

TRANSPARENTITIS VIRUS

PUBLIC PROCUREMENT
MONITORING AT THE
MINISTRY OF HEALTH

MARCH 2016





**PUBLIC PROCUREMENT
MONITORING AT THE
MINISTRY OF HEALTH**

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Publication of this report was made possible with support of the British Embassy in Prishtina. Opinions, findings and recommendations herein are a sole responsibility of KDI and do not necessarily represent views of the donor.

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LIST OF ACRONYMS

- AHF** → Agency of Health Funding
- CA** → Contracting Authority
- AKPM** → Kosovo Agency for Medicine Products and Equipment
- CPA** → Central Procurement Agency
- ASK** → Agency of Statistics of Kosovo
- ARBK** → Agency for Registration of Businesses in Kosovo
- CE** → Conformité Européenne
- EU** → European Union
- TD** → Tender Dossier
- WG** → Working Group
- ISO** → International Standardization Organization
- KDI** → Kosovo Democratic Institute
- RPPC** → Regulatory Public Procurement Committee
- ELM** → Essential List of Medicines
- PPL** → Public Procurement Law
- MH** → Ministry of Health
- MTI** → Ministry of Trade and Industry
- WHO** → World Health Organization
- EO** → Economic Operator
- PRB** → Procurement Review Board
- QKUK** → Clinical University Centre of Kosovo
- SHSKUK** → Hospital University Clinical Service of Kosovo
- TAPP** → Transparency and Accountability in Public Procurement
- TI** → Transparency International
- AI** → Administrative Instruction
- PO** → Procurement Officer
- OGA** → Office of General Auditor





EXECUTIVE SUMMARY

Non-provision of quality services by public health institutions continues to remain hostage of low budgets, which does not cover minimum needs of about 1.8 million Kosovo citizens. Kosovo spends five times less than Albania in public health, seven times less than Macedonia, and nine times less than Montenegro, Bosnia and Herzegovina, and Turkey. When we add to this problem the issue of mis-planning and mis-management of contracts, then this becomes unaffordable for patients who are forced to bear the costs of healing themselves from their own income, which are minimum anyway.

This report aims at testing transparency at the Ministry of Health (MH) and finding weaknesses in procurement system of the institution with the purpose of improving the situation. This was completed by measuring legislation implementation on public procurement through examination of contracts of Ministry of Health for supplies with cytostatic, anti-infective and supply materials, which were analysed in different phases. A total of nine medicinal products purchased through six contracts and which cover a broad spectrum of prices and use to obtain a better picture of procurement system in this institution were analysed.

Until 2013, MH had completed centralized procurements, which had increased the cost of expenditures, and it had purchased medicaments that were not essential for patients' health. In 2013, a list of Essential List of Medicines (ELM) was compiled, and as of 2014 MH makes purchases for centres of family medicine, and the procured items are submitted to

respective centres by Business Operators. Agency of Health Funding (AHF) consolidates the pre-calculated needs by hospital institutions, as well as those of primary care, which are processed by pharmaceutical division at MH. Prior to processing of requests at the Procurement Division, one of the roles of AFH is to verify the validity of the request, to ensure that drugs are part of ELM, and availability of financial resources. It is worth noting that the ELM has not been changed or updated since 2013.



According to Cobus de Swardt, Managing Director of Transparency International: "When products, which are ultimately paid for by citizens, are dangerous, inadequate or costly then there will be inevitable loss of public trust on government".

The analysis provided here unveils lack of transparency in this institution as one of the key problems. Deficiencies in transparency are justified by the Ministry with the lack of time and resources. Transparency is a mechanism that shows the institutional integrity,

and it is defined as access to information at the right time, information that is easily understood, and that protects the process of integrity and interests of all involved stakeholders.

Findings of the report on cytostatic show that the limited budget in combination with selection of drugs with very high cost results with limited fulfilment of needs only up to 40%. This shows that there is large room for improvement in planning purchase of drugs.

Purchase of supply materials such as sterile gas, gloves or scrubs is followed with many claims for irregularities. Low quality of these materials is a result of non-updating of ELD, a list which does not specify quality requirements. This results with purchase of low quality products.



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KDI has analysed the contract for supply with anti-viral medicines. Access to information on purchase of Peginterferon was not granted by the Ministry, irrespective of KDI request of August 2015. While findings for the Ribavirin medicine, about which access was granted, show that the procurement process was conducted within legal framework.

Based on the analysis of the report, with regard to which access was granted, we conclude that the main concerns related to procurement at MH pertain to extremely high prices of products, compared to the budget of the Ministry. This results with non-fulfilment of essential necessities. Non-updating of ELM causes a chain of problems in the procurement of these drugs, and amongst others, provides for low quality of supply materials.

However, the main effect is inflicted to the Kosovo citizens. According to the World Bank, Kosovo citizens on average have a life expectancy of five years shorter than those of neighbouring countries, and 10 years shorter than EU citizens as a result of a weak health sector.

To improve this situation, KDI has offered a number of recommendations pertaining to addressing the immediate needs such as the update of Essential List of Medicines, improvement of procurement planning, development of an electronic system for registration of patients and taking stock of consumption; analysis of products under patents and application of negotiation procedures for purchasing them; and the need for market analysis to have a closer overview of the offer that companies might have for certain products and to defend from fixed prices.

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HEALTH EXPENDITURE PER CAPITA

One of the main concerns of the society, as well as of service providers and suppliers⁵ is the low allocated budget for health expenditure per capita in Kosovo. While analysing Kosovo budget for 2013⁶, 2014⁷ and 2015⁸, we see that from amounts for Goods and Services and Capital Expenditure of the central level for these three years, only 6% were allocated to the Ministry of Health. According to MH, the cost of expenditure per capita in Kosovo for 2015 was 110.00 USD, which is the lowest in the region, and after this, the second lowest amount in

the region in 2013 was that of Albania at 539.00 USD⁹, which means that Kosovo spends 5 times less than Albania in public health, 7 times less than Macedonia, and 9 times less than Montenegro, Bosnia and Herzegovina, and Turkey.

5 According to individual interview and working group organized by KDI on 30 November 2015.

6 <https://mf.rks-gov.net/sq-al/Buxheti/Buxheti-i-Republikes-se-Kosoves/Buxheti-qendrore>

7 <https://mf.rks-gov.net/sq-al/Buxheti/Buxheti-i-Republikes-se-Kosoves/Buxheti-qendrore>

8 <https://mf.rks-gov.net/sq-al/Buxheti/Buxheti-i-Republikes-se-Kosoves/Buxheti-qendrore>

9 WHO: World Health Statistics 2015 (http://apps.who.int/iris/bitstream/10665/170250/1/9789240694439_eng.pdf?ua=1&ua=1)

10 <http://apps.who.int/gho/data/node.main.78?lang=en>

TAB. 1 – HEALTH COSTS PER CAPITA PER YEAR ACCORDING TO WHO¹⁰

#	Country	Expenditure in health per capita (PPP int. \$)	#	Country	Expenditure in health for capita (PPP int. \$)
1	Afghanistan	\$161.00	7	Argentina	\$1,725.00
2	Albania	\$539.00	8	Armenia	\$351.00
3	Algeria	\$778.00	9	Australia	\$4,191.00
4	Andorra	\$3,338.00	10	Austria	\$4,885.00
5	Angola	\$355.00	11	Azerbaijan	\$957.00
6	Antigua and Barbuda	\$1,021.00	12	Bahamas	\$1,688.00

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#	Country	Expenditure in health per capita (PPP int. \$)	#	Country	Expenditure in health per capita (PPP int. \$)
76	Island	\$3,646.00	107	Mauritania	N/A
77	India	\$215.00	108	Mauritius	\$864.00
78	Indonesia	\$293.00	109	Mexico	\$1,061.00
79	Iran	\$1,414.00	110	Micronesia	\$448.00
80	Iraq	\$695.00	111	Monaco	\$6,123.00
81	Ireland	\$3,867.00	112	Mongolia	\$567.00
82	Israel	\$2,355.00	113	Montenegro	\$926.00
83	Italy	\$3,126.00	114	Morocco	\$438.00
84	Jamaica	\$512.00	115	Mozambique	\$71.00
85	Japan	\$3,741.00	116	Myanmar	\$37.00
86	Jordan	\$761.00	117	Namibia	\$749.00
87	Kazakhstan	\$1,023.00	118	Nauru	\$644.00
88	Kenya	\$101.00	119	Nepal	\$135.00
89	Kiribati	\$187.00	120	Netherlands	\$5,601.00
90	Kuwait	\$2,375.00	121	New Zealand	\$3,405.00
91	Kyrgyzstan	\$221.00	122	Nicaragua	\$382.00
92	Lao People's Democratic Republic	\$95.00	123	Niger	\$60.00
93	Latvia	\$1,310.00	124	Nigeria	\$206.60
94	Lebanon	\$1,092.00	125	Niue	\$959.00
95	Lesotho	\$297.00	126	Norway	\$6,308.00
96	Liberia	\$88.00	127	Oman	\$796.00
97	Libya	\$764.00	128	Pakistan	\$126.00
98	Lithuania	\$1,579.00	129	Palau	\$1,288.00
99	Luxembourg	\$6,518.00	130	Panama	\$796.00
100	Madagascar	\$58.00	131	Papua New Guinea	\$114.00
101	Malawi	\$90.00	132	Paraguay	\$724.00
102	Malaysia	\$938.00	133	Peru	\$626.00
103	Maldives	\$1,260.00	134	Philippines	\$287.00
104	Mali	\$122.00	135	Poland	\$1,551.00
105	Malta	\$2,652.00	136	Portugal	\$2,508.00
106	Marshall Islands	\$703.00	137	Qatar	\$2,882.00
			138	Korea Republic	\$2,398.00

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METHODOLOGY

Research methodology in this report tries to measure implementation of legislation on public procurement, through examination of contracts of the Ministry of Health for supplies with cytostatic, supply and anti-infective materials, which were analysed at various phases.

Due to the nature of selected contracts, the analysis addresses five (5) procurement phases: needs, assessment and planning, preparation of technical specifications, evaluation of bids, contract implementation and performance monitoring, and auditing and concluding phase. In addition, this methodology addresses the level of transparency, proportionality, equal treatment and non-discrimination against Business Operators (BO), as well as complaints filed at the Procurement Review Body and decisions made by this body.

The research and monitoring methodology in public procurement is one of the practices that is widely used by oversight organizations and mainly by branches of Transparency International in various states.

The main priority of this methodology is the fact that it is inclusive and does not bypass any procurement phase. Special importance is given to cooperation with business operators, i.e. businesses which have contracting relations with the Central Procurement Authority.

Documents used during tender examination included the following: tender evaluation reports, announcements for award of contracts, announcement for contracts, tender dossiers, business operator bids, public contracts, PRB decisions, expertise reports, business operators' complaints. Active monitoring of the project will improve general performance of the institutions with budget/high risk, as well as inclusion of various actors in the process will bring benefits for all involved

parties in the process. Business community participants (who have not won the tender), NGOs, journalists if investigative journalism, members of the Committee for supervision of public finances, Contracting Authorities, Regulatory Commission of Public Procurement, and Office of General Auditor will have the possibility to benefit from KDI knowledge acquired through years.

ANALYSIS OF CONTRACT

Considering the limited budget for requests for medical care, especially with regard to supply with medicines and materials, WHO has applied VEN analysis (Vital, Essential, Needed), which is used for planning of required quantities which MH must provide as part of the first category to fulfil patients' needs. The primary focus of the methodology of this analysis is on provision of vital items, which affect saving a person's life, then provision of essential items, which are not necessarily required and whose role is to cure or extend the life of a person but not an immediate lifesaving intervention, and the third category includes the required medicines, which if there is enough budget may be provided by the responsible authority, but if there is no budget they would not cause vital problems for the institution. Also, another analysis applied during budget planning is the one referred to as ABC, which is an indicator for expensive medicines, and where care must be paid to save budget. This means that according to WHO, categorization of medicines and supply materials is done through identification of VEN and the based on price and amount for the year.

According to some analysis conducted by World Health Organization (WHO ¹¹, it was concluded that decentralized procurements were more adequate for the health sector since they increase flexibility of more rapid supplies, and they are also viewed as a mechanism for increasing accountability in the sector. However, decentralization of procurement in Kosovo, especially the one between MH and SHS-KUK, resulted with reduction of procurement effectiveness for health centres, as well as many debates and allegations addressed to one another during the

end of 2015¹². The following section covers planning of procurements for three sectors addressed in this analysis.

11 WHO: The World Medicines Situation 2011 - Procurement of Medicines (<http://apps.who.int/medicinedocs/en/m/abstract/Js18769en/>)

12 <http://www.kosova.info/?p=174224>; http://assembly-kosova.org/common/docs/proc/proc_2015_11_25_10_6218_al.pdf; http://www.fsshk.eu/new/index.php?option=com_content&view=category&id=8&layout=blog&Itemid=4

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SUPPLY WITH CYTOSTATICS

NEEDS ASSESSMENT AND PLANNING

During 2014 Oncological Clinic was visited by a total of 12,568 patients, from whom 800 cases were patients with breast cancer¹³. As a result of these figures, management unit had submitted the request for procurement of 790 units of TRASTUZUMAB 440mg, which is used for treating patients with HER2-positive for a one-year supply. This request was processed on 08.01.2015, with procurement number 206-15-001-111. TRASTUZUMAB is a medicine that is patented by Roche, whose representative for Kosovo is pharmaceutical company “Meditech” LLC.

During the working group meeting¹⁵ there was no complaint related to purchase of this item. This medicine is part of Essential List of Medicines of World Health Organization (WHO) as one of the most important medicines required or a fundamental health system¹⁶.

Sorafenib is another cytostatic from the Essential List that is primarily used for treatment of cancer in kidneys and liver, for treatment of most advanced stages of cancer among patients. This medicine was approved by the European Commission in October 2007 and by FDA in November 2007 for treating hepatocellular carcinoma (HCC), which is one of the most fre-

quent forms of kidney cancer. The United Kingdom had refused to approve this medicine due to its high price offered by pharmaceutical company Bayer. For patients’ needs, Oncology Clinic had submitted a request for 6,120 units of Sorafenib tbl 200mg, which was published on 14.07.2014 with procurement number 206-14-019-111. The recommended dose is two tablets a day, which means that the order only covers the needs of eight patients for a period of 365 days, while according to the Essential List of Medicines published by MH, planning was made for 10,800 units of Sorafenib, which is double the amount of the order submitted for this medicine. According to media reports, ELM does not fulfil not even 40% of patients’ needs¹⁷, and with under-planning compared to needs due to low budget of MH, patients’ needs have never been fulfilled 100%¹⁸.

PREPARATION OF TECHNICAL SPECIFICATIONS AND TENDER DOSSIER

During the working group meeting, as well as during individual interviews there was no complaint with regard to the used specifications for procurement of TRASTUZUMAB 440mg.

In the proposal of KEI, University of California and Alliance of Universities for Essential Medicines & Network of Young Professionals for chronic diseases, it is said: “We note that, as it was stated in the special meeting of Committee of Experts in 2002 for HIV/AIDS, that adding important medicines in the WHO Essential List of Medicines, whose price seems to be unaffordable, in fact may serve as a key mechanism to expand access to these medicines and making them

13 ASK: Seria 5: Statistikat Shoqërore, Publikimi i Statistikave për Shëndetësinë në 2014

14 <http://koha.net/?id=27&l=66907>

15 KDI Working Group on MH, held on 30 November 2015 at RINGS, Prishtina.

16 http://www.who.int/medicines/publications/essentialmedicines/EM-L2015_8-May-15.pdf

17 <http://www.kosovalive360.com/lista-esenciale-e-barnave-nuk-permbush-as-40-te-nevojave-te-pacienteve.html>

18 <http://koha.net/?id=27&l=28926>

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(b)(1)(b)(7)(C)

financially affordable”¹⁹. Also, referring to the same project proposal, “Based on studied priced (presented in USD), cost of Trastuzumab from Roche varies from a low price of 3,035.95 \$ per gram in Pakistan to a high price of \$10,000 per gram in Brazil and Oman. Price in the Federal Supply Catalogue in USA is 6,266.23 \$ per gram, and prices in the majority of countries are between \$5,000 and \$9,000 per gram. Even in India, where Roche has implemented low prices by producing cheaper versions of Trastuzumab (Herclon, Bicel-tis), Trastuzumab from Roche is still very expensive”²⁰.

Another argument related to the high cost of Trastuzumab, from the same project proposal, is that chances that Trastuzumab will be widely used, especially in developing countries, independent of its medical benefits, will be very low unless cheaper versions are introduced²¹.

Based on the above-mentioned quotes, from the submitter of the request for including Trastuzumab in the WHO Essential List of Medicines, and considering the extremely low Kosovo budget allocated for purchase of medicines and disposable materials, the question needs to be asked whether this is the right investment by MH, or maybe other cheaper alternatives could be used, which could support a larger number of patients in need?

Regarding the second cytostatic Sorafenib, produced by Bayer, which is part of this analysis, the complaints from the working group pertain to non-consideration

19 Proposal for the inclusion of trastuzumab in the who model list of essential medicines for the treatment of her2-positive breast cancer, KEI, University of California San Francisco, Universities Allied for Essential Medicines (UAEM) & Young Professionals Chronic Disease Network (YPCDN), Jan 2013, p. 3

20 Proposal for the inclusion of trastuzumab in the who model list of essential medicines for the treatment of her2-positive breast cancer, KEI, University of California San Francisco, Universities Allied for Essential Medicines (UAEM) & Young Professionals Chronic Disease Network (YPCDN), Jan 2013, p. 15

21 Proposal for the inclusion of trastuzumab in the who model list of essential medicines for the treatment of her2-positive breast cancer, KEI, University of California San Francisco, Universities Allied for Essential Medicines (UAEM) & Young Professionals Chronic Disease Network (YPCDN), Jan 2013, p. 16

by MH of Sunitinib (Sutent), produced by Pfizer, which according to the working group has a longer shelf life than Sorafenib. American Association of Clinical Oncology in a study of overall survival of patients treated with Sorafenib and those treated with Sunitinib, concluded that “overall survival with Sunitinib was not superior or equivalent but was significantly inferior to Sorafenib. Overall survival was comparable in Asian and hepatitis B-infected students. Overall survival was superior in hepatitis C-infected patients who received Sorafenib. Sunitinib-treated patients reported more frequent and severe toxicity”²².

Minimum qualifying requirements were those of professional suitability, requirements on financial and economic status, requirements on technical and/or professional capacities and securing tender in the amount of 3% of the total bid value but not less than 1,000.00 EUR. Another requirement was that prior to the signing of the contract, the successful bidder would submit a guarantee of execution in the amount of 10% of contract value.

EVALUATION OF BIDS

Trastuzumab is a product patented by Roche, whose representative in Kosovo is “Meditech” LLC, therefore in the response to contract notice only one bid was received by the above-mentioned company. The bid of “Meditech” met all the required conditions from the Tender Dossier as documented in the Report on Evaluation of Bids dated 10.02.2015. What is concerning is non-application of legal provisions related to award of contracts. According to Law no. 04/L-042, Article 35, Paragraph 2: “Contracting Authority may use negotiated procedures without prior publication of a contract notice to conduct a procurement activity having as its object the award of: 2.1. any public contract: (i) if, for objective and compelling technical and artistic rea-

22 <http://jco.ascopubs.org/content/early/2013/09/27/JCO.2012.45.8372.abstract>

(b)(1)(b)(7)(C)

TAB. 2 – OVERVIEW OF FINANCIAL BIDS

COMPANY	DESCRIPTION	QUANTITY	CURRENCY	PRICE PER UNIT	TOTAL BID VALUE
SANTEFARM	Sorafenib 200mg	6,120	EURO	35.49	217,198.80
ASGETO	Sorafenib 200mg	6,120	EURO	42.66	261,079.20
	DIFFERENCE		EURO	7.17	43,880.40

sons, the contract may be awarded only to a particular economic operator”. Considering that this product is patented, MH should have used this legal provision, which would accelerate procurement procedures, and would not present a need for revocation of Article 32.5 for awarding the contract 206-15-001-111.

To evaluate rationale of the price paid by MH in the amount of 1,470.00€ per unit, KDI completed a market research through electronic mechanisms, and it was found that the wholesale price is between 1,800.00 USD and 1,955.00 USD per dose ²³.

With regard to the announcement of contract 206-14-019-111, MH had received a total of 6 bids, respectively 2 bids for Lot 5, and supply with Sorafenib tbl 200mg. Companies that submitted bids included ASGETO, Prishtinë, with the bid for lot 5 in the total amount of 261,079.20€ and SANTEFARM, Prishtinë, with the total bid value of 217,198.80€. Bid of Asgeto did not include the security of tender as required, and for this, they were considered as irresponsible, and the contract was awarded to Santefarm, which was also the operator with the cheapest bid, for supplying 6,120 units of Sorafenib 200mg, with a price of 35.49€ per unit and a total bid value of Lot 5 in the amount of 217,198.80€. If we compare the two received bids, we

see that the difference in prices is about 20%, which is within norms of market competition.

COMPLAINTS AT PRB

Regarding Contracts 206-15-001-111 Lot 11 on supply with Trastuzumab, and 206-14-019-111 Lot 5 on supply with Sorafenib, there was no complaint submitted to PRB by business operators in relation to tendering, evaluation and awarding of contract phases.

23 http://erc.msh.org/dmpguide/resultsdetail.cfm?language=english&code=TRS440I&s_year=2014&year=2014&str=440%20mg&desc=Trastuzumab&pack=new&frm=VIAL&rte=INJ&class_code2=08%2E2%2E&supplement=&class_name=%2808%2E2%2E-29Cytotoxic%20and%20adjuvant%20medicines%3Cbr%3E

RECOMMENDATIONS

- Provision of transparency in public procurement is a requirement and not an issue of individual will. In this regard, Ministry of Health should provide more transparency, allow free and efficient access to MH office documents, in line with timelines stipulated in the Law for Access into Public Documents;
- Essential List of Drugs should be considered as a living document that needs to be updated and revised constantly in order to reflect the latest developments in the world of medicine. The Ministry of Health should provide care that ELD includes updated specifications of drugs and supply materials in order that those standards are met during their purchase.
- The Ministry of Health should improve planning of procurements, by creating a system of registration and keeping electronic track of patients and consumption;
- Ministry of Health should improve archive of procurements and maintain a database for all procured items based on the respective contracts;
- Products under patents, should be purchased with the procedure of contract negotiation with the producer in order to ensure getting a lower price in order to avoid paying for middle man, thus saving time and accelerating purchase procedures and delivery. Purchase through local distributors should take place only when direct purchase is impossible for objective reasons;
- A list of products should be created, and which are under patents and which are part of the essential list of drugs, in order for contracts to not be signed for a longer period of time than the expiration of the patenting deadline;
- Considering numerous changes in the market, prior to opening of the procurement procedures, the market should be researched, in order to obtain a closer overview of the offer that companies might have for certain products and to protect from fixed prices.

Cataloguing in publication – **(CIP)**
National and University Library of Kosovo

615: 658.72(496.51)"2016"

Virusi i transparentitis : monitorimi publik në ministrinë e shëndetësisë : mars 2016 / Instituti Demokratikë i Kosovës.
– Prishtinë : KDI, 2016. – 32 ; 21 cm.

ISBN 978-9951-8927-5-9

KDI is a Non-Government Organization (NGO) engaged to support development of democracy through inclusion of citizens in public policy-making and empowering civil society sector with the goal to influence increase of transparency and accountability among public institutions.

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