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Conducting a Market Analysis for Monitoring and Evaluating Procurement Processes for Essential Medicine and Health Care Infrastructure

Final Report

Conducting a Market Analysis for Monitoring and Evaluating Procurement Processes for Essential Medicine and Health Care Infrastructure

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A. Executive Summary

This report, commissioned by the Group for Legal and Political Studies (GLPS) and contracted to UBO Consulting under the project "Use of Social Accountability Tools to Increase Institutional Transparency and Accountability in Kosovo," supported by USAID Kosovo Municipal Integrity (KMI), provides a comprehensive market survey analysis. Price analysis of medicines from the essential list showed that open market prices were, on average, up to 92% more expensive compared to equivalent medicine prices from the tender contract of the Ministry of Health The comparative analysis highlights that the procurement process is efficient, which can be inferred from the significant cost advantage. While the procurement process demonstrates cost advantages, particularly for generic medicines, medicines for rare conditions exhibit limited competition and higher prices, and with no open market price reference, it remains unknown how efficient the procurement process concerning these medicines is.

A primary healthcare facility construction contract in Mamushë/Mamuša has been taken for comparative cost analysis in this study. The analysis highlights that the contract obtained via procurement is 21% below the reference costs obtained from the market research (market prices). Significant differences were found across contract categories such as construction, plumbing, electrical installations, HVAC, and medical gas systems. While the cost analysis reveals that the contract demonstrates a cost advantage, it fails to capture and communicate the project implementation in its entirety and to disclose that the project did not fully adhere to contractual terms, effectively leaving certain works incomplete. Limitations from the scope and purpose of this study allow only for a suggestion that the discrepancy between contracted prices and implementation is related to so-called “strategic bidding” by contractors and precipitated by insufficient project implementation oversight!

This report provides an in-depth analysis of the procurement process and cost evaluation of essential medicines in Kosovo's healthcare sector, as well as of the cost evaluation and procurement process for the healthcare infrastructure. The findings reveal a complex regulatory framework governing the procurement of medicines, with a focus on ensuring supply, managing costs, and meeting healthcare needs. The strategic direction outlined in the Healthcare Sectorial Strategy 2017 – 2021 emphasizes the improvement of the provision of healthcare services, particularly in the management of medical products at the primary healthcare level. The strategy also provides strategic objectives and goals for the Ministry of Health concerning the development of healthcare infrastructure, which also contemplates the procurement of works and other services pertinent to the development, maintenance, and expansion of the public healthcare infrastructure in Kosovo.

Key legal and institutional frameworks, the Law on Health and the Law on Price of Medical Products, including the regulation of the Ministry for Commission for Market Price Marketing for Medical Products and Devices and Consumables set the foundation for procurement practices and regulation of medicine markets. A dedicated SOP has also been signed into force to support activities for initiation of procurement for medicines from the essential list! The Kosovo Agency for Medical Products and Equipment plays a central role in overseeing the sector's regulation and registration. However, challenges persist, including limited competition for medicines related to rare conditions and dissatisfaction within the sector regarding pricing regulations, reflecting the fact of cases where a single company is in possession of marketing authorization for a specific medicine!

Responsibility for healthcare infrastructure lies within the Infrastructure Division of the Ministry, which manages project preparation, costing, and implementation. However, the division lacks specialized personnel, relying on external support for engineering expertise. Various laws and administrative instructions provide regulatory oversight for healthcare infrastructure projects, yet specific guidelines for design and norms are lacking. A dedicated Standard Operating Procedure (SOPs) has been developed and signed into force as of July 2023, “SOP for Initiation of Procurement Activities for Construction Works Contract” The SOP aims to streamline and regulate the contracting aspects and procurement processes pertinent to procurement contracts in construction.

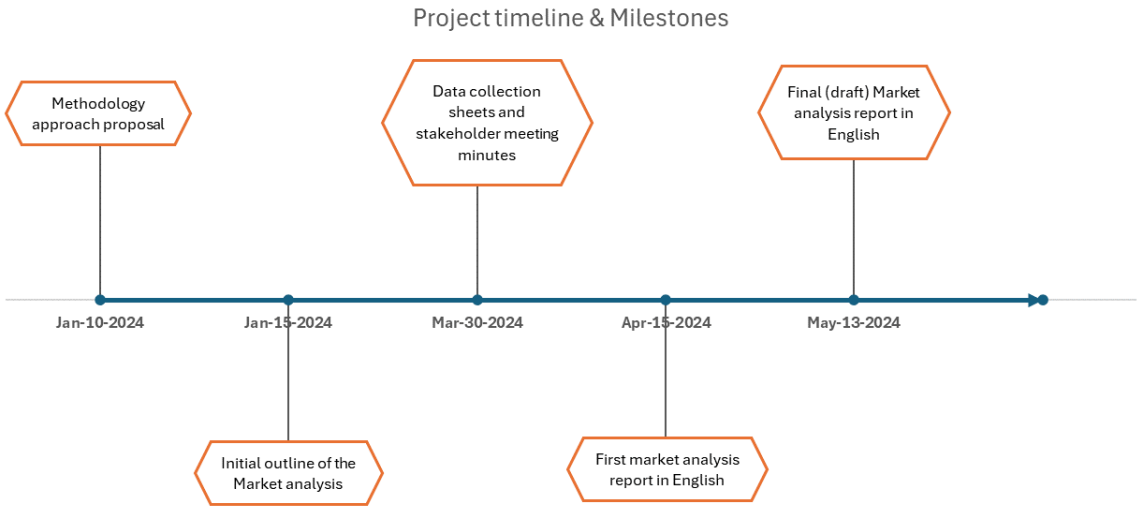
Recommendations include continued monitoring of procurement processes, addressing market challenges to enhance competition, and further aligning procurement practices with healthcare priorities. Additionally, efforts to streamline regulations and promote transparency can contribute to improved access to essential medicines and overall healthcare outcomes in Kosovo. Moving forward, MH plans to establish a dedicated workgroup to oversee healthcare infrastructure projects, aiming to enhance compliance with procurement regulations and ensure effective project implementation.

At the overarching policy level, the healthcare sector is found to be with an expired strategy, which at the nominal level provides strategic direction for the sub-sector segments pertinent to the procurement activities concerning medicines from the essential list of medicines, as well as implementation of activities related to the procurement of healthcare infrastructure. A revised and updated sectorial strategy which would encompass both objectives (medicines from the essential list and healthcare infrastructure) as well as the other sectorial objectives, would be expected to coordinate and articulate policy objectives and implementation activities, allow for prioritization and longer term structuring of resources and improve outputs and outcomes at the sector level in general, and in the domain of medicines of essential list in particular as well as in the healthcare infrastructure.

1. Project background

This is a study commissioned by the Group for Legal and Political Studies (GLPS) and contracted to UBO Consulting. The overarching project of the study is "Use of Social Accountability Tools to Increase Institutional Transparency and Accountability in Kosovo," supported by the USAID Kosovo Municipal Integrity Activity (KMI). The project seeks to help Kosovo's public institutions become more transparent, accountable, and citizen-centred. These institutions face systemic challenges such as resource constraints, intricate budget management, and concerns about procurement practices. To address these issues, KMI employs tools like Public Expenditure Tracking Survey PETS and Market Survey Analysis, with a central focus on improving efficiency and accountability in managing public funds and contracts at both local and central levels. This includes monitoring public administrations, encouraging civil society involvement, improving budget effectiveness, and providing data-driven inputs for policymakers. Additionally, the project aims to assess the quality and quantity of public services and promote public awareness and citizen engagement in financial oversight and institutional monitoring.

The scope of the project aimed to undertake a market survey analysis to monitor and evaluate the procurement process for essential medicines and capital projects related to healthcare infrastructure by the Ministry of Health and Hospital and University Clinical Service of Kosovo. The primary objective of this study has been to conduct an in-depth market analysis to compare procurement based contracted prices with actual market prices for essential medicines and healthcare infrastructure projects. The study aimed to identify the underlying causes of scarce essential medicine supply and the potential mismanagement of public funds in these processes.



The Terms of Reference (ToR) outlined specific requirements for conducting two parallel comparative studies, central to which is a market research component. Additionally, qualitative research was undertaken to examine the legal and institutional frameworks, understand the overarching processes and their associated dynamics, and analyse the competitive landscape of the relevant market sector. The project's Terms of Reference (ToR) also mandated the development of a study methodology, which used the ToR itself as the guiding framework and criteria for crafting the approach.

2. Methodology

To develop the research methodology, the UBO Consulting team of experts has undertaken exploratory research in the areas of the subject domains as part of the preparatory activities, (1) procurement processes for essential medicines by the Ministry of Health, as well as in the (2) procurement processes for the healthcare infrastructure. Findings from the exploratory research have been used to structure a methodology based on conventional social research methods for data collection and analysis. The developed methodology is organized in two parts and has been drafted to reflect specific ToR requirements and the overall requirements for such research.

UBO Consulting consulted extensively with the relevant stakeholders (GLPS, Ministry of Health, and KMI) in addition to the initial discussions with pharmaceutical professionals and construction sector stakeholders. The stakeholders represented their perspectives on the study and thus contributed to clarifying the objectives and the landscape for the forthcoming study. The structuring of the methodology for this study was based on the fact that the two fields of study are relatively separate, including the list of essential medicines and healthcare infrastructure. Furthermore, the insights from the preparatory activities showed that even at the Ministry of

Health, there are separate organizational units that manage these two functions. In addition, market research also considers separate industries and, hence, separate studies. No market research reports were readily available for the sectors at hand, thus necessitating marketing research for the targeted sector and doing so within the framework of the contract both in terms of time and resources.

2.1. Methodology Procurement of Essential Medicines

The study methodology for analyzing procurement processes of essential medicines by the Ministry of Health utilizes a two-step approach: an exploratory phase followed by data collection and analysis. Initially, the exploratory phase involves a thorough review of secondary data and conducting in-depth interviews with key informants from the Ministry of Health and the Kosova Medicines Agency. This phase helps to identify and understand the context, which in turn shapes the subsequent main research phase. Based on the insights gained, the main research phase is carefully structured to develop data collection instruments, identify appropriate data sources, and determine the necessary scope of data collection. This includes integrating context mapping with legal, institutional, and market intelligence to guide the research effectively.

The exploratory step of the research is based on the secondary data available (laws, bylaws, strategies, studies, manuals, SOPs, list of essential medicines, medicine authorization policies and regulations, list of authorized companies, statistical information for the volume of trade for medicines of the essential list, pricing policies, and other publications) available from the public domain, as well as from the Ministry itself.

Interviews were conducted with the key informants from the Ministry of Health (3), officials responsible for the determination of the list of essential medicines, officials responsible for processing marketing authorizations, and officials responsible for the procurement process and handling of supplies of medicines from the essential list, and officials responsible for statistical evidence or officials responsible for the quality assurance/audit. Interviews were planned with stakeholder entities from the CSO (1-2), Pharmacists Association (1), as well as with the Kosovar Association of Pharmaceutical Companies (1). The exploratory step has provided an in-depth understanding of the legal and institutional arrangements pertinent to the determination, procurement, and handling of medicines from the list of essential medicines. It also points to possible areas with problems related to the medicines from the essential list. The exploratory step has enabled us to have a better understanding of the list of essential medicines by group and also by price range/segmentation, the overall volume of medicines consumed, demand for these medicines by group, and the supply thereof. More specifically, the list of medicines from the essential list was disaggregated by the type of medicines/pharmacological group and then further disaggregated by other particularities such as routes of administration or application, packaging by strength-concentration or weight, amount, or volume. Other disaggregation categories have been observed based on the specific characteristics of particular medicines. The exploratory step has also provided an understanding of the key suppliers and the associated competitive landscape. The exploratory review provided a price reference for the medicines by group and medicines from the essential list (from analyzed contracts), which were then used for price comparison. Accordingly, the exploratory step has produced a pool of tendering contracts for the list of essential medicines. This pool has allowed for the identification and selection of a set of contracts that have been used as a comparative reference to the procurement of a contract for the supply of medicines from the list of essential medicines. The exploratory step also

provided the team with the initial outline of the market analysis based on the information collected and summaries from interviews with key stakeholders (key informants).

The main research phase was structured to gather and analyze data, focusing on a curated list of authorized medicine suppliers selected for interviews. Additionally, interviews were conducted with owners of private pharmacies to collect pricing data for the medicines or groups listed on the list of essential medicines. This approach provided comprehensive insights into the supply costs of these critical healthcare items. Private pharmacies are selected as key interlocutory points for price reference because these are the principal private sector outlets for medicines, including medicines from the essential list. Private pharmacies in Kosovo are supplied via wholesale businesses, which are regulated by the Ministry of Health via the Kosovo Medicines Agency, with the latter functioning as a regulatory agency that issues authorizations for the use of medicines in Kosovo as well as licensing companies to engage in production, import, and trading of medicines. During the exploratory step, it was learned that the Kosovo Medicines Agency has no significant role concerning the preparation and procurement of medicines from the essential list. The role of the agency principally remains with the registration of medicines (issues authorizations for use/trade in the country) as well as companies (issues authorizations for commercial activities, import, and sales – whole sales, medicines, and medical equipment), licensing of pharmacy (retail), and (pharmaceutical professionals - pharmacists). Accordingly, it was left out of the interviewing process.

Data collection was conducted through one-on-one interviews with private pharmacies across Kosovo, utilizing the Computer-Assisted Personal Interviewing (CAPI) technique. This approach focused on gathering detailed price information for medicines listed on the Ministry of Health's essential list, broken down by group and further disaggregated by type of administration/application and sizes. This comprehensive data collection specifically targeted the prices from the selected supply contracts (tenders) issued by the Ministry of Health, ensuring nationwide coverage in the data-gathering process.

Data on the prices of essential medicines have been systematically gathered through interviews with pharmaceutical commercial agents. These agents, who typically represent wholesale companies specializing in medical products, provided price information from the essential medicines list obtained from the Ministry of Health. The data collection encompassed a comprehensive national scope, engaging pharmaceutical commercial agents from various regions across the country.

Price of medicines data was collected using price scoping in private pharmacies for medicines from the essential list (medicines from the selected supply contract tender), where interviewers asked for 4 to 6 medicines from closely related groups, contemplating ordinary buyers. Interviewers have recorded price information received on the provided sheet. Interviewers have collected this information by visiting a considerable number of private pharmacies to ensure that all price information is collected.

A datasheet has been designed to store and process collected price data, listing medicines from the contract and the associated specification, in addition to price information from the market sources as well as price information from the tender contract. Data processing has enabled a price analysis for the identified medicines of the essential list to compare prices for medicines obtained from the public sector supply mechanisms (procurement contracts and processes) against the open market (private sector) at wholesale and retail.

The report was developed through a rigorous analytical approach, utilizing statistical evidence and a comparative analysis of prices between procurement contracts and market research prices. These quantitative elements were integrated with qualitative insights to generate contextual information pertinent to the study. The analysis also considered the regulatory and institutional frameworks, mapping the processes and key stakeholders involved. This comprehensive examination of the collected data aims to offer an in-depth view of procurement efficiency and to propose targeted recommendations for improvement.

The outline of the research steps in the process for the list of essential medicines is provided below.

1. Exploratory Step

1. **Review Secondary Data** (laws, bylaws, strategies and studies, Manuals and SOPs, list of essential medicines, medicine authorization policies and regulations, list of authorized companies, statistical information on trade volumes for essential medicines, pricing policies and other relevant publications):
2. **Conduct In-Depth Interviews**:
    - Interview key informants within the Ministry of Health (Officials responsible for the determination of the list, Officials responsible for processing marketing authorizations, Officials responsible for procurement and handling of essential medicines, Officials responsible for statistical evidence or quality assurance/audit)
    - Interview stakeholder entities (CSO, Pharmacists Association, Kosovar Association of Pharmaceutical Companies)
3. **Data Analysis**
    - Understand legal and institutional arrangements,
    - Identify potential problem areas related to essential medicines,
    - Categorize essential medicines by type, price range, volume, demand, and supply,
    - Identify key suppliers and the competitive landscape,
    - Perform price reference and comparison,
    - Compile a pool of tendering contracts for essential medicines,
    - Conduct initial market analysis.

2. Main Research Step

4. **Data Collection from Authorized Suppliers** (Select suppliers for interview based on the list of authorized suppliers, Collect information from private pharmacy owners regarding supply prices)
5. **Interviews with Private Pharmacies** (Collect price information for essential medicines using the Computer-Assisted Personal Interviewing (CAPI) technique; visit pharmacies across the country to ensure comprehensive data collection
6. **Interviews with Pharmaceutical Commercial Agents** (Collect price information from commercial agents representing wholesale companies)
7. **Price Scooping in Private Pharmacies** (Collect price data for selected medicines from supply contracts, Ensure wide coverage by visiting numerous private pharmacies)
8. **Data Storage and Processing** (Design datasheet for storing and processing price data, List medicines from contracts with associated specifications and prices from market sources, Compare public sector procurement prices with open market prices)

3. Data Analysis and Reporting

9. **Analysis** (Conduct statistical analysis and comparative price analysis, Integrate quantitative data with qualitative insights, Map regulatory and institutional frameworks and identify key stakeholders)
10. **Report Development** (Develop a comprehensive report with findings and targeted recommendations for improving procurement efficiency

2.2. Methodology Procurement of Healthcare Infrastructure

The methodology for analysis of costs for capital projects is based on the comparative analysis of specific contracted construction costs (healthcare facilities – capital investment category) against construction costs at the market level. For this methodology, a contract of the Ministry of Health for infrastructure has been selected as a comparative reference for the cost aspect; so the methodology is based on the identification of a representative capital project from the list of capital investments of the Ministry of Health, using a set of projects awarded and implemented in the most recent year. The idea was that the identified project was to be further analyzed and broken down into project components to obtain volumes and costs of the associated materials and works. Market-based costs for the identified construction items/categories enable analysis of the costs for capital projects on a comparative basis between the contracted costs and equivalent costs that prevail at the market level. This methodology is based on a two-step approach: the exploratory step and the data collection and analysis.

The exploratory step of the research is based on information from secondary data sources (laws, bylaws, strategies, studies, manuals, SOPs, list of facilities that were planned for construction and were built, contracts and contracting procedures for infrastructure, project management procedures and policies, list of companies that have applied in the tender and their offers, statistical information for the volume of capital investment and categories of capital investment, costing policies for budget planning purpose - allocation, and other publications) available from the public domain, as well as from the institutional units.

Interviews were conducted with the key informants from the Ministry of Health (4), with officials from the unit responsible for planning, building, and management of healthcare facilities (2), procurement unit (1), and supervisory unit for the infrastructure unit (1), principally, with officials responsible for the policy planning and implementation for healthcare facilities - infrastructure, officials responsible for design and costing of capital investment projects, and officials responsible for procurement process and project management - oversight, and officials responsible for supervising the infrastructure unit from a superior hierarchical position. The purpose of the exploratory study is to provide information about typical capital investment facilities, enable a summary analysis of associated costs between similar project facilities, and identify a representative facility for in-depth cost analysis. Interviews were also planned to be conducted with stakeholder entities from the CSO (2-3), Kosovar Association of Architects and Civil Engineers (1), Kosovar Association of Construction Companies (1), as well as with the Kosovar Association of Producers of Construction Materials. Accordingly, the exploratory step has produced a contract that has been used as a comparative reference concerning the procurement and implementation of a healthcare infrastructure project. The identified project was planned to be used to break down the amount of work and materials for the major construction part – structure and basic finishing works. The project documentation was planned to be used to identify the number of major construction inputs. On the category of materials,

analysis was planned to identify the amount and costs for concrete, steel, timber, bricks, tiles, roofing materials, flooring materials, hydro isolation, thermos-isolation, door and window framing, plumbing and HVAC, electrical installations, and other materials associated with the project. In the category of labor, an analysis was planned to identify the amount and costs for the amount of work required and the man-days for each position to produce the total amount of labor. In the category of works or services, an analysis was planned to identify what works and equipment are needed, the volume of work and equipment (i.e., earthworks), transportation costs, and the associated equipment and fuel. Here, we also include the amount of earthworks and types of earthworks, such as gravel, moving, compacting, etc. At this stage, the methodology was designed to itemize and catalog all cost components. It involved collecting comprehensive cost data for construction projects executed in the open market by private construction companies. Additionally, interviews were conducted to gather detailed price information for various cost categories—such as materials, labor, and machinery/equipment—from owners of private construction companies, as well as from civil engineers and architects, to cover all associated costs comprehensively.

Subsequently, a comprehensive list of cost items was compiled to facilitate the collection of cost data from implemented construction projects. Specifically, data collection will be based on this detailed list, which will serve as a questionnaire during interviews with private construction company owners and civil engineers/architects. These interviews aim to gather detailed information on the unit costs of materials, labor, and machinery/equipment, providing insights into supply pricing. The exploratory step served as a preparatory phase for the main research phase, having produced the initial outline of the capital investment analysis (the context, selected project for analysis, list of costs and inputs for data collection), as well as a summary of information and data collected during the exploratory step.

The primary research was structured around the specific capital investment contract for constructing a Primary Healthcare Facility in Mamushë/Mamuša. The project was analyzed based on construction line items, along with their associated volumes and costs, to gather cost information from the open market. More specifically, the list of construction materials, labor, equipment, and other detailed costs developed during the exploratory phase was utilized to collect data and facilitate a comparative analysis in the subsequent stages.

Private construction companies, as well as civil engineers and architects, were identified initially as the key interlocutory point (sources of information) for the costing reference because these are the principal private sector outlets for works in the construction sector, including also civil engineering works related to the construction of healthcare facilities. As a measure of precaution regarding objectivity and impartiality, potential interview candidates (companies and individuals) were screened in case potential parties are currently or have been recently involved as contractors or in other forms related to works associated with the Ministry of Health. Data has been collected over interviews with the construction companies and civil engineers/architects in Kosovo, specifically to collect price information for the supply prices for the civil engineering categories – construction work from the list. This information has been collected from (6) construction sector entities in the country. A piece of important price-related information during the collection has been to collect prices for the position (material, work, equipment, other) for the period 2020-2021; in the subsequent period, there has been a significant price increase in construction overall and in the domain of construction materials in particular; Inflation in the period between 2020 and 2024 has been very intensive and has had a significant impact in the economy overall and in the construction sector in particular.

Accordingly, price information for the major categories of construction materials, concrete, steel, timber, bricks, thermal insulation, door and window frames, gravel, fuel, and other identified cost categories as significant, have also been collected from the general market – construction materials warehouses and concrete factories/cement factory. Price data were collected via interviews with construction materials warehouse salesperson(s). Price information has been collected from these agents for the main construction cost categories, as information from the market-level operations. These outlets supply these products at generally open/free market assumption. This information has been collected from (3) construction materials warehouses – concrete factories/cement plants across the country. Statistical publications from the Kosovo Statistics Agency [KAS] have also been reviewed to identify possible references to the costs of construction materials, as KAS regularly prepares and publishes the Construction Cost Index for Kosovo. This index is an aggregated and weighted index of costs associated with the construction sector, materials, equipment/machinery, labor, energy, etc. Collected data has been recorded and processed in a custom-designed dataset, with provisions for construction materials categories, works, transportation, labor, and other associated cost categories. For each construction cost category, there will be a reference for the price or cost information obtained from the interviews and retail prices collected from the private sector agents (construction material warehouses, concrete factories/cement plants). The principal construction cost reference for the Healthcare Infrastructure has been the construction contract selected to be measured against the cost that reflects open market prices, specifically the contract for the construction of the Primary Healthcare Facility in the municipality of Mamushë/Mamuša. This contract is organized into five sub-sections, each corresponding to different phases of construction. Within these sections, provisions for work are presented in aggregate positions, encompassing the supply of construction materials and labor, complete with dimensions and technical specifications. These aggregate positions offer limited scope for further breaking down the work into more detailed categories of materials, labor, equipment, and other associated costs. As a result, for these positions, a comparative analysis necessitated gathering cost estimates from interviewed respondents—including construction companies and experts—regarding the execution of these activities. This analysis included specific remarks on price references for the years 2020-2021. Cost analysis for the capital investment project was then undertaken, comparing costs for construction items/categories as obtained from the public sector supply mechanisms, procurement contracts, cost ranges from the private sector, cost information, and prices for materials obtained from the research (data collection).

Statistical analysis, enhanced by the use of advanced data tools, has facilitated accurate and objective benchmarking against market prices. This analysis, coupled with the synthesis of qualitative data, has generated valuable insights that have enriched the research. The resultant report provides a comprehensive overview of procurement efficiency and offers targeted recommendations for improvements.

The outline of the research steps in the process for the procurement of healthcare infrastructure is provided below.

1. Exploratory Step

1. **Review Secondary Data:**
    - Collect information from laws, bylaws, strategies, manuals, SOPs, lists of planned and completed facilities, contracts, project management procedures, company tenders, and statistical data on capital investments and costing policies.
2. **Conduct In-Depth Interviews:**
    - Interview key informants from the Ministry of Health (4 informants from planning, procurement, and supervisory units).
    - Interview stakeholder entities (CSOs, Kosovar Association of Architects and Civil Engineers, Kosovar Association of Construction Companies, Kosovar Association of Producers of Construction Materials).
3. **Identify and Analyze Representative Capital Project:**
    - Select a representative project and break it down into components to analyze the volumes and costs of materials and works.
    - Prepare an initial outline of cost items for further data collection and analysis.

2. Main Research Step

4. **Project Analysis and Data Collection:**
    - Analyze the selected project (e.g., Primary Healthcare Facility in Mamushë/Mamuša) by construction line items.
    - Collect cost information from private construction companies, civil engineers, and architects for materials, labor, and equipment.
5. **Market Price Analysis:**
    - Collect market prices for major construction materials (concrete, steel, timber, bricks, thermal insulation, door/window frames, gravel, fuel) from construction materials warehouses and concrete factories/cement plants.
    - Review construction cost indices from the Kosovo Statistics Agency (KAS).
6. **Data Recording and Processing:**
    - Record collected data in a custom-designed dataset, categorizing materials, works, transportation, labor, and other costs.
    - Compare public sector procurement costs with market prices.
7. **Cost Analysis and Reporting:**
    - Perform statistical and qualitative data analysis to benchmark costs against market prices.
    - Develop a comprehensive report with findings on procurement efficiency and recommendations for improvements.

B. Findings

1. Procurement of essential medicines

The pharmaceutical sector, medicines in general, are a very highly regulated industry at all levels, from R&D, testing, approval, marketing, disbursement, and administration up to the necessity of destroying expired medicines, including handling of medical waste. The Ministry of Health does not have a current strategy document pertinent to the domain of list of essential medicines, neither is current health sector strategy, which would include the domain as a subset of strategic objectives.

The latest available strategy for healthcare in Kosovo remains the Healthcare Sectorial Strategy 2017 – 2021[1], which provides strategic level objectives for improvements in the supply of medical products (medicines), specifically formulated in objective 7, Improvement of provision for healthcare services, which needs to be read with strategic result 7.5 Improved management of medical products at the level of PHC. The strategic plan itself does not provide a strategic objective concerning improvement in supply or management of supply processes with medicines at the level of secondary and tertiary level institutions of healthcare (regional hospitals and University Clinical Centre in Prishtina). Nonetheless, strategic direction is provided herein to provide direction and allow for prioritization and coordination of activities and allocation of resources.

1.1. Legal and institutional background, description of the market for providers

The basic law that provides the legal foundation for the list of essential medicines is the Law on Health, Nr. 04/L-125 sets forth in Article 12 Measures and Activities, paragraph 1.7, Ensure supply with medicines and consumable materials such as medical equipment. Further, in Article 59 Services of Basic Healthcare, para 1 says that basic healthcare services will be covered by the Agency for Financing of Healthcare, which will be determined in the list of services formulated by the technical committee established by the Health Minister starting each fiscal year. In the definitions section of the law, 1.16 List of medicines and consumable materials, a list of medicines and consumables in the healthcare that the government funds along with the participatory contributions required from citizens.

The basic law that regulates the supply of medicines/medicines market in Kosovo is the law on the price of medical products Nr. 08/L-220, stipulating in articles 5 through 12 regulation of prices for medicines that are supplied in Kosovo in both wholesale and retail. Article 14 stipulates the pricing methodology for the supply of medicines to public authorities. Likewise, the basic law Nr. 04/L -190 on medical products and equipment names the Kosovo Agency for Medical Products and Devices as the authority to oversee the sector, registration, and marketing of medicines. The agency was established as an independent executive body of the Ministry of Health to regulate the medical products and equipment sector. However, the law on the price of medical products, in Article 13, establishes a dedicated committee for the price of medical products, with the mandate to implement and oversee the implementation of the law that regulates the prices of medicines in Kosovo. The essence of the law centres on conducting comparative market research across a selected group of countries for specific medicines, coupled with the enforcement of a preset profit margin as a ceiling, thus imposing an obligation on authorized marketing companies to declare their prices beforehand. The law entered into force on 30 Aug 2023, with a 6-month adjustment period, which makes it effectively fully applicable at the time of writing this report. For the purpose of conducting a market research on prices of essential list of medicines, USAID KMI has assisted the Ministry of Health for development of the market research methodology for medicine prices; the methodology is developed in the form of a regulation for the Commission for Market Price Marketing for Medical Products and Devices and Consumables. Furthermore, USAID KMI has trained members of the commission in the new regulation related to undertaking of the market research for prices of medicines.

[1] https://msh.rks-gov.net/Documents/DownloadDocument?fileName=Strategjia%20Sektoriale%20e%20Sh%C3%ABndet%C3%ABsis%C3%AB%20(2017%20%E2%80%93%202021)54528803.4504.pdf

Subsequently, the Ministry of Health has adopted the aforementioned regulation by issuing the decision Nr. 144/III/2023, which establishes the Commission for Market Price Marketing for Medical Products and Devices and Consumables. According to the decision, the mandate of the Commission is to:

- produce the report with average unit price for prices of the group of medicines and recommend the final price inclusive of VAT
- prepare and share the report in optimal period to the requesting unit/Pharmaceutical Division of the Ministry of Health in tabular format (excel) electronically or hardcopy via archive

The commission is obliged to work according to the internal regulation, which is part of the decision act! The regulation stipulates that the commission is mandated to collect price information for medicines and medical devices and consumables based on the essential list and also some other items not included in the list for the needs of the Ministry of Health. The responsibility for determination of the essential list of medicines for procurement, market research, and tendering and contracting lies with the Ministry of Health. The process for preparation of the list of essential medicines starts with the Ministerial decision for establishment of the Technical Committee, which is tasked with determination of the list of essential medicines. The request for medicines principally originates from the healthcare sector – service providers, University Clinical Center of Prishtina, Regional Hospitals, and Primary Healthcare level providers via Municipal Directorates for Healthcare.

Regarding the determination of the price of medicines and inherently cost of the list, the process starts with the secretary of the ministry naming the commission to undertake market research in Kosovo and in the region to collect price information about medicines of interest that are part of the list of essential medicines, according to the dispositions of the decision 144/III/2023 and the associated regulation! The market research aims to collect information and establish the price of medicines relevant to the essential list. Information for the price of medicines from the essential list is handed to the Pharmaceutical Division of the Ministry of Health, which in further activities works to prepare and determine the cost of the list, which is then compared against the budgetary constraints. Costing, as one of the most critical aspects of the list, is considered by the Technical Committee and decided by the Pharmaceutical Division in respect of the budgetary ceiling information, whereby a list of essential medicines is finalized before the year's end, which is then valid for procurement and supply for the coming year. The list of essential medicines, upon a determination by the technical committee and the approval of the minister, is handed to the pharmaceutical division of the Ministry, which proceeds with preparations before starting the procurement process. The list is revised up to 4 times per year. However, the law stipulates it at least annually, and according to the respondents interviewed, there isn't any legal instrument that regulates this activity, except for the decision of the minister to establish the respective committee. Upon preparation of the list for the procurement process, ensuring generic names where applicable, forms, formulations and strengths, amounts, and other specifications, the process continues with the procurement division.

With medicines of generic characteristics, competition is abundant, and authorized marketing companies are very active; It is also important to note that there are cases where only a single company is in possession of the necessary marketing authorization for a certain medicine, limiting bidding process to a single bidder. This also is found with cases of companies and the associated marketing authorization for medicines related to rare conditions, which are more

often found to be exclusively produced by a single or a small number of pharmaceutical companies, effectively limiting competition in the sense of the bidding process.. According to the law on pharmaceutical products, Law Nr. 04/L -190, these are defined in article 3 Definitions, para 1.8 Orphan Medical Products, para 1.7 Medical Products of Advanced Therapies, para 1.5 Immunology based Medical Product.

At the time of undertaking this study, the new law on prices of medical products is still in its first year of application, and from the unwillingness of authorized marketing agencies to participate in the interviews and conditions of confidentiality under which those who did participate shared price information suggest a dissatisfaction within the sector. Prices collected and analysed indicate that the price of medicines in Kosovo remains largely unregulated.

According to the interviewed respondents, one of the outstanding issues regarding the supply of medicines on the essential list, especially medicines that are of low value in terms of price, is the hesitation of companies to participate or supply these medicines with such low prices. This is specifically related to tenders by the Ministry of Health, whereas, in similar tenders that are organized by Municipal Directorates for Health (level of local government), companies have a higher interest to participate because of higher price markups, despite the significantly lower volumes of medicines contracted. It is important to note that procurement activities concerning medicines from the essential list, undertaken in some cases by the Municipal Authorities (Municipal Directorates for Health and Social Welfare) are done so without any legal basis! In general, the local level of government is not authorised to initiate procurement activities for supply with medicines of the primary health care, as only the Ministry of Health is the authorised entity, but nevertheless the Municipalities initiate these types of procurement activities.

The 2023 budget for the Ministry of Health has allocated € 60 million for the procurement and supply of medicines on the essential list. The list was prepared following the procedures, with the list being prepared by the technical committee for the development of the list of essential medicines (also observing the budgetary constraint).

The SOP that guides the procurement process for the medicines of the essential list, has been approved in January of 20203. This SOP has been provided with the assistance of a USAID KMS program, with the intention to regulated the preparatory and procurement processes pertinent to the initiation of the procurement procedure for medicines from the essential medicines list!

The tendering process is subject to the respective Law on Public Procurement 04/L-042 and the associated secondary legislation, as well as to the responsible institutional bodies Procurement Division in the MH, Central Procurement Agency, Public Procurement Regulatory Commission, and the Procurement Review Body.

1.2. Description of the evaluated contract

For the evaluation of contract costs for essential medicines, five contracts from the tendering process have been identified and selected for analysis. Selected contracts with the following procurement identification numbers:

#	Tender identification number – procurement	Name of the tender
1	206-22-10662-1-1-1	Furnizim me barna nga Lista Esenciale
2	206-23-9209-1-1-1	Furnizim me Dornase alpha dhe Imiglucerase nga LE
3	206-23-6276-1-1-1	Furnizim me Barna nga Lista Esenciale
4	206-23-7805-1-1-1	Furnizim me Interferon beta 1a nga Lista Esenciale
5	206-23-8451-1-2-1	Furnizim me Pancreatic enzymes kapsula 150mg dhe 300mg nga LE

Contracts are from the period 2022 to 2023, making them relevant for analysis.

Selected contracts feature a list of essential medicines structured into lots, and lots are awarded to different companies based on their competitive offer in the tender. Criteria used for the contracts:

- Contracted lot implementation (a contract that has been implemented)
- Implemented in a recent period (relevant in current conditions)
- The contracted lot features generalization characteristics of the list of medicines (medicines should be representative – typical)
- The contracted lot should disclose contract positions with a detailed description of the medicine contracted, name, form, formulation, strength, and volume.
- The contracted lot should provide medicine with a description and price that allows for comparison.

For this purpose, the team has screened all healthcare infrastructure tenders by MH in the period 2020 – 2023; in total, 20 tendering activities concerning procurement of medicines from the list of essential medicines have been reviewed, where five selected contracts have best met all the listed criteria.

The contract format follows a standard public procurement model in Kosovo, which is stringently governed by procurement laws. In this system, tendering parties submit bids for listed lots that include highly standardized descriptions. These descriptions cover various aspects such as the medicines' generic names (where applicable), form and formulation, strength, usage, method of administration, and the quantity or volume required for procurement.

The competitive landscape shows improvement, yet there is still notable fragmentation in the market for low-cost medicines. This stimulates competition due to numerous contracting activities and individual contracts that generally have a low total value. Conversely, medicines for rare conditions command very high prices and typically face little to no competition, operating within a market where they dominate.

1.3. Cost analysis

Prices of medicines used in this comparative analysis are VAT inclusive, meaning that prices have the corresponding share of VAT calculated in the price, subject to the applicable VAT rates as they vary across medicines. The reason for comparing VAT-inclusive prices is that they are featured at the point of sales for the end-users and are thus relevant at the point of transaction/sales.

The list of medicines from the analyzed contracts contains 49 medicines, which are procured for a total of € 3,164,260. The ensuing analysis reveals that there are five medicines in the list that represent 66% of the share of the total cost, more specifically, € 2,095,196. These five medicines represent a group of medicines with the highest cost, clearly delineating a group of medicines with significantly higher costs of purchase.

#	Name	Euro/Sub-total	Unit Price (tender)	Units - Procured
1	Dornase alpha	572,508	16.74	34200
2	Interferon beta 1a 22mcg	125,482	43.57	2880
3	Imiglucerase	589,732	1365.12	432
4	Interferon beta 1a 44mcg	712,800	55	12960
5	Pancreatic enzymes	94,675	0.2705	350000
	TOTAL			**EUR** 2,095,196

Table 1: Medicines with the largest share of contract value

From the perspective of comparative analysis, it is also important to emphasize the observation that the market research part of the study did not find any market price references for any of the medicines from the group of 5. As a consequence, no price references are available for comparison or any further analysis for any of these five medicines. The interviewed respondents in the course of market research have said that these medicines are not provided in the wholesale or retail/pharmacies and, thus, are not commonly available in the commercial market for pharmaceutical products; likewise, pharmacies do not keep any of these medicines from the group of 5 in stock.

The market research, in addition to lacking price references for the above-listed five (5) medicines, also did not provide price references for another four (4) medicines, or in total, nine (9) medicines from the analyzed list of essential medicines were not found to be traded in the market for medicines in regards to the interviewed authorized wholesalers and retailers.

The list of medicines that are not provided in the retail/pharmacies is given below, and for which no corresponding market price was available:

#	Name
1	Dornase alpha
2	Interferon beta 1a 22mcg
3	Pancreatic enzymes
4	Imiglucerase
5	Interferon beta 1a 44mcg
6	Pancreatic enzymes
7	Furosemide
8	Diazepam
9	Oxytetracycline + hydrocortisone

Table 2: Medicines that were not available in terms of market price

In terms of share of the cost, the list of medicines that have no corresponding commercial market price reference represents 68.8% of the total cost of the contract, or in absolute value, € 2,177,803.

The group of nine (9) medicines was excluded from the analysis due to a lack of comparative commercial market price reference. Comparative analysis with the remainder of the medicines from the contract list for medicines of the essential list demonstrates a significant price advantage of the procurement process by the Ministry of Health. Specifically, the pricing analysis of 40 medicines from the public procurement list sum to €986,573, compared to €1,990,024 based on market research prices—a comparative difference of 98%. This demonstrates a substantial price advantage in the procurement process conducted by the Ministry of Health.

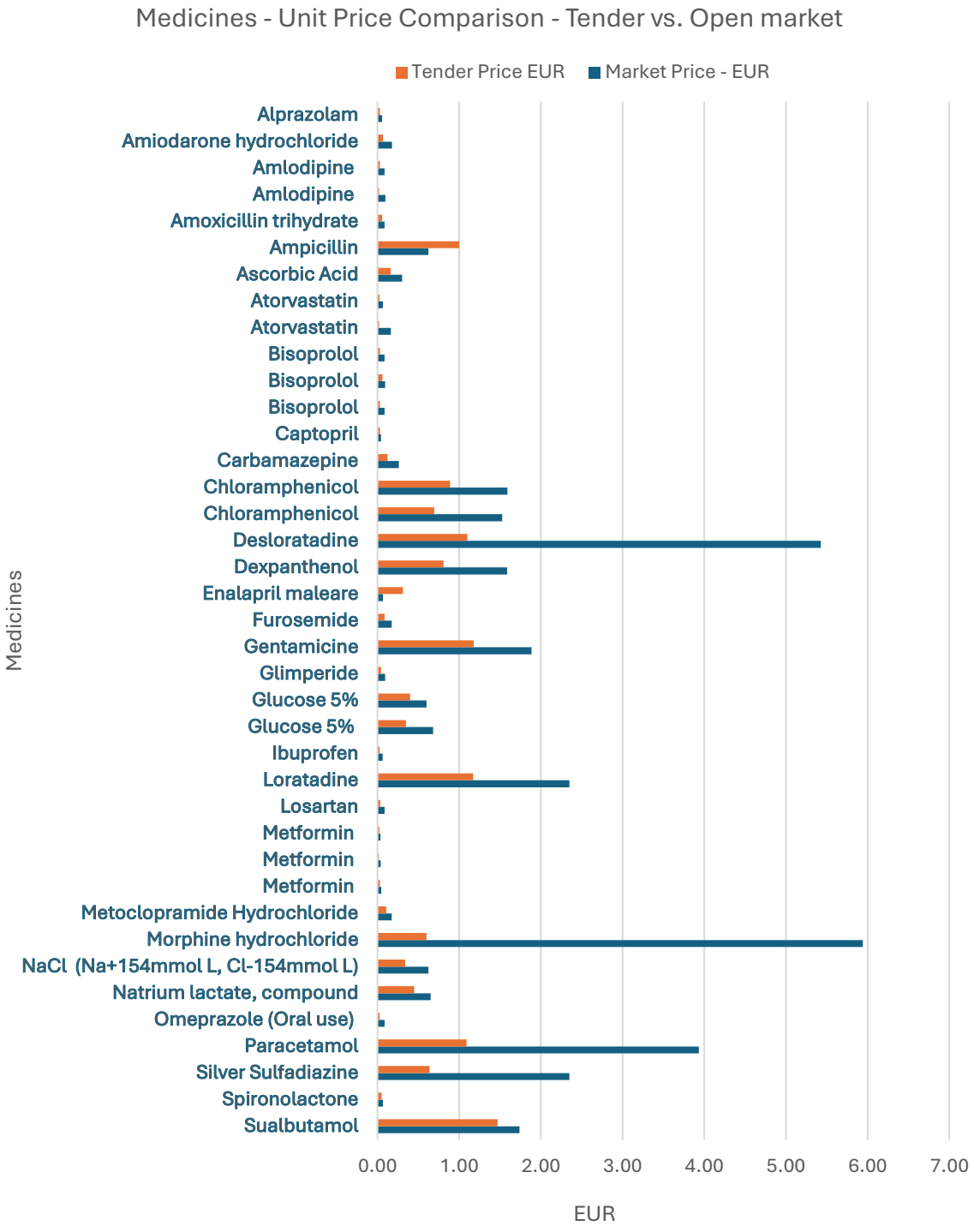


Figure 1: Price comparison for medicines

The graph above, *Figure 1*, illustrates the price comparison for (39) individual medicines from the tender contract and the price references obtained from the market research across the reference price line. In the graph below, *Figure* 2, a separate graph is provided for one medicine, anti-tetanus immunoglobulin, which has been excluded from the graph with all medicines since its significantly higher price affects the graph in its entirety, and it distorts the visibility by imposing a much larger reference scale.

Analysis of price differences and the subsequent observations from the graph above, *Figure 1*, a pattern with some consistency is observable, suggesting a mean price differential of 152% between procurement-obtained contract prices and commercially available prices for the compared medicines. There are outstanding differences or what could be considered outliers, such as the case with Morphine hydrochloride with a difference of 890%, Atorvastatin with a difference of 785%, Desloratadine with a difference of 393%, Amlodipine with a difference of 392%, and few other cases with large differences. These cases with high differences contribute significantly to the statistical variance of the price difference of 347%. A comparison of price differences after omitting the price differences from the above four (4) medicines produces an average difference of 101% between the contract prices of the procurement list and the commercial market-obtained price references, with the public procurement process of the Ministry of Health producing 101% less costly prices for the compared medicines.

From the entire list, there were only two cases of medicines that were priced with a lower price in the commercial market compared to the contracted prices in the public procurement contract: Enalapril maleate €0.07 vs €0.31 and Ampicillin injection 1g €0.63 vs €1.0. Descriptive statistical analysis reveals that the average price unit for almost all of the analyzed medicines is significantly lower for the medicines from the procurement contract compared to the average unit prices obtained from the market research. More specifically, the average price of a procurement contract is €0.64 compared to €1.23, which is the average price obtained by market research. Descriptive statistics further show that the variance, in this case, the standard deviation, is much lower for the unit prices of medicines from the procurement obtained contract, €1.87, as opposed to € 2.65 for the unit prices of medicines obtained from the market research. Differences in variation, or in this case in the standard deviation, suggest strongly that prices in the commercial market float in a rather wide range as opposed to the prices in the procurement contract, which have a much tighter floating range or are commanded towards a narrow convergence by a much stronger commercial interest (much higher total value of the contract in the public procurement). Summed price units of compared medicines produce a value of €25.49 as a sum for the price from the procurement contract and a value of €49.05 for summed unit prices references from the market research, or a difference of €23.56 or 92% when compared to the procurement-based contract prices. The implication is, therefore, that the price total for the medicines from the open market is nearly twice as expensive compared to the medicine prices from the tender contract. The evidence supports the position that medicines procured via the tender process are procured at a significant cost advantage. In addition, there is a strong convergence toward efficiency with reduced variation in prices overall as opposed to open-market – retail for the same medicines. The position, which suggests a significant cost advantage of medicines procured via the tender process by the Ministry of Health, is supported by a fraction of analyzed and cost-compared medicines, noting that a significant share in the total value of contracted medicines was not subject to analysis.

Figure 2 represents the visual comparison of [Anti-tetanus immunoglobulin], which was not included in the overall *Figure 1*.

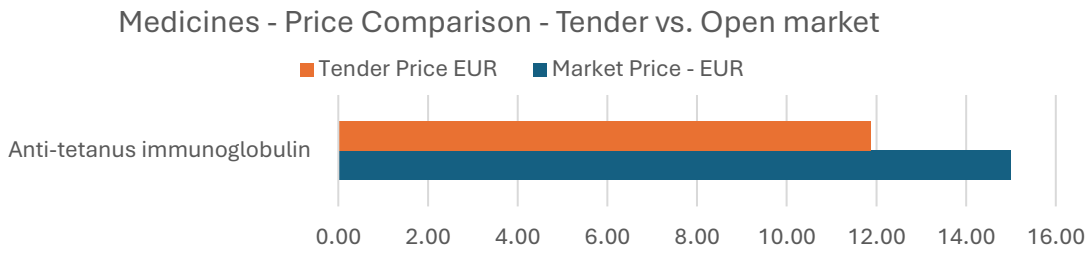


Figure 2: Price comparison for Anti-tetanus immunoglobulin

At the contract level, the individual price differentials and the quantities procured account for a total discrepancy of €1,003,451 (€1,990,024 - €986,573). A detailed breakdown of how each medicine's specific price difference contributes to this total can be found in *Figure 3*. The overall difference in the sum of the unit price of medicines is 92%. Still, the total for the procured amounts is 98%, and this is because quantities of medicines are not equally or uniformly distributed, and some medicines have a higher price differential, which affects contribution by increasing the total difference at the contract level. Significant differences that contribute to higher differences in total contract price vs market obtained prices are observable with two lots for Atorvastatin 10mg and 20mg with a cost difference of €161,380 and €65,745, respectively; likewise, for Metformin 1g, the cost difference at the lot level is €130,465, for Omeprazole 20mg the difference of cost at the lot level is €100,391. For NaCl isotonic solution 0.9% 100ml, the difference in cost at the lot level is €64,390. Further in the list, notable cases of cost differences at the lot level that drive up the total difference are Losartan 40mg with a cost difference of €43,183 and Ascorbic Acid injection with a cost difference of €44,506. Listed examples of medicines and the corresponding lots in the contract represent the major drivers of the total cost difference.

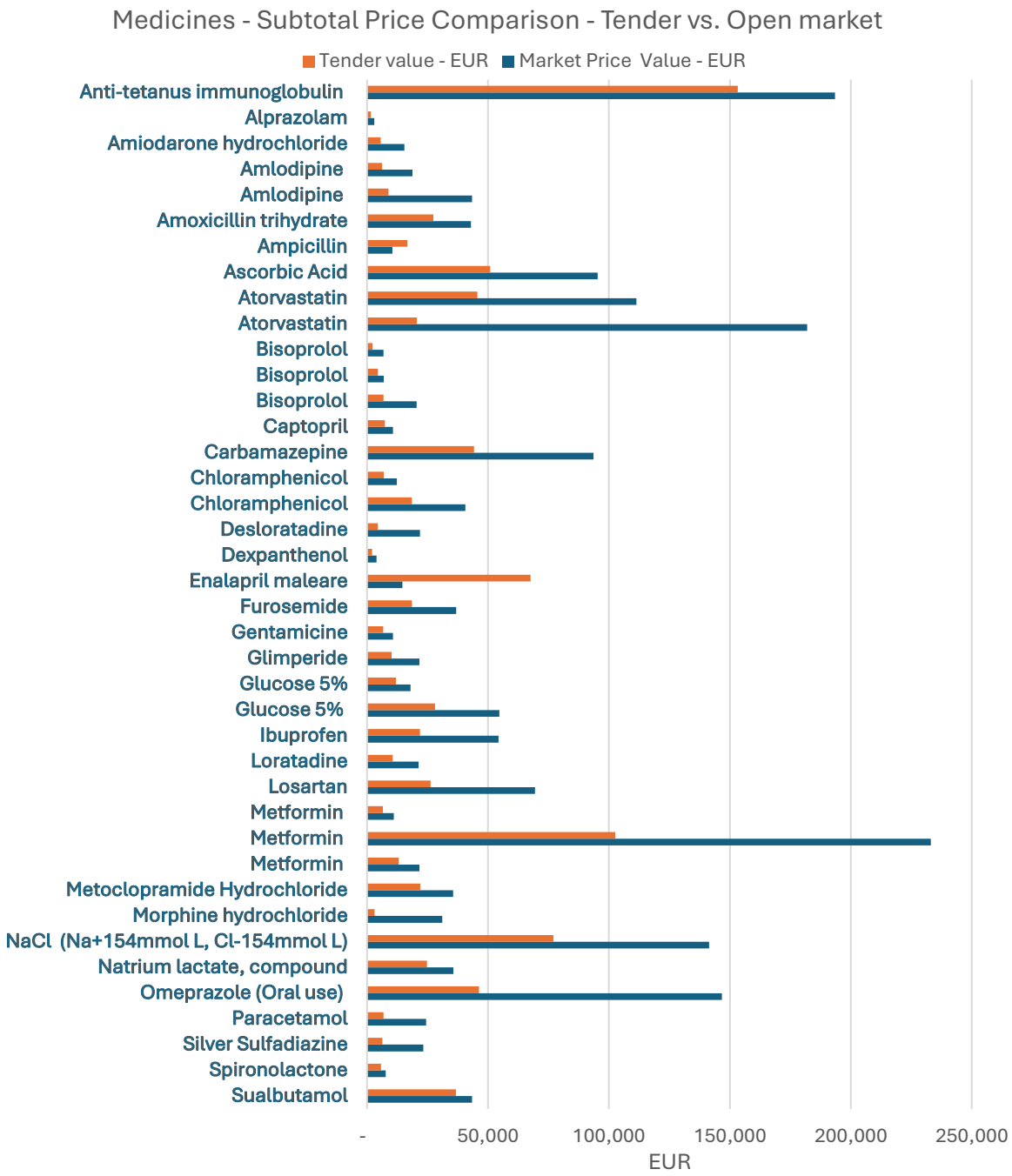


Figure 3: Contribution of each medicine to the total difference

A tabulated view of prices for the analysed prices of medicines is given in *Table 3* below.

Part /Lot	Article	Strength	Form	Contract ammount - 12 months	Market Price - EUR	Tender Price EUR	Tender value - EUR	Market Price Value - EUR	Difference EUR	Difference %
1	Amlodipine	10mg	Tablet	441,000	0.10	0.02	8,820	43,423	-34,602.8	-392%
1	Ibuprofen	400 mg	Tablet	840,900	0.06	0.03	21,863	54,304	-32,441.0	-148%
2	Bisoprolol	5mg	Tablet	234,000	0.09	0.03	6,786	20,530	-13,743.6	-203%
2	Morphine hydrochloride	10 mg/1 ml	Injection	5,238	5.94	0.60	3,143	31,114	-27,970.9	-890%
3	Captopril	25mg	Tablet	246,000	0.04	0.03	7,331	10,660	-3,329.2	-45%
3	Paracetamol	1g	Injection	6,198	3.93	1.09	6,756	24,379	-17,623.0	-261%
4	Desloratadine	2.5 mg / 5 ml	Solution	4,033	5.43	1.10	4,443	21,886	-17,443.0	-393%
4	Enalapril maleare	10mg	Tablet	218,150	0.07	0.31	67,627	14,671	52,955.9	78%
5	Loratadine	1mg/mL	Oral solution	9,068	2.35	1.17	10,610	21,310	-10,700.2	-101%
5	Silver Sulfadiazine	0.01	Topical	9,900	2.35	0.64	6,306	23,265	-16,958.7	-269%
6	Carbamazepine	400mg	Tablet	356,944	0.26	0.12	44,261	93,638	-49,377.3	-112%
6	Furosemide	10mg ml,2ml	Injection	212,600	0.17	0.09	18,496	36,833	-18,336.8	-99%
7	Amoxicillin trihydrate	500mg	Hard capsules - oral	497,544	0.09	0.06	27,365	42,913	-15,548.3	-57%
8	Ampicillin	1g	Injection powder	16,695	0.63	1.00	16,695	10,434	6,260.6	38%
8	Spironolactone	25mg	Tablet	114,000	0.07	0.05	5,700	7,763	-2,062.9	-36%
9	Amiodarone hydrochloride	200mg	Tablet	86,525	0.18	0.07	5,624	15,451	-9,826.8	-175%
10	Amlodipine	5mg	Tablet	216,000	0.09	0.03	6,264	18,765	-12,501.0	-200%
10	Metoclopramide Hydrochloride	5mg ml,2ml	Injection	205,000	0.17	0.11	21,935	35,533	-13,598.3	-62%
11	Atorvastatin	10mg	Tablet	1,099,320	0.17	0.02	20,557	181,937	-161,380.2	-785%
11	Chloramphenicol	0.01	Eye ointment	26,600	1.53	0.70	18,487	40,609	-22,122.3	-120%
12	Alprazolam	0.25mg	Tablet	54,200	0.06	0.03	1,626	3,035	-1,409.2	-87%
12	Atorvastatin	20mg	Tablet	1,709,160	0.07	0.03	45,635	111,380	-65,745.7	-144%
13	Bisoprolol	10 mg	Tablet	75,000	0.09	0.06	4,500	6,885	-2,385.0	-53%
14	Bisoprolol	2.5 mg	Tablet	80,000	0.09	0.03	2,320	6,820	-4,500.0	-194%
15	Losartan	50mg	Tablet	814,276	0.09	0.03	26,301	69,485	-43,183.8	-164%
15	Sualbutamol	100mcg per dose	Inhlalation	25,000	1.74	1.47	36,750	43,450	-6,700.0	-18%
16	Chloramphenicol	5%	Topical	7,720	1.59	0.89	6,871	12,288	-5,416.9	-79%
16	Glucose 5%	5% (izotonik), 100ml	Solution for infusion	30,000	0.60	0.40	12,000	18,000	-6,000.0	-50%
17	Dexpanthenol	0.05	Topical	2,500	1.59	0.81	2,025	3,967	-1,941.7	-96%
17	Glucose 5%	(izotonik), 500ml	Solution for infusion	80,400	0.68	0.35	28,140	54,672	-26,532.0	-94%
18	Gentamicine	0.10%	Topical	5,659	1.89	1.18	6,661	10,667	-4,006.6	-60%
18	NaCl (Na+154mmol L, Cl-154mmol L)	0.9%, 100ml, izotonik	Solution for infusion	226,500	0.62	0.34	77,010	141,401	-64,390.7	-84%
19	Natrium lactate, compound	compound 500 ml	Solution for infusion	54,900	0.65	0.45	24,705	35,685	-10,980.0	-44%
20	Ascorbic Acid	500mg 5ml	Injection	317,900	0.30	0.16	50,864	95,370	-44,506.0	-88%
20	Omeprazole (Oral use)	20 mg	Hard capsules - oral	1,715,848	0.09	0.03	46,328	146,720	-100,391.6	-217%
21	Anti-tetanus immunoglobulin	250IU	Injection	12,900	15.00	11.88	153,252	193,500	-40,248.0	-26%
21	Glimperide	2 mg	Tablet	235,460	0.09	0.04	10,172	21,631	-11,459.1	-113%
22	Metformin	1 g	Tablet	470,340	0.05	0.03	13,170	21,610	-8,440.0	-64%
23	Metformin	850 mg	Tablet	5,730,530	0.04	0.02	102,576	233,042	-130,465.1	-127%
24	Metformin	500mg	Tablet (oral use)	300,000	0.04	0.02	6,600	11,000	-4,400.0	-67%
Total							**986,573**	**1,990,024**	**-1,003,451**	**-98%**

Table 3: Contribution of each medicine to the total difference

The table above, *Table 3*, provides per item (medicine) overview of price comparisons between tender contract prices and market research-based prices, also extending the column for analysis of differences at the unit price level in absolute value as well as in percentage. The analysis does not account for the cost of sale associated with these medicines. To clarify, the volumes of medicines procured through public contracts are significantly higher than the volumes sold through private pharmacies (retail). This discrepancy highlights how economies of scale substantially influence the observed price differences. Additionally, retail-specific costs in small pharmacies, along with significant costs related to wholesale activities like distribution and

marketing, further contribute to these price variations. These costs certainly may be paralleled via the distribution structure of medicines through the public sector. Upon intake from the point of delivery by tender contractors, the public sector distributes and handles medicines through its institutional structures, levels, and units, cascading down to the end patient. However, this cascading network of institutional structures does not generate any explicit costs associated with the associated logistics. Hence, no costs are assigned to medicines from the point of intake to the point of administration, which can hardly support the idea that there are real costs associated with the activity.

2. Procurement of Healthcare Infrastructure

The Ministry of Health is the principal authority responsible for the provision of healthcare infrastructure, which is provided along the hierarchy of the healthcare system: primary, secondary, and tertiary. With regard to infrastructure, MH is also responsible for specialized institutions and the provision of healthcare-associated facilities. At the level of primary healthcare facilities, the responsibility is shared with the local government authorities (municipal authorities), who also bear some responsibility for infrastructure.

2.1. Legal and institutional background, description of the market for providers

There is no current strategy document of the Ministry of Health for the healthcare infrastructure. In the absence of a more recent strategy, the Healthcare Sectorial Strategy 2017 – 2021[2] remains the only strategy for healthcare in Kosovo, providing strategic level objectives for healthcare infrastructure, specifically formulated in objective 7, Improvement of provision for healthcare services, which needs to be read with strategic result 7.3 Construction of a functional healthcare infrastructure. This is further sanctioned in the basic legislation act, the Law on Health Nr. 04/L-125, in article 9 - Direction and Regulatory Role, paragraph 1.6 Management and development of healthcare infrastructure. At the government level, Ministry of Health, the responsibility for healthcare infrastructure belongs to the Infrastructure Division of the Ministry of Health, currently headed by an acting head.

The responsibility of the Infrastructure Division is principally project preparation (new facilities, renovation, extension, and other healthcare infrastructure-related engineering/construction works) and project costing. In terms of organizational functioning, the division is responsible for the preparation and implementation of the annual activity plan, which stems from the mandate of the division, the strategic plan of the sector, and the law on health.

The division has practically no specialists working there, with the exemption of the acting head, who by qualification is an Electrical Engineer and often asks for and receives some engineering support from an engineering department (infrastructure) that is part of the University Clinical Centre of Prishtina (a subordinate entity of the Ministry). According to the budgetary circular[3] of the Ministry of Finance, the budget for the year 2024 for the Ministry of Health specifies € 24.6 million for capital expenditure.

[2] https://msh.rks-gov.net/Documents/DownloadDocument?fileName=Strategjia%20Sektoriale%20e%20Sh%C3%ABndet%C3%ABsis%C3%AB%20(2017%20%E2%80%93%202021)54528803.4504.pdf

[3] https://konsultimet.rks-gov.net/Storage/Consultations/10-11-23-31052023/Qarkorja-Buxhetore-2024_01-1.pdf

The selection of capital investment projects in the Ministry of Health starts with the identification of requests, which are communicated by specific entities and are then prioritized at the political level with respect to a preliminary costing and the associated benefits, as well as the urgency of the investment. Screening at the political level allows projects to enter a pipeline of works, which are then passed to the Infrastructure Division for further analysis and costing, where these costs are then sent back to the political level for budgeting purposes. Upon budget approval, the Infrastructure Division proceeds with the preparation of the ToR for tendering of the project design, which is contracted with design companies that provide the design and cost parameters for implementation (construction).

The regulatory context for healthcare infrastructure is provided by the construction Law and the norms act of the Ministry for Spatial Planning and Infrastructure, AI MMPH-NR.08/2017. Construction activity in Kosovo is regulated via the basic act, Law on Construction, 04/L – 110, referencing here also the Euro Code as the norming reference for the quality of construction. In addition, there is administrative instruction from the Ministry of Trade and Industry, No. 03/2019, which regulates the performance of construction materials (technical characteristics). At the same time, two major administrative instructions are referenced for designing (functional requirements – parameters) of healthcare infrastructure, Annex I - AI Health - MSH-04/2020-UA, and Statute (GRK) no. 01/2023 of the Hospital and University Clinical Care of Kosova. However, within the Infrastructure Division of the Ministry of Health, there are no specific policies/strategies, or guidelines that provide orientation in the process of design and norms that relate to healthcare infrastructure projects. Interviews with all the relevant stakeholders confirm that there is no specific design guideline or a norming act that regulates the design of the healthcare facilities in Kosovo (no national norming act) and that most often, design professionals/companies resort to international (WHO) or other national regulations (UK/Germany) as a framework to guide their work processes.

Recently, one Standard Operating Procedure (SOP) has been developed with support from the USAID KMI program. The SOP pertains to the management of development processes, specifically the design and procurement of infrastructure projects for healthcare facilities.

The tendering process is governed by the Law on Public Procurement 04/L-042 and its associated secondary legislation. Oversight and regulation are provided by several institutional bodies, including the Procurement Division within the Ministry of Health (MH), the Central Procurement Agency, the Public Procurement Regulatory Commission, and the Procurement Review Body.

The construction sector in Kosovo is one of the largest in terms of its share in the economy, with both private and public investments driving demand strongly over the last 15 years. Based on the interviews with construction sector representatives, and in particular with the representative of the association of construction sector companies, it is estimated that there are around 70,000 employees in the construction sector, with nearly 50% being informally employed. Statistics from the Agency of Statistics report that the workforce in the construction sector is around 39,000. According to a Kosovo Tax Administration publication[4], there were 7,790 companies in the construction sector in Kosovo in 2021, with a declared turnover for 2022 at €983 million. The sector is vibrant and competitive yet insufficiently regulated.

[4] https://www.atk-ks.org/wp-content/uploads/2021/06/RaportPlaniNdertimtari2019-2021.pdf

2.2. Description of the evaluated contract

The selected contract for evaluation is a construction contract for a primary healthcare facility in the town of Mamushë/Mamuša, a small city in the southwestern part of Kosova. Formal title of the contract is "Ndertimi i objektit te QKMF ne Mamushë/Mamuša" trans. Construction of PHC facility in Mamushë/Mamuša. Procurement number 206-20-6739-5-1-1 was awarded to "Construmax Shpk" for a total of € 757.608, and the contract was dated 26.01.2021.

Criteria used for the sample contract:

- Project implementation (a project that has been implemented)
- Implemented in a recent period (relevant in current conditions)
- The project features generalization characteristics of investment projects in healthcare infrastructure (project should be representative – typical)
- The project should disclose contract positions with detailed/sufficient technical descriptions, works, dimensions, and materials.
- The project should provide positions/contract positions with cost descriptions that can be disaggregated into materials and works, which allow for comparison.

For this purpose, the team has screened all healthcare infrastructure tenders by MH in the period 2020 – 2023. In total, 14 contracts were taken for review, and the one selected best meets all the listed criteria.

The development of the Primary Healthcare (PHC) facility in Mamushë/Mamuša began with a request from the local municipal authorities, who also provided partial funding for the project. Initially, the municipal authorities handled the tendering for the project design. However, due to repeated failures in securing the necessary co-funding, the Ministry of Health (MH) was compelled to assume control over the project's implementation. This implementation was carried out based on a design prepared by a design bureau, which had been selected through a tender contract issued by the municipal authority of Mamushë/Mamuša.

Contract format is a standard public procurement contract in Kosovo, regulated intensively under the procurement law, where tendering parties practically apply to the listed positions for construction, typically works, supplies, and install construction materials and equipment. The inviting party has prepared a project with all the necessary descriptions, architectural, structural, and functional parameters for the building and the equipment pertinent to the building (electrical, plumbing, hvac, ict, etc.).

These contracting formats, commonly employed in public works across Kosovo, present challenges in accurately distinguishing between the costs of materials, labor, equipment, fuel, energy, and other specific expenses. Implementing FIDIC standards for civil engineering contracts could significantly improve the measurement and evaluation of work progress, as well as enhance cost transparency regarding materials, labor, and equipment. Moreover, such standards facilitate proper risk allocation and management in construction projects, which is particularly beneficial for indexing costs during inflationary periods and for projects extending over multiple years.

Despite the fact that the current procurement law provides for the possibility to do indexing costs during periods of inflation, still the contracting authorities (in this case the Ministry of Health) are not using this practice. According to the procurement expert, lack of application of indexing in public procurement contracts may be explained due to the lack of knowledge, and partially

because of the fact that Kosovo does not have an authorized price referencing mechanism, or a public price catalogue for construction works! Whereas in the case of application of FIDIC contracting procedures, the contracting authorities would need subscribe for these standards against a fee! Still, similar structuring of contracts can be considered, asking for bidding companies to submit disaggregated prices for positions, in separate price schedules for labour, materials, equipment, etc.

2.3. Cost analysis

Cost analysis is undertaken as a cost comparison between contracted costs for positions in the awarded contract vs the price for the position obtained via market research. Market prices for the positions pertinent to the construction position (typically a supply of materials/equipment and installation/works) have been asked as price reference to the year of the contract. In total, there are 379 data points in the contract for which open market price references have been collected and processed. The prevailing contract requirement is supply and installation, which involves materials/equipment and work, which makes it difficult to disaggregate positions into costs for materials, costs for labor, and profit margins. It would be tempting to identify the price of materials and subtract it from the cost of the position. Still, the allocation of labor vs the allocation of profit margin cannot be determined with any certainty due to a lack of knowledge of how businesses strategize when they structure costs in such a complex contract.

Comparing the contracted costs (tender) and market prices (research) for the specific materials and works reveals that contract prices (tender) are up to 21% below the market prices. Significant differences in contracted costs for each of the five categories of the construction contract have been observed with respect to market prices for the year 2021. According to information from the interviewed respondents, the typical cost of construction for a primary healthcare facility is found to range from €600 to €1,000 per square meter. The analysed contract features a Primary Healthcare Facility with a gross constructed area of 1,500 square meters for a contract value of €757,584, or €505 per square meter. Using the rule of thumb for comparison, as suggested by interviewed experts, the actual contract is somewhat 16% shorter in funds needed for implementation, or €142,415.

A comprehensive cost analysis is provided below, extrapolating from at least 3 data points for each of the 379 data points of the contract pertinent to positions in the contract for construction of the PHC facility (material, work, and equipment) is provided below.

Price analysis is grouped into five categories of construction contracts:

1. Construction (site prep work, earthworks, structure, masonry, plastering & facade, carpentry, exterior and landscaping);
2. Plumbing & Sanitation;
3. Electrical installations;
4. HVAC;
5. Medical gas system

The construction category of costs accounts for 86% of the total contract value, amounting to €652,313. By comparison, a market research-based assessment indicates that costs within the construction category represent 80% of the total estimated cost for implementing this contract.

Figure 4, Construction cost analysis, provides a graphical presentation of a comparative analysis of the position of costs within the construction category. Overall comparison of cost positions

between contracted values and market research shows a coherence, with a dominant small-scale cost difference towards the market obtained price references; the average difference in price between contract and market research is 15% for the total construction category of costs, with contracted costs falling behind the market. A noticeable difference is observed in the sub-category of excavation costs as well as steel/rebar works, corresponding to 68% and 34% higher contracted values than market-rated costs. Likewise, the subcategories of costs, concrete and exterior works, indicate significantly undervalued contract costs, 25% and 65%, respectively.

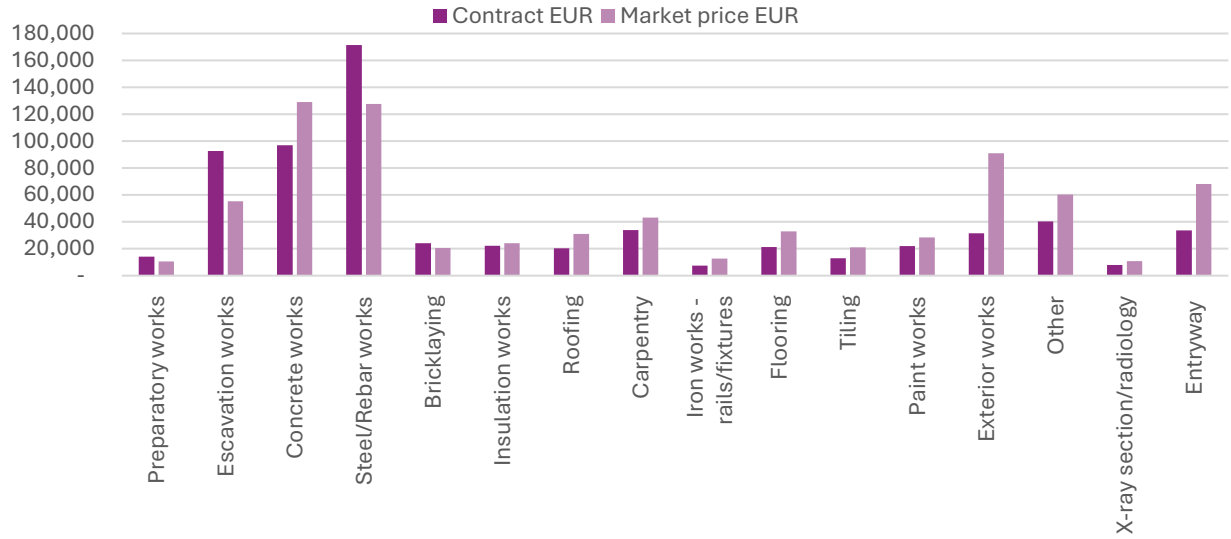


Figure 4: Construction cost analysis

The cost breakdown for analysis is provided in *Table 4* (*please note that VAT has been added back to contract values for the listed positions for comparison, as opposed to added VAT at the end of the contract for the total sum*).

	Construction positions	Contract EUR	Market price EUR	Difference EUR
1	Preparatory works	14,068	10,679	3,389
2	Excavation works	92,723	55,323	37,399
3	Concrete works	96,972	129,147	-32,175
4	Steel/Rebar works	171,315	127,662	43,652
5	Bricklaying	24,037	20,502	3,535
6	Insulation works	22,149	24,073	-1,924
7	Roofing	20,224	30,935	-10,711
8	Carpentry	33,854	43,200	-9,346
9	Iron works - rails/fixtures	7,410	12,602	-5,191
10	Flooring	21,248	32,941	-11,694
11	Tiling	12,959	21,143	-8,183
12	Paint works	22,006	28,522	-6,516
13	Exterior works	31,496	91,095	-59,599
14	Other	40,193	60,251	-20,058
15	X-ray section/radiology	7,969	10,842	-2,873
16	Entryway	33,691	68,236	-34,545
	Total	652,313	767,153	-114,840

Table 4: Cost breakdown for construction cost

The total value of the difference in the category of construction is € 114,840 (netting differences of all positions) when compared between the contracted value and the value for the works obtained from the market research! The value of difference for the category of construction costs represents approximately 15% of the value in total for the category based on the cost information obtained from market research.

The Plumbing & Sanitary category of costs constitutes 1% of the total contract value, totalling €11,009. However, a market research-based assessment shows that these costs account for 2% of the total estimated cost for implementing this contract.

Figure 5 presents a graphical analysis of Plumbing & Sanitary Works costs, offering a comparative view of cost positions within the construction category. It highlights a 41% cost discrepancy between the contracted values and those derived from market research, with contracted costs significantly lower than market values for this category. Specifically, within the Plumbing & Sanitation category, the sub-categories of construction works and plumbing show contracted values that are 75% and 42% below the market-assessed costs, respectively.

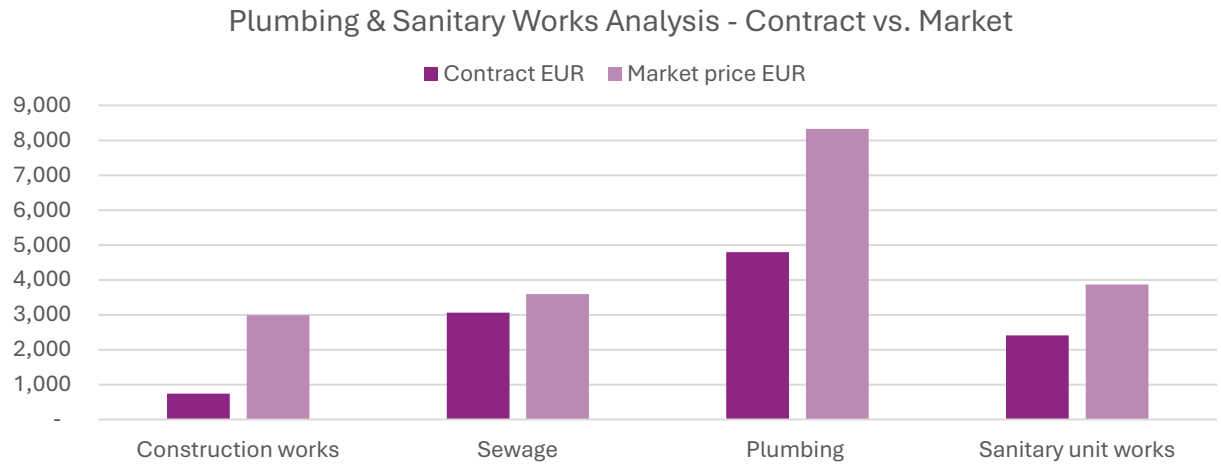


Figure 5: Plumbing & Sanitary Works cost analysis

The cost breakdown for analysis is provided in *Table 5* (*please note that VAT has been added back to contract values for the listed positions for comparison, as opposed to added VAT at the end of the contract for the total sum*).

	Plumbing/Sanitary Positions	Contract EUR	Market price EUR	Difference EUR
1	Construction works	743	2,987	-2,243
2	Sewage	3,061	3,598	-537
3	Plumbing	4,798	8,327	-3,529
4	Sanitary unit works	2,407	3,866	-1,458
	Total plumbing & sanitary	11,009	18,778	-7,769

Table 5: Plumbing & Sanitary Works cost breakdown

The total outstanding value for the category of Plumbing and Sanitary works is € 7,769 (netting differences of all positions) when compared between the contracted value and the value for the works obtained from the market research! The value of difference for the category of Plumbing and Sanitary costs represents approximately 41% of the value in total for the category based on

the cost information obtained from the market research. In terms of absolute values, Plumbing & Sanitation remain a very marginal cost in the context of the entire contract; thus, variations do not bear a large significance overall.

The Electrical Installations category accounts for 5% of the overall contract value, amounting to €35,054. In contrast, a market research-based assessment shows that these costs represent 7% of the total estimated cost for implementing this contract.

Figure 6 provides a graphical representation of the Electrical Installations cost analysis, offering a comparative overview of cost positions within this category. The analysis reveals significant underpricing in the contract for specific items. For instance, the cost position for power cables and connecting cabinets is 57% lower than the market-rated value, amounting to an absolute difference of €14,954. Additionally, a notable discrepancy is observed in the cost of the Continuous Power Supply (a local generator unit 80kVA), where the contracted value is 69% below the market rate, translating to an absolute difference of €6,550.

The remaining cost positions within the Electrical Installations category show smaller deviations, with contracted values generally being lower than those based on market research. However, market prices consistently remain somewhat higher than the contracted values for these items.

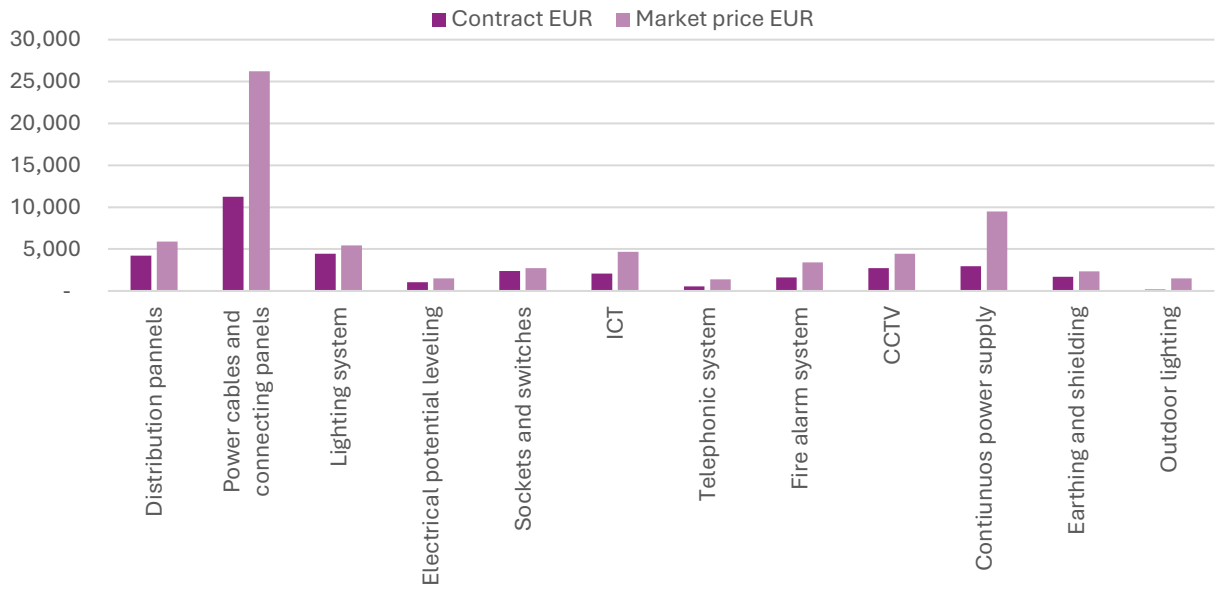


Figure 6: Electrical Installation Cost Analysis

The cost breakdown for analysis is provided in *Table 6* (please note that VAT has been added back to contract values for the listed positions for comparison, as opposed to added VAT at the end of the contract for the total sum).

	Electrical Installation Positions	Contract EUR	Market price EUR	Difference EUR
1	Distribution panels	4,232	5,900	-1,667
2	Power cables and connecting panels	11,265	26,219	-14,954
3	Lighting system	4,428	5,446	-1,018
4	Electrical potential levelling-earth	1,023	1,497	-474
5	Sockets and switches	2,393	2,738	-345
6	ICT	2,055	4,688	-2,633

7	Telephonic system	526	1,370	-844
8	Fire alarm system	1,607	3,422	-1,815
9	CCTV	2,730	4,458	-1,728
10	Continuous power supply	2,950	9,500	-6,550
11	Earthing and shielding	1,694	2,334	-640
12	Outdoor Lighting	150	1,510	-1,360
	Total electrical systems	**35,054**	**69,083**	**-34,030**

Table 6: Electrical Installations cost analysis cost breakdown

The total outstanding value for the Electrical Installations category, considering the net differences across all positions, amounts to €34,030 when comparing the contracted value to the market research value. This discrepancy represents approximately 49% of the total value for this category based on market research cost information. Although electrical installations account for a smaller proportion of the overall contract cost in absolute value, their importance should not be underestimated, as variations in this category can be significant.

The HVAC category of costs represents 7% of the total contract value, € 50,020. In contrast, a market-research-based assessment of costs produces a cost total that represents a 9% share of the total assessed value for the implementation of the entire contract.

Figure 7, HVAC cost analysis, provides a graphical presentation of a comparative analysis of the position of costs within the HVAC category. Further analysis shows that the cost position for the Central Furnace and Cooling Unit in the contract is significantly underpriced compared to the market-rated value for the position, with a difference of 66% or in terms of absolute value € 27,15.

The remainder of cost positions within the category of HVAC indicates a deviation of a smaller scale with respect to contracted values as opposed to market-research-based values, with market prices remaining somewhat above the contracted values.

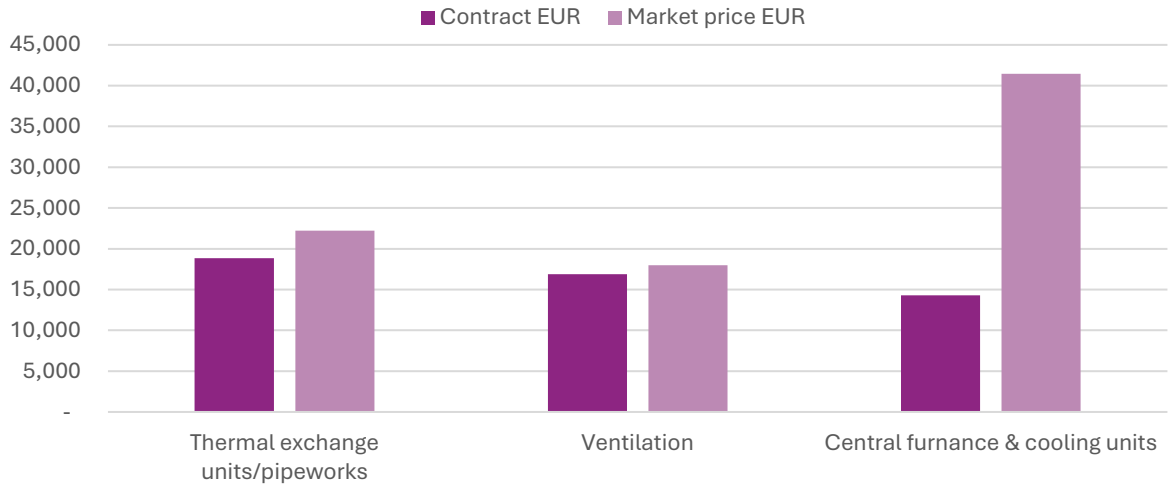


Figure 7: HVAC cost analysis

The cost breakdown for analysis is provided in *Table 7* (*please note that VAT has been added back to contract values for the listed positions for comparison, as opposed to added VAT at the end of the contract for the total sum*).

	HVAC -Works Positions	Contract EUR	Market price EUR	Difference EUR
1	Radiators-heating units/pipework	18,847	22,236	-3,388
2	Ventilation	6,886	17,971	-1,085
3	Central furnace & cooling units	4,287	41,439	-27,152
	Total HVAC - Mechanical/electrical	50,020	81,646	-31,626

Table 7: HVAC cost breakdown analysis

The total outstanding value for the HVAC category, accounting for net differences across all positions, is €31,626 when comparing the contracted value to the market research value. This discrepancy accounts for approximately 39% of the total HVAC costs based on market research. Although HVAC represents a smaller portion of the overall contract cost in absolute terms, the deviations are significant and impactful for cost planning and contract implementation.

In the Medicinal Gases category, the total contract value is represented by 1%, amounting to €9,188. However, a market research-based assessment indicates that these costs constitute 2% of the total assessed value for the contract implementation.

Figure 8 provides a graphical analysis of the Medicinal Gases category, highlighting substantial differences in cost positions. Specifically, the contracted values for Oxygen, Compressed Air, and Vacuum are 67%, 81%, and 74% below the market-assessed costs, with absolute differences of €2,785, €5,529, and €3,476, respectively. Furthermore, the cost position for sockets for medical gases is also significantly lower than the market estimate by 85% or an absolute value of €1,946. These findings underscore the importance of accurate cost assessments in medical gas provisions within healthcare facility projects.

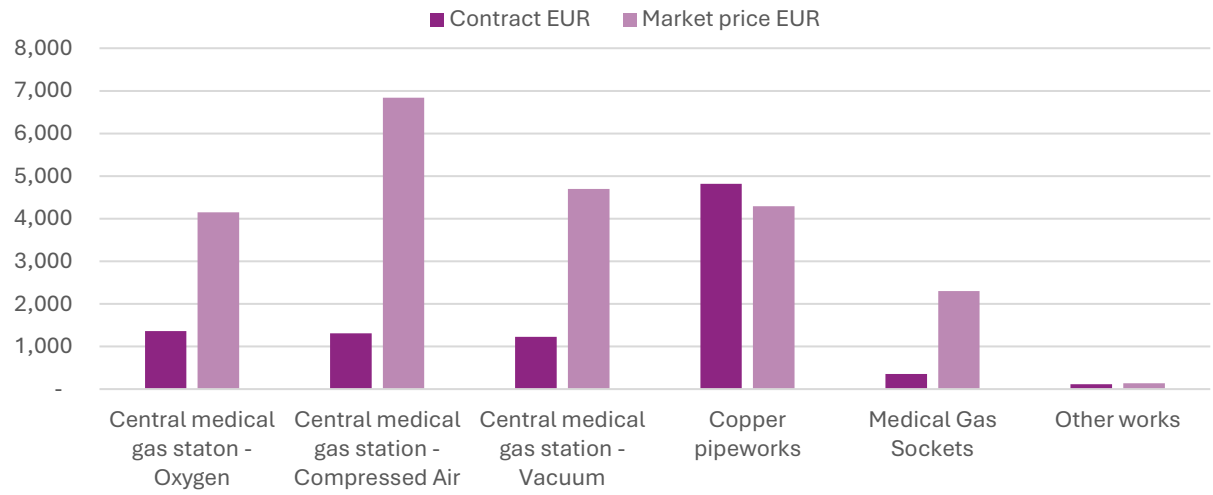


Figure 8: Medicinal Gases cost analysis

The cost breakdown for analysis is provided in *Table 8*. (*please note that VAT has been added back to contract values for the listed positions for comparison, as opposed to added VAT at the end of the contract for the total sum*).

	Medicinal Gases Works Positions	Contract EUR	Market price EUR	Difference EUR
1	Central Medical gas station - Oxygen	1,365	4,150	-2,785
2	Central Medical gas station - Compressed Air	1,311	6,840	-5,529
3	Central medical gas station - Vacuum	1,224	4,700	-3,476
4	Copper pipework	4,816	4,290	526
5	Medical Gas Sockets	354	2,300	-1,946
6	Other works	118	138	-20
	Total medical gases	**9,188**	**22,418**	**-13,231**

Table 8: Medicinal Gases cost breakdown analysis

The total outstanding value for the Medicinal Gases category, after accounting for the net differences across all positions, stands at €13,231 when comparing the contracted values to those obtained from market research. This discrepancy represents about 59% of the total value for this category based on the market research data. Although medicinal gases constitute a very small marginal cost in the context of the entire contract, the variations in cost, while noticeable, do not significantly impact the overall financial scope of the project.

Analysis of the cost differences is provided in the pie chart below (*Figure 9*), showing that the most significant cost differences between contracted cost positions and cost estimates from the market research are found in the cost category of construction.

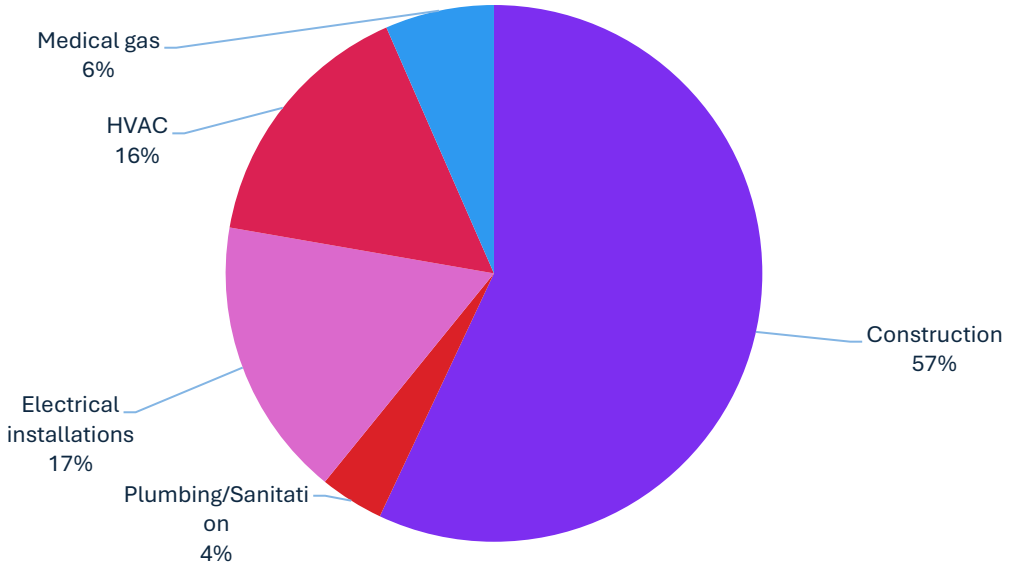


Figure 9: TOTAL cost difference - By Structure

The table below (*Table 9*) summarizes the comparative analysis of costs between the contracted values and the values/prices obtained from the open market for the same position (material/work/equipment). It can be observed that the largest difference in cost categories is in the construction, with an absolute difference of € 114.840, which is then, in relative terms, the lowest difference. The highest relative difference is found in the cost category of medicinal gases, where the range of prices for the equipment showed a large difference, depending on the approach of the respondents, but still, in relative terms, it is shown as the second lowest difference, € 13,231.

The total difference amounts to €201,459. However, deeper insights can be gleaned from examining the distribution of the cost breakdown comparing the distribution of costs in the tender contract to those derived from market research. Construction stands out as the top cost category, with an 86% share of the tender contract value as opposed to 80% of the value according to market assessment. It is reasonable to conclude that the 15% positive difference in the construction cost category, identified through a comparative analysis of contracted costs versus open market costs, is not enough to cover the remaining costs of the entire contract. Analysis of how cost differences are distributed (breakdown) shows that construction exhibits the largest share, 57%, followed by electrical installations and HVAC, 17% and 16%, respectively.

Cost categories	Tender Contract prices EUR	Market prices EUR	Difference EUR	Compared to market prices	Tender contract cost breakdown	Market research cost breakdown	Cost differences breakdown
Construction	652,313	767,153	-114,840	-15%	86%	80%	57%
Plumbing / Sanitation	11,009	18,778	-7,769	-41%	1%	2%	4%
Electrical installations	35,054	69,083	-34,030	-49%	5%	7%	17%
HVAC	50,020	81,646	-31,626	-39%	7%	9%	16%
Medical gas	9,188	22,418	-13,231	-59%	1%	2%	7%
Total	**757,584**	**959,079**	**-201,495**	**-21%**			

Table 9: The comparative analysis of costs

The oversight of the project, which should encompass both technical aspects and contractual (legal) compliance, is reported to be only nominally effective. Although reports documenting the work are filed, there are typically no consequences for contractors who violate contract terms, except for contract termination during implementation if the contract no longer benefits the contractor.

The cost advantage is obvious from the price analysis of the contract cost and the costs obtained from the open market for similar works, by approximately 21% measured from the cost assessment using open market prices, inferring efficiency and superiority of the procurement process. However, interviews with MH officials in the Infrastructure Division and contract supervisors, as well as with procurement officials, have revealed that the project in Mamushë/Mamuša has not been implemented fully in accordance with the terms of the contract, leaving flooring works and reserve power supply positions not completed. Likewise, the interviews with private sector construction companies and architects have contemplated that the lowest price for such projects is not good and is actually very far from an effective solution, with companies leaving several positions not fulfilled near the end of the construction/ending phase of the project. Companies choose to abandon positions with lower values, strategically positioned in the contract near the end, by the time companies have completed most of the construction terms of the contract and have received the majority of payments for works completed (strategically overpriced) in the early phases of the contract.

Effectively, low prices in the initial procurement process increase the risk of defaulting on the contract in the period close to completion, when the contract has been compensated for the most part (payments received for work completed). This is also further complicated by contract managers who are not qualified in the area of civil engineering but rely on external support (inter-institutional or contracted third-party experts). According to the new regulation in MH, in the future, an assigned workgroup will be established with the responsibility to oversee the implementation of healthcare infrastructure projects, as opposed to a single person responsible as contract manager – contemplating Procurement Law requirements.

3. Limitations

This section outlines several key limitations encountered during the study on the procurement of essential medicines and healthcare infrastructure. These constraints have impacted the accuracy and comprehensiveness of our findings and include challenges such as poor cooperation from key stakeholders, non-transparent market conditions, and significant understaffing within critical healthcare infrastructure units. Each limitation is detailed below to provide a clear understanding of how they may affect the results and the extent to which they influence the recommendations made in this report.

3.1. Procurement of Essential Medicines

- No sectorial strategy on healthcare is currently in force, and the last strategy did not have a specific focus on actionable measures to improve the situation regarding the preparation, budgeting, and procurement of medicines from the essential list of medicines.
- Critical medicines from the list (representing 2/3 of the contract value) are not available in the open market, making it difficult to implement the methodology.
- Poor cooperation of authorized marketing companies and poor cooperation of private pharmacies made it difficult to implement the methodology in full, in addition to the inability to provide a concise price list. Medicines are traded at a price range rather than a specific price.
- A list of procurement contracts that have been analysed occurred in the period prior to the enforcement of the law on prices of medical products; likewise, the comparison is drawn to the prices and price differences in the past.
- Limited market competition for high-value medicines, principally since authorized marketing companies (with authorization of the manufacturer) represent a single provider with absolute dominance of the market.
- Little or no domestic producers of medicines. The existing producers mainly produce generic medicines that are of low value and principally repackaging and branding or low added value (transformational processes).
- Statistics for the total consumption of medicines in Kosovo are obscure. Little or no statistics are available on the consumption of medicines pertinent to the list of medicines from the essential list. Ministry of Health has no statistical evidence about the total consumption of medicines in Kosovo, referring here to medicines in total, which includes medicines that citizens pay out of their pockets.

3.2. Procurement of Healthcare Infrastructure

- No sectorial strategy on healthcare is currently in force, and the last strategy did not have a specific focus with actionable measures to improve the situation regarding the identification and prioritization of projects in healthcare infrastructure; likewise, for budgeting and procurement of projects for healthcare infrastructure, including here also measures to improve oversight of implementation of these projects.
- The organizational unit within the Ministry of Health responsible for Healthcare Infrastructure was found to be seriously understaffed, with one acting head of the department/division engineer (electrical engineer). For the analyzed contract, the contract manager was found to be a ministry official with no qualification in civil engineering, who was assigned the role at a later date, as it had been originally assigned to another official of the ministry.
- The contract that has been analysed for comparison on several occasions (positions) has erroneous unit references, stating m2 instead of m3 and vice-versa. These mistakes have been rectified for analysis under the assumption that the contractor has also reflected on these.

4. Recommendations

Improvement measures are evident in the series of activities undertaken by the Ministry of Health; however, to ensure more coordination and long-term sustainable improvement, initiatives need to be considered at the strategic level. A set of recommendations that relate to the findings from this study are provided in the following list, ordered according to the potential impact and feasibility, and considering implementation periods "short-term", "medium-term", and "long-term."

4.1. Procurement of Essential Medicines

Short-term recommendations

1. Lack of trust by the interviewed companies in the pharmaceutical sector is stated explicitly, with remarks about the formulation of the list of essential medicines and the fact that there are companies that continuously get awarded tender contracts. Still it should be noted, as there are cases where a single company is in possession of the marketing authorization for a certain medicine, and represents the sole economic operator in this case and a unique bidder. These are the characteristics of the highly regulated market such as is the case of market for medicines, creating the situation of a natural monopoly. However, acting on a broader perspective and taking into account inputs of the pharmaceutical sector, a recommendation is to **establish a platform for sustainable dialogue** between the Ministry of Health and the sector of medicine marketing companies to facilitate transparency and trust-building in addition to producing improved decisions regarding the formulation of lists of essential medicines and determining the most optimal costing approach (ensuring compliance with the respective law).
2. It is advisable to wait until pharmaceutical companies begin declaring their medicine prices in compliance with legal requirements before revising the list of essential medicines. This approach will allow for the incorporation of the most recent pricing

information, facilitating the generation of accurate cost estimates for the current or potentially revised and expanded list of essential medicines.

Mid-term recommendations

3. Establish a better **inventory control for medicines** from the essential list to be able to control the stock of medicines in real-time and ensure a more precise demand forecast for medicines, thus improving efficiency in the procurement chain, including the formulation and revision of the list itself.

Long-term recommendations

4. Conduct a comprehensive study to determine the total consumption of medicines listed as essential, including those acquired through the public healthcare system (publicly financed) and those purchased directly by citizens (distributed via the private sector). This analysis will provide insights into the overall demand and identify any gaps in achieving full coverage across the healthcare sector.
5. **Develop a strategy**, preferably a section of the overarching sectorial strategy, which would articulate and complement the other measures in the healthcare sector (HIS, Healthcare funding system, public health forecasts, etc.). The strategy would need to articulate measures to improve effectiveness and efficiency in the preparation of the list of essential medicines, as well as in the budgeting (marketing intelligence and public finance procedure) and the procurement process.

4.2. Procurement of Healthcare Infrastructure

Short-term recommendations

1. **Specification of the bill of quantities and cost estimates should be done in more detail**, breaking down specifications separately for materials, labour, equipment, services, etc. Lump sum positions in the contract obscure the real costs, allowing for strategically formulating tender offer such that the total cost is low (most competitive offer), allocating cost positions in unreal terms, either too many costs upfront and then abandoning implementation near the end, once the majority of the contracted positions have been executed as extraordinary high costs and payments received.
2. Consider **price adjustment for construction materials (indexing)**, particularly for projects with multi-year implementation periods, to protect both parties in the contract from inflation shocks. This has become increasingly important in recent years due to high inflation rates and rising costs. The price volatility has been uneven across materials, with significant fluctuations in items such as steel, energy, fuel, copper, microprocessors, long-distance transport costs, and labor.

Mid-term recommendations

3. **Develop the human resources of the infrastructure department of the Ministry of Health** or consider sub-contracting external experts for professional services. Without the necessary human resources and expertise, which represent the critical resource for any possible course of action, it will not be possible to produce any improvements. Consider **third-party oversight,** which is contracting with a professional oversight company with a history of credibility and high liability third-party insurance policy.

4. Consider **requesting the manufacturer's authorization** or similar first-hand endorsement by a producer or authorized representative for high-value positions such as the case with HVAC equipment, medical gases, elevator and electrical installations (smart building). This is to prevent lump sum and strategic structuring of contracts below real construction costs.
5. Consider **requiring manufacturers' authorization** or a direct endorsement from a producer or authorized representative for high-value items such as HVAC equipment, medical gases, elevators, and electrical installations in smart buildings. This measure would help prevent the underestimation of real construction costs through strategic contract structuring and lump sum agreements.

Long-term recommendations

6. **Establishing a guideline or normative standard** for the planning and development of healthcare infrastructure is recommended. This standard would serve as a mandatory design reference for architects and engineers. Options include developing national standards and technical norms specific to healthcare infrastructure, creating a framework that references international standards, or adopting an advanced national standard from a third country.
7. Possibly, introducing FIDIC standards for contracting for projects in healthcare infrastructure would require a feasibility study and possibly increase total costs (in absolute terms). Still, in the cost analysis, costs are associated with numerous failures in contracts related to healthcare infrastructure. Working with FIDIC standards will necessitate the use of project management tools (i.e. Microsoft Project) and further improve the allocation of duties and responsibilities, allocation of risks, and reporting cycles. The actual contracts resemble partially, but the aggregation of work positions and insufficient oversight create obscurities that are then opportunistically materialized by contractors (profit maximization). An alternative to FIDIC standard contracts is to consider contracts that allocate contract risks better than the current forms, not to allow the bulk of the value in the first part of the contract, or to consider higher retaining provisions such that risks bear more significantly against the defaulting contractor.

C. Annexes

Annex I – Essential medicines analytical table for price analysis

Part/Lot	Article	Strength	Form	Contract amount - 12 months	Market Price - EUR	Tender Price EUR	Tender value - EUR	Market Price Value - EUR	Difference EUR	Difference %
1	Amlodipine	10mg	Tablet	441,000	0.10	0.02	8,820	43,423	-34,602.8	-392%
1	Ibuprofen	400 mg	Tablet	840,900	0.06	0.03	21,863	54,304	-32,441.0	-148%
2	Bisoprolol	5mg	Tablet	234,000	0.09	0.03	6,786	20,530	-13,743.6	-203%
2	Morphine hydrochloride	10 mg/1 ml	Injection	5,238	5.94	0.60	3,143	31,114	-27,970.9	-890%
3	Captopril	25mg	Tablet	246,000	0.04	0.03	7,331	10,660	-3,329.2	-45%
3	Paracetamol	1g	Injection	6,198	3.93	1.09	6,756	24,379	-17,623.0	-261%
4	Desloratadine	2.5 mg / 5 ml	Solution	4,033	5.43	1.10	4,443	21,886	-17,443.0	-393%
4	Enalapril maleare	10mg	Tablet	218,150	0.07	0.31	67,627	14,671	52,955.9	78%
5	Loratadine	1mg/mL	Oral solution	9,068	2.35	1.17	10,610	21,310	-10,700.2	-101%
5	Silver Sulfadiazine	0.01	Topical	9,900	2.35	0.64	6,306	23,265	-16,958.7	-269%
6	Carbamazepine	400mg	Tablet	356,944	0.26	0.12	44,261	93,638	-49,377.3	-112%
6	Furosemide	10mg ml,2ml	Injection	212,600	0.17	0.09	18,496	36,833	-18,336.8	-99%
7	Amoxicillin trihydrate	500mg	Hard capsules - oral	497,544	0.09	0.06	27,365	42,913	-15,548.3	-57%
8	Ampicillin	1g	Injection powder	16,695	0.63	1.00	16,695	10,434	6,260.6	38%
8	Spironolactone	25mg	Tablet	114,000	0.07	0.05	5,700	7,763	-2,062.9	-36%
9	Amiodarone hydrochloride	200mg	Tablet	86,525	0.18	0.07	5,624	15,451	-9,826.8	-175%
10	Amlodipine	5mg	Tablet	216,000	0.09	0.03	6,264	18,765	-12,501.0	-200%
10	Metoclopramide Hydrochloride	5mg ml,2ml	Injection	205,000	0.17	0.11	21,935	35,533	-13,598.3	-62%
11	Atorvastatin	10mg	Tablet	1,099,320	0.17	0.02	20,557	181,937	-161,380.2	-785%
11	Chloramphenicol	0.01	Eye ointment	26,600	1.53	0.70	18,487	40,609	-22,122.3	-120%
12	Alprazolam	0.25mg	Tablet	54,200	0.06	0.03	1,626	3,035	-1,409.2	-87%
12	Atorvastatin	20mg	Tablet	1,709,160	0.07	0.03	45,635	111,380	-65,745.7	-144%

13	Bisoprolol	10 mg	Tablet	75,000	0.09	0.06	4,500	6,885	-2,385.0	-53%
14	Bisoprolol	2.5 mg	Tablet	80,000	0.09	0.03	2,320	6,820	-4,500.0	-194%
15	Losartan	50mg	Tablet	814,276	0.09	0.03	26,301	69,485	-43,183.8	-164%
15	Sualbutamol	100mcg per dose	Inhlalation	25,000	1.74	1.47	36,750	43,450	-6,700.0	-18%
16	Chloramphenicol	5%	Topical	7,720	1.59	0.89	6,871	12,288	-5,416.9	-79%
16	Glucose 5%	5% (izotonik), 100ml	Solution for infusion	30,000	0.60	0.40	12,000	18,000	-6,000.0	-50%
17	Dexpanthenol	0.05	Topical	2,500	1.59	0.81	2,025	3,967	-1,941.7	-96%
17	Glucose 5%	(izotonik), 500ml	Solution for infusion	80,400	0.68	0.35	28,140	54,672	-26,532.0	-94%
18	Gentamicine	0.10%	Topical	5,659	1.89	1.18	6,661	10,667	-4,006.6	-60%
18	NaCl (Na+154mmol L, Cl-154mmol L)	0.9%, 100ml, izotonik	Solution for infusion	226,500	0.62	0.34	77,010	141,401	-64,390.7	-84%
19	Natrium lactate, compound	compound 500 ml	Solution for infusion	54,900	0.65	0.45	24,705	35,685	-10,980.0	-44%
20	Ascorbic Acid	500mg 5ml	Injection	317,900	0.30	0.16	50,864	95,370	-44,506.0	-88%
20	Omeprazole (Oral use)	20 mg	Hard capsules - oral	1,715,848	0.09	0.03	46,328	146,720	-100,391.6	-217%
21	Anti-tetanus immunoglobulin	250IU	Injection	12,900	15.00	11.88	153,252	193,500	-40,248.0	-26%
21	Glimperide	2 mg	Tablet	235,460	0.09	0.04	10,172	21,631	-11,459.1	-113%
22	Metformin	1 g	Tablet	470,340	0.05	0.03	13,170	21,610	-8,440.0	-64%
23	Metformin	850 mg	Tablet	5,730,530	0.04	0.02	102,576	233,042	-130,465.1	-127%
24	Metformin	500mg	Tablet (oral use)	300,000	0.04	0.02	6,600	11,000	-4,400.0	-67%
						Total	**986,573**	**1,990,024**	**-1,003,451**	**-98%**

Annex II I – Healthcare infrastructure analytical table for price analysis

	Construction positions	Contract EUR	Market price EUR	Difference EUR
1	Preparatory works	14,068	10,679	3,389
2	Excavation works	92,723	55,323	37,399
3	Concrete works	96,972	129,147	-32,175
4	Steel/Rebar works	171,315	127,662	43,652
5	Bricklaying	24,037	20,502	3,535
6	Insulation works	22,149	24,073	-1,924
7	Roofing	20,224	30,935	-10,711
8	Carpentry	33,854	43,200	-9,346
9	Iron works - rails/fixtures	7,410	12,602	-5,191
10	Flooring	21,248	32,941	-11,694
11	Tiling	12,959	21,143	-8,183
12	Paint works	22,006	28,522	-6,516
13	Exterior works	31,496	91,095	-59,599
14	Other	40,193	60,251	-20,058
15	X-ray section/radiology	7,969	10,842	-2,873
16	Entryway	33,691	68,236	-34,545
	Total	652,313	767,153	-114,840
	Plumbing/Sanitary Positions	**Contract EUR**	**Market price EUR**	**Difference EUR**
1	Construction works	743	2,987	-2,243
2	Sewage	3,061	3,598	-537
3	Plumbing	4,798	8,327	-3,529
4	Sanitary unit works	2,407	3,866	-1,458
	Total plumbing & sanitary	11,009	18,778	-7,769
	Electrical Installation Positions	**Contract EUR**	**Market price EUR**	**Difference EUR**
1	Distribution panels	4,232	5,900	-1,667
2	Power cables and connecting panels	11,265	26,219	-14,954
3	Lighting system	4,428	5,446	-1,018
4	Electrical potential levelling-earth	1,023	1,497	-474
5	Sockets and switches	2,393	2,738	-345
6	ICT	2,055	4,688	-2,633
7	Telephonic system	526	1,370	-844
8	Fire alarm system	1,607	3,422	-1,815
9	CCTV	2,730	4,458	-1,728
10	Continuous power supply	2,950	9,500	-6,550
11	Earthing and shielding	1,694	2,334	-640
12	Outdoor Lighting	150	1,510	-1,360
	Total electrical systems	**35,054**	**69,083**	**-34,030**

	HVAC -Works Positions	Contract EUR	Market price EUR	Difference EUR
1	Radiators-heating units/pipework	18,847	22,236	-3,388
2	Ventilation	6,886	17,971	-1,085
3	Central furnace & cooling units	4,287	41,439	-27,152
Total HVAC - Mechanical/electrical		50,020	81,646	-31,626

	Medicinal Gases Works Positions	Contract EUR	Market price EUR	Difference EUR
1	Central Medical gas station - Oxygen	1,365	4,150	-2,785
2	Central Medical gas station - Compressed Air	1,311	6,840	-5,529
3	Central medical gas station - Vacuum	1,224	4,700	-3,476
4	Copper pipework	4,816	4,290	526
5	Medical Gas Sockets	354	2,300	-1,946
6	Other works	118	138	-20
Total medical gases		**9,188**	**22,418**	**-13,231**

Annex III – List of respondents

List of respondents

#	**Organization-Entity**	**Respondent name**	**Role**
1	Construction company	Gazmend Haxholli	CEO
2	Enggroup (Civil Eng Bureau – Construction Factory – Construction Materials factory)	Kreshnik Shehu	CEO
3	Association of Construction Companies of Kosova	Faton Hoxha	Director
4	Toni Ing (Construction Company)	Zijadin Hoxha	CEO
5	Urban Plus (architecture design bureau, project management in construction)	Prof. Ilir Gjinolli	CEO
6	Prefer not to disclose (Large Construction Company)	Sh.M.	Director
7	Ministry of Health – Procurement	Berat Mamurllaku	Division head
8	Ministry of Health – Infrastructure Division	Tevide Konjusha	Dep. Division Head
9	Preferer not to disclose (Electrical installations company	D.E.	Director
10	ALT Shpk (ICT & electrical installations in civil engineering)	Luftar Braha	CEO
11	URBAN Plus (architecture design bureau, project management in construction)	Prof. Ardita Byci Jakupi	Architect & Project Manager
12	Ministry of Health	Rrahmon Sylejmani	Contract manager
13	Ministry of Health - Procurement	Egzon Ukshini	Procurement officer
14	Contanti Generator (supplier electrical systems – Generators)	Sales person	Price quotation
15	Prefer not to disclose (Medical gases installation company)	CEO	Price quotation
16	Prefer not to disclose (Electrical systems provider)	Director	Price quotation
17	Prefer not to disclose (HVAC systems provider)	Project manager	Price quotation
18	Metron Shpk (elevators)	Chief engineer	Price quotation
19	Prefer not to disclose (construction materials – aggregate rocks & Concrete)	Prefer not to disclose	Price quotation
20	Ministry of Health – External expert (USAID KMI)	Enver Bytyqi	Observer
21	Ministry of Health (Pharmaceutical division)	Mentor Syla	Head of division
22	Sante Farm	----------	CEO
23	Medical Group	----------	Admin/Procurement Officer

Annex IV - Secondary sources

Healthcare sector strategies 2017 – 2021 https://kryeministri.rks-gov.net/wp-content/uploads/2022/05/Strategjia-sektoriale-e-shendetesise-final-nentor-2016-ALB_.pdf

Laws

Law on health - LIGJI_Nr._04_L-125_PËR_SHËNDETËSI

Law on medical products and equipment - LIGJI NR. 04/L -190 PËR PRODUKTE DHE PAJISJE MEDICINALE

Law on prices for medical products - LIGJI NR. 08/L-220 PËR ÇMIMIN E PRODUKTEVE MEDICINALE

Administrative instruction on PHC - UDHËZIMI ADMINISTRATIV (SHËNDETËSI) NR. 04/2020 KUJDESI PARËSOR SHËNDETËSOR

Law on construction LIGJI NR. 04/L – 110 PËR NDËRTIM

Administrative Instruction on Technical Norms for Infrastructure Planning - UDHËZIM ADMINISTRATIV MMPH-NR.08/2017 MBI NORMAT TEKNIKE TË PLANIFIKIMIT HAPËSINOR

Law on public procurement LIGJI NR. 04/L-042 PËR PROKURIMIN PUBLIK NË REPUBLIKËN E KOSOVËS (incl. subsequent amendments).

Public procurement reference prices - LISTA E ÇMIMEVE NJËSI PËR PUNË NDËRTIMORE KRPP

Contracts for public works – healthcare infrastructure

Contract for PHC in Mamushë/Mamuša

Contract for Emergency unit in PHC in Lipjan

Contract for Renovation of Paediatric Hospital Mitrovica

Decision of the Procurement Dept of Municipality of Prishtina on Prices for Escavation (contractor complaint) date 11.02.2021 Procurement nr. 616 – 20-7123-211

Challenges in research of public procurement prices in Kosovo – 2020 KDI, SFIDAT NË HULUMTIMIN E TREGUT DHE PROBLEMET ME ÇMIMET E PROKURIMEVE PUBLIKE NË KOSOVË

Towards open public procurement in municipalities, efficient and accountable (2018), Democracy Plus and USAID Kosovo

Construction Index in Kosovo (2023) Kosovo Statistics Agency

Annex V – Data collection instruments

INTERVIEW GUIDE [Project name]

1	Interview no	
2	Date	
3	The name of the respondent	
4	The position of the respondent	
5	Respondent's contacts (email/tel)	

Interviewer's introduction: Hello, my name is:_____ and I work for UBO Consulting, which is a market research company in Pristina. At the moment we are conducting a comparative research of the prices of capital investments (health infrastructure) with market prices in Kosovo. The purpose of the interview with you is to understand more precisely the institutional and legal context related to capital projects in the field of health infrastructure, the process of monitoring the implementation of capital projects in the development of health infrastructure. Also to identify potential challenges related to this issue! Prices and financial/economic aspects will be collected from a survey with economic operators, construction, design companies, associations and experts in the field, and with suppliers of construction materials and related equipment, respectively will not be requested from you through this interview.

We would be very grateful if you could give us 45-60 minutes of your precious time to conduct an interview with you. Your data will be kept completely confidential and will only be used for the purposes of this research.

Information about the interviewed official:

1. Position and responsibilities:

Can you inform us of your position, namely, what your function is and what your responsibilities are within the Ministry of Health?

Interview guide: Unit responsible for infrastructure construction supervision

Purpose: To provide key information regarding the role, challenges, and results of the supervisory unit responsible for the supervision of health infrastructure projects and to better understand the relationship with other units related to infrastructure development.

1. The role and function of the unit responsible for supervising the implementation of infrastructure projects for health-capital projects (construction)

a. Summary of Responsibilities

Can you summarize the role and function of the health infrastructure project monitoring unit? What is your unit's contribution to the overall success of the project?

b. Ensuring compliance with regulations and standards

How does the oversight unit ensure the compliance of health infrastructure projects with the regulatory framework and standards in force? Is there any specific guide or set of criteria (manual/handbook) that should be followed during the supervision process?

2. Challenges and successes related to ensuring project compliance:

a. Common challenges

What are the common challenges faced by the unit responsible for supervision in ensuring the compliance of projects in the process of implementation? How do you address or choose these challenges or problems? Think about the challenges/problems related to compliance during the implementation of projects at different stages of the process. What about cases of exceeding costs or deadlines?

3. Relationship with other units responsible for infrastructure development:

a. Cooperation with the planning and construction unit

How does the cooperation between the supervision unit and the planning and construction unit work during a project cycle? Are there concrete points of coordination or joint decision-making?

b. Cooperation with the procurement unit

What is the form of cooperation between the supervision unit and the procurement unit considered in the process of ensuring that the contracted projects respect the compliance criteria (meet the work standards)? Are there challenges during the collaboration process?

c. Communication with stakeholders

How does the monitoring unit communicate with other stakeholders involved in infrastructure projects? Are there regular forms of gathering information or recommendations, as well as communications from the parties during the process, and how do the participants raise this information (may be remarks or concerns) in the process treated?

Conclusion:

4. Last questions:

Do you have something to add regarding the topics discussed, or add any other important issue or aspect related to the topic of the interview (implementation and monitoring of health infrastructure projects)?

Thank you very much for your time and information

If the respondent has promised to forward the documents related to the questions, such as laws or by-laws, strategies or something else, to exchange contacts and the modality of receiving these materials!

Also, if any other source of information is referenced or a party is used for interviewing, get the information (contacts)!

This interview guide is designed to explore key aspects of the role and function of the health infrastructure project monitoring unit. During the interview, modifications can be made based on

the flow of the interview, taking into account key points related to the context as well as additional and relevant information that is potentially presented during the survey.

INTERVIEW GUIDE [Project name]

1	Interview no	
2	Date	
3	The name of the respondent	
4	The position of the respondent	
5	Respondent's contacts (email/tel)	

Interviewer's introduction: Hello, my name is:_____ and I work for UBO Consulting, which is a market research company in Pristina. At the moment we are conducting a comparative research of the prices of capital investments (health infrastructure) with market prices in Kosovo. The purpose of the interview with you is to understand more precisely the experience and perspective of construction companies in the process of implementing construction projects in the field of health infrastructure. Also to identify potential challenges related to this issue!

We would be very grateful if you could give us 45-60 minutes of your precious time to conduct an interview with you. Your data will be kept completely confidential and will only be used for the purposes of this research.

Information about the interviewed official:

1. Position and responsibilities:

Can you let us know your position, namely, what your function is and what your responsibilities are within the organization?

1. Unit costs of materials, labor, and machinery/equipment:

a. Materials costs

Can you tell us about the costs of building materials which make up most of the construction projects? How do you provide this information, and how do you calculate the cost of construction projects (when preparing the tender offer and during the implementation process)?

How have prices moved over the past few years, and how have construction companies managed this price exposure?

b. Labor cost

What are the determinants of labor costs in construction projects? How do construction companies ensure the provision of the necessary labor force for the implementation of construction projects, thinking here in the provision of sustainable wages (according to wages in the labor market)? The level of salaries is also considered here, ensuring the sustainability or competitiveness of the project as a whole! The economic aspect of the project, in general

c. Costs of machinery and equipment

What are the costs of the works for which the engagement of construction machinery is necessary? (trucks, excavators, excavators, cylinders, drilling machinery, etc.).

How to calculate the costs of the necessary equipment for the necessary equipment during the implementation of construction projects, such as skeleton, temporary electrical network, tanks, containers, and other supporting elements for construction works!

Did they use standards or approximate forms to calculate the costs of machinery and equipment?

With what margin of appreciation are the costs of machinery and equipment calculated, and what is the scale required for these cost categories usually known?

d. Relationship with suppliers

How do construction companies manage reporting with companies that supply materials, equipment, and machinery? Are more favourable prices provided in relation to those in the market? We are talking about construction materials (what improvement in price)? Do you have long-term relationships with companies that supply construction materials? Do construction companies use other strategies to ensure stability and better prices or better conditions in terms of liability for construction materials?

2. Management of construction projects and experiences gained:

a. Project planning and construction works

Can you tell us, based on your experience from past projects, how the preparation and planning part goes and how it affects the construction process in general? What measures do you take to ensure that projects (construction activities) are implemented according to the original plan?

b. Cooperation with the involved parties of interest

How do you organize the cooperation process with other parties involved, such as architects, construction engineers, and subcontractors, during the implementation process? Do you face challenges in terms of coordination during the implementation of construction projects?

c. Time limits and their realization

Can you tell us how you manage the project in terms of timelines, thinking here in ensuring completion according to the planned schedule? Can you tell us about the cases when you faced delays and what the factors that contributed to these delays were?

3. Challenges and achievements in determining construction costs:

a. Costing method

What methods do you use to determine project costs, including the costs of materials, labor, and other expenses? Do you use standardized tools or software applications for the construction sector to determine costs, and how do you evaluate the impact of these methods?

b. Factors in determining costs

What external factors or unforeseen circumstances have the greatest impact on determining costs? Can you tell us how you evaluate and take into account this aspect, as well as the changes in circumstances during the implementation of the project?

Conclusion:

4. Last questions:

How has the movement of construction material prices and labor costs, including energy costs, affected the process of implementing construction projects? How are these challenges reflected in the sustainability of construction contracts?

Do you have something to add regarding the topics discussed, or do you have any other issues or aspects of importance related to the interview topic (Architecture professionals and the perspective of design and construction of health infrastructure projects)?

Thank you very much for your time and information

If the respondent has promised to forward the documents related to the questions, such as laws or by-laws, strategies or something else, to exchange contacts and the modality of receiving these materials!

Also, if any other source of information is referenced or a party is used for interviewing, get the information (contacts)!

The purpose of this interview is to gather information and develop knowledge on the determination of costs at the level of work units and the experience in the implementation of construction projects, as well as the challenges and competence achieved for the determination of construction costs by private companies of construction. During the interview, modifications can be made based on the flow of the interview, taking into account key points related to the

context as well as additional and relevant information that is potentially presented during the survey.

INTERVIEW GUIDE [Project Name]

1	Intervista no:	
2	Date	
3	Name of respondent:	
4	Job position:	
5	Contact (email/tel)	

Interviewer Introduction: Hello, my name is:_____ and I work for UBO Consulting, a market research company based in Pristina. Currently, we are conducting a comparative study of medicine prices from the essential list against market prices in Kosovo. The purpose of this interview is to better understand the role and function of authorized marketing companies about the provision of medicines from the essential list, the procurement process of these medicines, and their application in the procurement processes of the Ministry of Health. We also aim to identify potential challenges related to this issue. Pricing and financial/economic aspects will be collected through a survey with economic operators, and medicine suppliers, and will not be requested from you during this interview.

We would greatly appreciate if you could offer us 45-60 minutes of your valuable time to conduct this interview with you. Your data will be kept strictly confidential.

Information on interviewed official:

1. Job Position and Responsibilities:

Could you please inform us about your position and what your role entails? What are your responsibilities within the organization (pharmaceutical company)?

Participation in Procurement Processes for Supplying Medicines from the Essential List

2. Could you tell us whether your organization/company participates in the supply processes for medicines from the essential list? Or have you participated in the past; what has been your experience with the procurement process?

Collaboration between Pharmaceutical Marketing Companies and the Ministry of Health

3. Level of Collaboration between the Ministry of Health and Authorized Marketing Companies

Could you describe the level of collaboration between the Ministry of Health and companies involved in importing and supplying medicines from the essential list? How regulated is the sector, and how prepared and cooperative is the Ministry (or the Agency) in this regard?

Competition

4. How would you assess the level of competition in the market for medicines from the essential list? What is the number of companies involved, and would you say it is a free, competitive market?

5. How are the prices of medicines from the essential list determined? Are they influenced by the prices at which companies compete? How much can the profit margin be? Is it uniform, or does it vary according to the medicines?

6. What are the main factors that influence the pricing of medicines from the essential list? Please list at least three factors of importance.

7. How does the regulation of the sector, specifically the licensing and authorization of companies and medicines, impact the pricing of medicines? How significant are the costs associated with obtaining authorization?

8. How difficult or easy is it for companies to participate in public procurement processes to supply medicines from the essential list? Consider aspects such as obtaining information

(announcements), meeting administrative requirements, and preparing tender documentation.

8. From the companies' perspective, how fair is the procurement process perceived to be? What supports this viewpoint?

Closure

9. Last questions

If you have anything to add regarding the topics discussed, or if there are any other issues or aspects you consider important related to the interview topic (essential medicines list, its determination, procurement, and management), please feel free to share.

Thank you very much for your time and information

INTERVIEW GUIDE [Project Name]

1	Interview no.	
2	Date	
3	Name of the respondent	

4	Position of the Respondent	
5	Contact (email/tel)	

Interviewer Presentation: Hello, my name is: _____ and I work for UBO Consulting, which is a market research company in Prishtina. Currently, we are conducting a comparative study of the prices of essential medicines from the essential list with market prices in Kosovo. The purpose of the interview with you is to better understand the institutional and legal context regarding the essential list of medicines, the practices of preparing and implementing the list, determining the medicines, and the procurement process. Also, to identify potential challenges related to this issue! Prices and financial/economic aspects will be gathered from a survey with economic operators, suppliers of medicines, and will not be requested from you through this interview. We would be very grateful if you could offer us 45-60 minutes of your valuable time to conduct an interview with you. Your data will be kept completely confidential and will only be used for the purposes of this research.

Information about the interviewee:

1. Position and responsibilities

Can you please inform us about your position, specifically what is your role and what are your responsibilities within the Ministry of Health/Medicines Agency?

Could you describe the legal and institutional framework, as well as the policies and strategies, for how the system operates to supply public health institutions with medicines from the essential list? The laws, administrative guidelines, regulations, strategies, and other policy documents!

2. Legal and institutional framework

Legal framework

Can you provide a description of the legal framework that determines the essential medicines list, the costing (budget allocation), how the procurement process is conducted, and how the supply and distribution of medicines from the essential list function in practice?

How do laws and subordinate acts affect decision-making processes regarding the essential medicines list?

Institutional framework: Role and function of institutions:

Who are the main officials or bodies responsible (individual or body-commission/council) for determining the medicines for inclusion in the essential list? What is the body and who is the responsible official within this institution?

Whose responsibility is the provision of necessary medicines from the essential list, how is the costing done, specifically how is the budgeting done?

How is the procurement process of medicines from the essential list managed, who is responsible for organizing and overseeing it?

Challenges and issues related to the preparation of the list, procurement, and management of the supply and distribution of medicines from the essential list? From your perspective, if any, can you tell us what are the challenges that characterize the preparation or determination of the list, budgeting, procurement, or even the distribution of these medicines? In other words, the problems or challenges you would highlight!

From these highlighted challenges or problems, can you tell us how they are addressed by your institution (Ministry/Agency), i.e., if problems/challenges have been highlighted? What success has the institution had in managing these challenges/problems?

Familiarity with the essential medicines list

3. Construction and composition of the list:

Can you provide a summary of how the essential medicines list is prepared, taking into account pharmacological groups and segmentation according to prices/costs?

How often is the list updated, and what are the factors that influence the decision-making process for inclusion or removal from the list?

Disaggregation/subcategorization of categories:

Can you tell us how the medicines are disaggregated (divided into sub-categories) from the essential list, according to the type or pharmacological group?

Are they further disaggregated based on specific criteria (where these criteria are defined), such as the method of administration, packaging, concentration or strength, weight, rare diseases, etc.?

Supply chain and competition in the medicines market:

4. Perspective on the supply chain:

Can you describe in a summarized form the general supply chain of essential medicines, from procurement to distribution?

Who are the main suppliers, and how competitive is the market for the supply of medicines?

Price referencing and comparisons:

5. Price determination:

How are policies regarding the prices of medicines from the essential list determined, if there are strategies or methodologies for assessing prices for necessary medicines (which should be costed for inclusion and budgeting)?

If there is or if any information system is used for assessing costs, or prices for medicines under review for inclusion, or if any framework is used for price determination?

Have you ever conducted market research on the prices of medicines from the essential list?

Stakeholder perspectives

6. Involvement of stakeholders:

How does the Ministry/Agency ensure the involvement of stakeholders such as civil society, pharmacists, or pharmaceutical companies (including marketing companies with medicines)? Involvement is understood in the process of drafting the list and related processes with the list and the supply of essential medicines!

Involvement of observations, comments, or even gathering information with the aim of improving the work process:

Can you tell us if you have had any cases where stakeholders have approached you with information, requests, or recommendations regarding the system or process of preparing and implementing the essential medicines list?

How and to what extent are recommendations or observations from stakeholders taken into account or included, and how does your institution treat this information? It is thought of as inclusion as part of the improvement cycle, similar to quality management! If this is done continuously.

7. Safety and quality of medicines from the essential list

Considering that the lowest price is a determining criterion for selection in public procurement processes (once technical criteria are met), how is the quality assurance for the supplied medicines ensured and for which marketing authorization is obtained? Who is the responsible institution, and to what extent are those rules applied? How does the implementation of quality assurance affect the cost of medicines?

Statistics of medicines from the essential list

8: How do the demands and supplies of medicines from the essential list vary according to value?

(if there are publications, can we access them/ensure access to statistical publications)

What are the annual supply demands for medicines from the essential list for the past 3 years, broken down by year, in value?

2023

2022

2021

What are the annual supplies of medicines from the essential list for the past 3 years, broken down by year, in value?

2023 2022 2021

Closing:

9. Final Questions

If you have anything else to add regarding the topics discussed, or if you want to add another issue or aspect related to the interview topic (essential medicines list, determination, procurement, and management of medicines from the essential list)?

We thank you very much for your time and the information provided.

If the respondent has promised to provide documents related to the questions, such as laws or subordinate acts, strategies, or anything else, contact information and the modality for obtaining these materials should be exchanged!

Also, if another source of information has been referenced or another party has been mentioned for interviewing, the information (contacts) should be taken!

The interview guide can be adapted during the interview to follow up on interesting information that may arise! This can be based on the responses and the role or responsibilities, or other elements reflected in the interview process.