.periton.
86	ACETYLCYSTEINE	sol per inf.	200mg/ml	i.v
87	ANTI-INHIBITOR COAGULANT COMPLEX	plv per sol	500IU	i.v
88	DANTROLENE	plv per sol	20mg/ml	i.v
89	FLUMAZENIL	sol per inj.	0.1mg/ml, 5m	i.v

Citostatikes

1		2	ASPARAGINASE	sol per inj	10MIU, 10ml
2		9	CHLORAMBUCIL	tbl	2mg
3		12	CITARABIN	sol per inj	100mg/ml, 1ml
4		16	DAUNORUBICIN	plv per inj	20mg
5		30	HYDROXICARBAMIDE	caps	500mg
6		37	6 MERCAPTOPURIN	tbl	50mg
7		39	MELFALAN	tbl	2mg
8		41	METHOTREXAT	tbl	2.5mg
9		47	PROCARBAZINE	tbl	50mg
10		50	SODIUM CLODRONAT	caps	800 mg
11		51	SODIUM CLODRONAT	konc.per sol	60mg/ml, 5ml
12		54	TEMOZOLAMIDE	caps	250 mg
13		56	TIOGUANINE	tbl	40mg
14		**23**	**FLUDARABIN**	**plv per sol p**	**50 mg**
15		**24**	**FLUDARABIN**	**tbl**	**10mg**
16		**26**	**5 FLUOURACIL**	**sol per inj**	**50 mg/ml, 5ml**

Annex 4. Sample list of Medicines supplied outside ELM

Medicines supplied outside ELM for year 2016			
Generic Name	Quantity	Total €	Requested from
Surgical patties for protection 1.2x4.5m	3750	10,425	Neurosurgery clinic
Propane 2 ol 447,Propan 1ol Decosept	732	10,269.37	HUCSK clinics
Acid Hyaluronic 1ml 2%	1000	9,450	Ophthalmology clinic
Oxygenator Tubing set	24	9,048	Cardiac surgery clinic
Propane 2 ol 447,Propan 1ol Decosept	268	3,759.83	HUCSK clinics
Fogarty catheter for embolectomy no 3	150	3,525	Emergency clinic
Fogarty catheter for embolectomy no 4	150	3,525	Emergency clinic
Hematuria catheter ch 24	300	3,240	Urology clinic
Alcohol 96%	1480	3,056.94	HUCSK clinics
Urethral stem DJ ch 6-28	140	2,870	Urology clinic
Tension meter	150	2,385	HUCSK clinics
Intraocular Lens PMMA 21	250	2,268	Ophthalmology clinic
Hematuria catheter ch 22	200	2,160	Urology clinic
Hematuria catheter ch 20	200	2,160	Urology clinic
Urethral Stem DJ Ch 4.8-20cm	100	2,050	Urology clinic
Intraocular lens PMMA 21.5	50	1,175	Vascular clinic
Tension meter	50	15.9	HUCSK clinics
Mercury Thermometer	800	792	HUCSK clinics
Formalin 35% sol	41	533	HUCSK clinics
Urine sterile container	5500	467.5	HUCSK clinics
Hydrogen 30%	150	354	HUCSK clinics
Ultra sound gel 1kg	200	126.79	HUCSK clinics
Electrodes for EKG	1800	85.54	HUCSK clinics
Sclerotherapy needle Teflon tube 23G 230cm	2	65.88	Gastroenterology clinic
Sclerotherapy needle 24G 170cm	1	32.94	Gastroenterology clinic
Total amount		74,351.99	

Annex 5. List of Medicines without Contract for 2017

Generic Name	Pharmaceutical form	application	VEN	Contract expiry date
CARBAMAZEPINE	sir	oral	V	No contract
SODIUM VALPROATE	susp	oral	E	No contract
PALONOSETRON	sol per inj	i.v	N	No contract
FLUCONAZOLE	plv per susp	oral	E	No contract
PEGINTERFERON ALFA 2b	shiringe e mbushur/plv & sol per inj	s.c	E	No contract
RIBAVIRIN	sol per inj	i.v	V	No contract
TRI-HEXYPHENIDYL	tbl	oral	E	No contract
DARBEPOETIN ALFA	shiringe e mbushur/sol per inj	s.c & i.v	N	No contract
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA	shiringe e mbushur/sol per inj	i.v	N	No contract
ACENOCOUMAROL	tbl	oral	E	No contract
OCTREOTID	plv per inj	s.c &i.m	V	No contract
OCTREOTID	plv per inj	s.c &i.m	E	No contract
HYDROCORTISONE	tbl	oral		No contract
ALPROSTADIL	sol per inj	i.v	V	No contract
ACID IBANDRONIK	tbl	oral	E	No contract
VAKSINA KUNDER ETHEVE TE VERDHA	susp i stabilizuar i virusit 17D	i.m &s.c	V	No contract
VAKSINA KUNDER ETHEVE TIFOIDE	antigj. polisacarid te salmonella tifi	i.m	V	No contract
VAKSINA KUNDER MENINGJITIT	antigjen korp. i ACË136 Y	i.m & s.c	V	No contract
VAKSINA KUNDER GRIPIT	A(H3N2),A(H1N1) and B	i.m	V	No contract
VAKSINA KUNDER GRIPIT (PEDIATRI)	A(H3N2),A(H1N1) and B	i.m	V	No contract
VAKSINE E KONJUGUAR KUNDER PNEUMOKOKUT (PCV)	1,4,5,6B,7F,9V,14,18C,19F, 23F	i.m	V	No contract
VAKSINA BCG	according to the immunization calendar	i.d	V	No contract
VAKSINA DTP	as per immunisation calendar	i.m	V	No contract
VAKSINA DaPT -Hib-IPV	as per immunisation calendar	i.m	V	No contract
VAKSINA KUNDER HEPATITIT	as per immunisation calendar	i.m	V	No contract
VAKSINA DT	as per immunisation calendar	i.m	V	No contract
VAKSINA OPV	as per immunisation calendar	orale	V	No contract
VAKSINA Td	as per immunisation calendar	i.m	V	No contract
VAKSINA MMR	as per immunisation calendar	s.c	V	No contract
VAKSINA TT	as per immunisation calendar	i.m	V	No contract
DANTROLENE	plv per sol	i.v	V	No contract
DOBUTAMINE	sterile injection	i.v	V	No contract
FLUMAZENIL	sol per inj.	i.v	V	No contract

Annex 6. Sample of the reporting method for medicines and days of delay until the reporting date

Type of Medicine	Requested	Reported	Days/work
PHENOBARBITAL	1/17/2016	12/22/2016	240
ATORVASTATINE	1/17/2016	12/22/2016	240
NALOXONE	21.03.2016	6/27/2016	50
PROTAMIN SULPHATE	21.03.2016	6/27/2016	50
VANCOMYCIN	21.03.2016	6/27/2016	50
DOPAMINE	21.03.2016	6/27/2016	50
GLYCERYL TRINITRATE	21.03.2016	6/27/2016	50
AMPICILLIN	6/22/2016	22.12.2016	125
AMOXICILLIN	6/22/2016	22.12.2016	125
BENZYLPENICILLIN	6/22/2016	22.12.2016	125