



TRANSPARENTITIS VIRUS

PUBLIC PROCUREMENT MONITORING AT THE MINISTRY OF HEALTH

MARCH 2016

















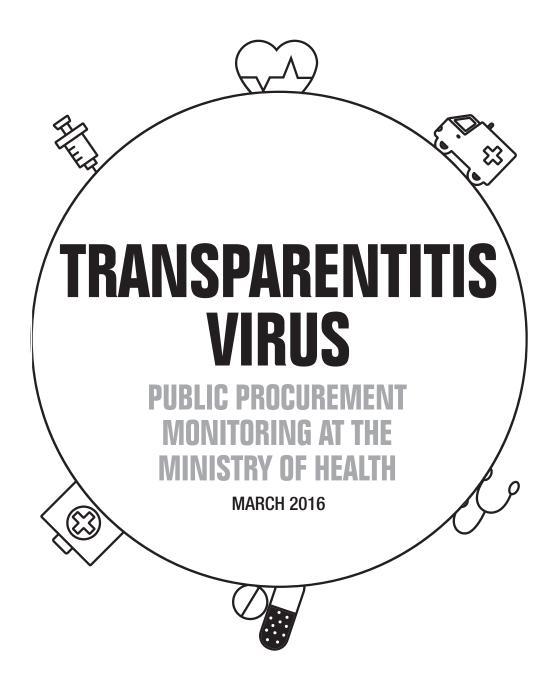












PUBLIC PROCUREMENT MONITORING AT THE MINISTRY OF HEALTH

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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 Monte-

negro, 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 improv-

ing 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.

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 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.

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". 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.

For drafting this report, KDI

analysed 730 documents and

publications, with over 12,000

pages; it had tens of meetings

and phone conversations, tens

of communications through

electronic mail and it has

submitted 9 requests for access

to office documents, etc.

INTRODUCTION

According to reports published by government authorities in 2014¹, out of a total of 1,589 million Euros ² of total government budget, 445.2 million Euros ³ were

spent through procurement procedures. This represents 28% of the overall budget value. Spending public funds through public procurement in Kosovo is to a large extent closed for public and as a result there is no access or oversight from civil society, media and public, and as such this represents a serious potential for mismanagement. Analysis of tendering procedures and implementation of legislation (that regulates public procurement area, highlighting irregularities and advocating for taking measures against abusers) is

considered a key element that would affect development of a more competitive environment, where businesses are free and equal in the market. Kosovo Democratic Institute (KDI), as part of Transparency and Anti-Corruption Programme, and public procurement monitoring respectively, has researched and published many reports on procedures of drafting specific techniques, process of tendering and evaluation of bids, awarding of contracts, contract management, complaints and PRB decisions, and findings in various public procurement phases.

Public Procurement in Kosovo is faced with various and numerous problems including insufficient legal

provisions, lack of adequate training, lack of good will and integrity, lack of transparency and accountability, etc., and it is considered as most corrupted and

mismanaged sector within Kosovo public institutions ⁴.

In this regard, procurement within the Ministry of Health continues to remain one of the most discussed topics in local media for mis-planning, mis-management and tender set-up.

The purpose of this report is to analyse tendering procedures and awarding of contracts for supply items in three sections of the Kosovo Clinical University Centre (KCUC), i.e. Oncology with cyto-

static, supply materials for KCUC needs, and supplies with anti-viral medicines for Invective Clinic.

¹ For comparison, publications of 2014 were considered, since publications for 2015 are still under development by respective institutions

² https://mf.rks-gov.net/sq-al/Buxheti/Buxheti-i-Republikes-se-Kosoves/Buxheti-qendrore

³ https://krpp.rks-gov.net/krpp/PageFiles/File/Raportet%20Vjeto-re/2014/Raporti%20vjetor%202014%20Shqip%20KRPP.pdf

⁴ EU: Progress Report 2015 Kosovo*, 10/11/2015 Brussels

HEALTH EXPENDITURE PER CAPITA

One of the main concerns of the society, as well as of service providers and suppliers ⁵ is the low allocated budget for health expenditure per capita in Kosovo. While analysing Kosovo budget for 2013 ⁶, 2014 ⁷ and 2015 ⁸, 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.

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

# Country		Expenditure in health per capita (PPP int. \$)
1	Afghanistan	\$161.00
2	Albania	\$539.00
3	Algeria	\$778.00
4	Andorra	\$3,338.00
5	Angola	\$355.00
6	Antigua and Barbuda	\$1,021.00

#	Country	Expenditure in health for capita (PPP int. \$)
7	Argentina	\$1,725.00
8	Armenia	\$351.00
9	Australia	\$4,191.00
10	Austria	\$4,885.00
11	Azerbaijan	\$957.00
12	Bahamas	\$1,688.00

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-gendrore

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-gendrore

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

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

#	Country	Expenditure in health per capita (PPP int. \$)	#	Country	Expenditure in health per capita (PPP int. \$)
13	Bahrain	\$1,900.00	45	Cyprus	\$2,197.00
14	Bangladesh	\$95.00	46	Czech Republic	\$1,982.00
15	Barbados	\$1,060.00	47	Democratic Republic of	\$26.00
16	Belarus	\$1,081.00		Congo	
17	Belgium	\$4,526.00	48	Denmark	\$4,552.00
18	Belize	\$458.00	49	Djibouti	\$247.00
19	Benin	\$82.00	50	Dominica	\$597.00
20	Bhutan	\$275.00	51	Dominican Republic	\$631.00
21	Bolivia	\$372.00	52	Ecuador	\$789.00
22	Bosnia and Herzegovina	\$928.00	53	Egypt	\$539.00
23	Botswana	\$851.00	54	El Salvador	\$539.00
24	Brazil	\$1,454.00	55	Equatorial Guinea	\$1,170.00
25	Brunei Darussalam	\$1,812.00	56	Eritrea	\$36.00
26	Bulgaria	\$1,213.00	57	Estonia	\$1,453.00
27	Burkina Faso	\$109.00	58	Ethiopia	\$69.00
28	Burundi	\$62.00	59	Fiji	\$328.00
29	Cote d'Ivoire	\$172.00	60	Finland	\$3,604.00
30	Cabot Verde	\$279.00	61	France	\$4,334.00
31	Cambodia	\$229.00	62	Gabon	\$735.00
32	Cameroon	\$138.00	63	Gambia	\$99.00
33	Canada	\$4,759.00	64	Georgia	\$697.00
34	Central African Republic	\$24.00	65	Germany	\$4,812.00
35	Cad	\$74.00	66	Ghana	\$214.00
36	Chile	\$1,678.00	67	Greece	\$2,513.00
37	China	\$646.00	68	Grenada	\$729.00
38	Columbia	\$843.00	69	Guatemala	\$467.00
39	Comoros	\$90.00	70	Guinea	\$59.00
40	Congo	\$242.00	71	Guinea-Bissau	\$79.00
41	Cook Islands	\$513.00	72	Guyana	\$426.00
42	Costa Rica	\$1,369.00	73	Haiti	\$160.00
43	Croatia	\$1,517.00	74	Honduras	\$400.00
44	Cuba	\$1,828.00	75	Hungary	\$1,839.00

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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	124 125	Nigeria	\$206.60
94	Lebanon	\$1,092.00	126	Niue	\$959.00
95	Lesotho	\$297.00	127	Norway	\$6,308.00 \$796.00
96	Liberia	\$88.00	128	Oman Pakistan	\$126.00
97	Libya	\$764.00	129	Palau	\$1,288.00
98	Lithuania	\$1,579.00	130	Panama	\$796.00
99	Luxembourg	\$6,518.00	131	Papua New Guinea	\$114.00
100	Madagascar	\$58.00	132		\$724.00
101	Malawi	\$90.00	133	Paraguay Peru	\$626.00
102	Malaysia	\$938.00	134	Philippines	\$287.00
103	Maldives	\$1,260.00	135	Poland	\$1,551.00
104	Mali	\$122.00	136	Portugal	\$2,508.00
105	Malta	\$2,652.00	137	Qatar	\$2,882.00
106	Marshall Islands	\$703.00	138	Korea Republic	\$2,398.00
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#	Country	Expenditure in health per capita (PPP int. \$)
139	Moldova	\$553.00
140	Romania	\$988.00
141	Russian Federation	\$1,587.00
142	Rwanda	\$162.00
143	Saint Kitts and Nevis	\$1,332.00
144	Saint Lucia	\$898.00
145	Saint Vincent and Grenadines	\$555.00
146	Samoa	\$379.00
147	San Marino	\$3,709.00
148	Sao Tome and Principe	\$203.00
149	Saudi Arabia	\$1,681.00
150	Senegal	\$96.00
151	Serbia	\$987.00
152	Seychelles	\$937.00
153	Sierra Leone	\$228.00
154	Singapore	\$3,578.00
155	Slovakia	\$2,147.00
156	Slovenia	\$2,595.00
157	Solomon Islands	\$106.00
158	South Africa	\$1,121.00
159	South Sudan	\$52.00
160	Spain	\$2,846.00
161	Sri Lanka	\$304.00
162	Sudan	\$221.00
163	Suriname	\$744.00
164	Swaziland	\$564.00
165	Sweden	\$4,244.00
166	Switzerland	\$6,187.00
167	Syria	\$169.00
168	Tajikistan	\$170.00
169	Thailand	\$658.00
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#	Country	Expenditure in health per capita (PPP int. \$)
170	Macedonia	\$759.00
171	Timor-Leste	\$96.00
172	Togo	\$119.00
173	Tonga	\$250.00
174	Trinidad and Tobago	\$1,663.00
175	Tunisia	\$791.00
176	Turkey	\$1,053.00
177	Turkmenistan	\$276.00
178	Tuvalu	\$663.00
179	Uganda	\$146.00
180	Ukraine	\$687.00
181	United Arab Emirates	\$2,233.00
182	The United Kingdom	\$3,311.00
183	United Republic of Tanzania	\$126.00
184	United States of America	\$9,146.00
185	Uruguay	\$1,715.00
186	Uzbekistan	\$330.00
187	Vanuatu	\$115.00
188	Venezuela	\$656.00
189	Viet Nam	\$308.00
190	Yemen	\$200.00
191	Zambia	\$192.00
192	World Average	\$1,240.86
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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.

TRANSPARENCY

Transparency is a concept synonymous to good governance, accountability, and increasing citizens' trust about public institutions. Transparency of access to public documents is a basic right of all citizens in order to be informed how public money is being spent.

This is the fourth time KDI is monitoring the Ministry of Health, and it is worth mentioning that despite claims for cooperation and transparency, access to public documents in this institution has not been the easiest. Also, maintenance of data and organization of archive is at a concerning level. According to communication with MH dated 07 August 2015, the Procurement Division had asked to add the number of tender to the identified list of items of interest for monitoring, since this division did not possess data about what items were purchased under what contract.

Also, non-possession of a specific managed archive caused delays in receiving relevant documents by the Ministry. Even though the positive response from the MH was received within timelines stipulated in the Law no. 03L-215 on Access to Office Documents, none of the requested documents were received until 11 November 2015, after a complaint has been submitted by KDI to the MH permanent secretary, when KDI received minutes from bid opening.

In between August 2015 – March 2016, KDI had requested access to 11 contracts for purchase of drugs and supply material through a total of five requests for access to official documents, and one request for information, but up to drafting of this report tender dossiers of only six contracts were received. Also, since one of the main complaints was the lack of time and human resources to grant the requested access, KDI had divided original requests directed to Procurement Division, by submitting new requests to the department of finances about invoices and to the division of inter-

nal audit related to internal auditor reports for these contracts, for which KDI did not receive documents from MH.

Also, two requests were submitted to CPA about planning of procurement during 2012 – 2015, and one request was submitted to PRB for access to PRB complaints and decisions related to these procurements, and in both cases it had received the requested documents within a one-week timeline.

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=catego-ry&id=88klayout=blog&Itemid=4

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 cancer¹³¹⁴. 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 meeting ¹⁵ 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 system ¹⁶.

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' needs ¹⁷, 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

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, Biceltis), 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 introduced ²¹.

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 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-

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 (YP-CDN), 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 (YP-CDN), 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 (YP-CDN), Jan 2013, p. 16

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

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=en-glish&code=TRS440l&s_year=2014&year=2014&str=440%20 mg&desc=Trastuzumab&pack=new&frrn=VIAL*tre=INJ&class_code2=08%2E2%2E&supplement=&class_name=%2808%2E2%2E%-29Cytotoxic%20and%20adjuvant%20medicines%3Cbr%3E

SUPPLY WITH DISPOSABLE MATERIALS

One of the main public complaints pertains to supplies with disposable materials, especially about their lack of quality. Main concerns presented during the working group meeting were uncertainties in ELM and technical specifications of products, since they were incomplete and did not address all the requirements

need for a product. KDI had submitted requests for access to public documents for the following contracts: 206-15-025-111, 206-14-088-111, 206-15-015-111, 206-14-022-111, and documents were provided for all contracts but 206-15-015-111, which aimed to analyse supply with surgery sterile gloves.

NEEDS ASSESSMENT AND PLANNING

The following table presents planned quantities per year, for the given supplies, according to ELM, and referential prices at KRPP for these products:

TAB. 3 – PLANNED QUANTITIES ACCORDING TO ELM, AND REFERENTIAL PRICES ACCORDING TO KRPP.

DESCRIPTION	FORMAT / SPECIFICATIONS	VEN	UNITS PER YEAR	PREDICTED VALUE	KRPP: REFERENTIAL PRICE PER UNIT
GAUZE ABSORBENT COTTON, ROLL, 90 cm x 100 m, jo me pak se 13 fije	Weight from 2.4 up to 3kg	V	17,200	335,400.00	20.33 €
GLOVES EXAMINATION	Large	V	2,263,820	72,442.24	0.79 €
GLOVES EXAMINATION	Medium	V	2,877,624	94,961.59	0.79€
GLOVES EXAMINATION	Small	V	987,650	29,629.50	0.79€
GOWN SURGICAL STERILE DISPOSABLE	Large	V	67,105	97,302.25	1.80 €
GOWN SURGICAL STERILE DISPOSABLE	Medium	V	70,355	102,014.75	1.80 €

PREPARATION OF TECHNICAL SPECIFICATIONS AND TENDER DOSSIER

During the meeting of the working group, main concerns related to the above-mentioned supplies were that contract items for supply with Cotton Roll, mentions package weight, while ELM does not specify the weight of cotton, which made supplying companies to be uncertain about how to define the product accurately.

With regard to items of the second contract on supply with examination gloves, it was not specified whether these gloves are required with powder or without powder. According to business operators, gloves with powder are used far less in the world today because they are less healthy, but in Kosovo this fact is bypassed due to lower price.

While the third contract for supply with disposable sterile scrubs, it was not specified whether these scrubs will be used for purposes of visits or during surgery, since those used in surgery have 4 layers, but this is not specified in the FLM.

CONTRACT MH 206-15-025-111, LOT 4— SUPPLY WITH GAUZE ABSORBENT COTTON, ROLL, 90 CM X 100 M, NOT LESS THAN 13 THREADS, WITH WEIGHT FROM 2.4 UP TO 3KG

Tender 206-15-025-111 was divided into 10 Lots, where point of interest for this analysis includes lot 4 – supply with gauze absorbent cotton roll, $90 \, \text{cm} \, \text{x} \, 100 \, \text{m}$, no less than 13 threads.

Preparation of specifications for the given contract was in compliance with the ELM. Minimum qualifying requirements were those for professional suitability, requirements on financial and economic status, and requirements for technical and/or professional capacities. Another contract was that prior to signing of contract, the successful bidder had to submit a guarantee of 10% of contract value for a duration of 3 months or 90 days.

As evidence of professional suitability, BE were required to submit the following documentation:

- EVIDENCE 1: Copy of business certificate;
- EVIDENCE 2: Copy of registration certificate in country of origin (for international companies);
- EVIDENCE 3: Copy of certificate of fiscal number;
- EVIDENCE 4: Copy of VAT certificate (for domestic companies).

As evidence of technical and professional capacities, BE had to submit the following documentation:

- EVIDENCE 1: Authorization from the producer signed and sealed (with detailed information about the producer: address, phone number, email, etc., in order that Contracting Authority has the possibility to verify)
- EVIDENCE 2: ISO 13485: 9001
- EVIDENCE 3: European CE
- EVIDENCE 4: Evidence that the product is produced or registered in at least one Schengen country, The United Kingdom, Switzerland, USA, Canada, Japan, Israel, Australia, New Zealand, Turkey (produced in Turkey).
- EVIDENCE 5: Licence as a wholesale operator for medicine equipment;
- EVIDENCE 6: Minimum of 1 reference or contracts for similar supplies, within past 3 years (2012, 2013, 2014);
- EVIDENCE 7: Catalogue or brochure from producer for bid items, where for all items dimensions are clearly specified and lot is underlined and indicated with number;
- EVIDENCE 8: Sample for all bid items are evidenced with the number of lots and divided according to lots – REQUIRED;
- **EVIDENCE 9:** Statement from international companies where they state that they will register their

representative offices at MTI (Ministry of Trade and Industry) immediately after awarding the contract, and prior to signing of the contract

In case the business operator includes a group of operators, the draft contract must specify the group leader, will authorize group leader to sign the tender, contract, and other relevant documents and defines tasks and responsibilities within the group.

- For sterile equipment an additional document:
 - Certificate/Statement of sterility from competent authority
- For blood products and vaccines additional document:
 - Official Batch Release Certificate
- For products with human and animal origin additional document:
 - Certificate of Suitability for TSE

2 CONTRACT MH 206-14-088-111 - LOTS 98, 99, 100 SUPPLY WITH GLOVES EXAMINATION, L, M, S

Tender 206-14-088-111 was divided into 146 Lots, where points of interest for this analysis include lots 98, 99, 100 for supply with GLOVES EXAMINATION, L, M, S.

Preparation of specifications for the given product was done in compliance with ELM. Minimum qualifying requirements were those for professional suitability, requirements on financial and economic status, and requirements for technical and/or professional capacities.

Same as in the previous contract, business operators had to submit the following documentation as evidence of professional suitability:

- EVIDENCE 1: Copy of business certificate;
- EVIDENCE 2: Copy of registration certificate in country of origin (for international companies);
- EVIDENCE 3: Copy of certificate of fiscal number;

EVIDENCE 4: Copy of VAT certificate (for domestic companies).

As evidence of technical and professional capacities, business operators were asked to submit the following documentation:

- EVIDENCE 1: Authorization from the producer signed and sealed (with detailed information about the producer: address, phone number, email, etc., in order that Contracting Authority has the possibility to verify)
- **EVIDENCE 2:** ISO 13485; 9001
- EVIDENCA 3: European CE
- EVIDENCA 4: Evidence that the product is produced or registered in at least one Schengen country, The United Kingdom, Switzerland, USA, Canada, Japan, Israel, Australia, New Zealand, Turkey (produced in Turkey).
 - For sterile products an additional document:
 - Certificate/Statement of sterility from the competent authority.

CONTRACT MH 206-14-022-111 - LOTS 13 AND 14 SUPPLY WITH GOWN SURGICAL STERILE DISPOSABLE, L, M.

Tender 206-14-088-111 was divided into 60 lots, where points of interest for this analysis include lots 13 and 14 for supply with GOWN SURGICAL STERILE DISPOSABLE, L. M.

Preparation of specifications for the given product was done in compliance with ELM. Minimum qualifying requirements were those for professional suitability, requirements on financial and economic status, requirements on technical and/or professional capacities and securing the tender with an amount of 3% of bid value, but not less than 1,000.00 EUR. Another request prior to signing the contract was that the successful bidder had to submit a guarantee for execution in amount of 10% of contract value for a duration of 25 months.

Similar to the previous contract, as evidence of professional suitability business operators were asked to submit the following documentation:

- EVIDENCE 1: Copy of business certificate;
- EVIDENCE 2: Copy of registration certificate in country of origin (for international companies);
- **EVIDENCE 3:** Copy of certificate of fiscal number;
- EVIDENCE 4: Copy of VAT certificate (for domestic companies

As evidence of technical and professional capacities, business operators were asked to submit the following documentation:

- EVIDENCE 1: Authorization from the producer signed and sealed (with detailed information about the producer: address, phone number, email, etc., in order that Contracting Authority has the possibility to verify)
- EVIDENCE 2: ISO 13485; 9001
- EVIDENCE 3: European CE
- EVIDENCE 4: Evidence that the product is produced or registered in at least one Schengen country, The United Kingdom, Switzerland, USA, Canada, Japan, Israel, Australia, New Zealand, Turkey (produced in Turkey)...
 - For sterile products an additional document:
 - Certificate/Statement of sterility from the competent authority.

EVALUATION OF BIDS

CONTRACT MH 206-15-025-111, LOT 4- SUPPLY WITH GAUZE ABSORBENT COTTON, ROLL, 90 CM X 100 M, NOT LESS THAN 13 THREADS, WITH WEIGHT FROM 2.4 UP TO 3KG

In response to tender call 206-15-025-111 Lot 4, a total of three bids were received, where two out of the three bids met all qualifying requirements and were considered as responsible, enabling award of contract to the bidder with lowest bid price, without revoking Article 32.5 of LPP no. 04/L-042. Bid of Made-kos, which was the cheapest for this lot, did not meet technical requirements, submission of product samples respectively. Triomed was awarded with the contract. The following table presents received bids for this product:

TAB. 4 – OVERVIEW OF FINANCIAL BIDS FOR 206-15-025-111

COMPANY	DESCRIPTION	QUANTITY	CURRENCY	PRICE PER UNIT	TOTAL BID VALUE
TRIOMED	GAUZE ABSORBENT COTTON ,ROLL, 90 cm x 100 m, not less than 13 threads	5,300	EURO	11.55	61,215.00
KOM-MED	GAUZE ABSORBENT COTTON ,ROLL, 90 cm x 100 m, not less than 13 threads	5,300	EURO	13.80	73,140.00
MADE-KOS	GAUZE ABSORBENT COTTON ,ROLL, 90 cm x 100 m, not less than 13 threads	5,300	EURO	11.30	59,890.00

2 CONTRACT MH 206-14-088-111 - LOTS 98, 99, 100 SUPPLY WITH GLOVES EXAMINATION, L, M, S

In response to tender call 206-14-088-111 Lots 98, 99 and 100, a total of 9 bids were received, where three of them were considered as irresponsible for the following reasons:

- Bid of Exclusiv Pharma did not meet the requirement of having 2 references or contracts for similar supplies in institutions in past 3 years (2011, 2012, 2013);
- Bid of Made Kos for lots 98, 99, 100, had bid with producer Mexpo while submitted samples were produced by Bloson, which was a mismatch, since

ISO and CE were not from Blosom but from Mexpo;
Bid of Jona Med for lots 98, 99, 100, did not meet the requirement for offering samples of bid items.

This contract was awarded to AGANI Company as the bidder with lowest bid price.

Five out of six companies evaluated as successful had offered competitive prices with a difference of 7 to 15% compared to the lowest bid, while bid of Liri Med had non-competitive prices which 44% higher than the cheapest bid, and 36% higher than the bid ranked as fifth in terms of bid price.

The following table presents received bids for this product:

TAB. 5 - OVERVIEW OF FINANCIAL BIDS 206-14-088-111

COMPANY	DESCRIPTION	LOT	QUANTITY	CURR.	PRICE PER UNIT	TOTAL BID VALUE
AGANI Ltd	GLOVES EXAMINATION, L	98	2,509,700	EURO	0.0279 €	70,020.63 €
	GLOVES EXAMINATION, M	99	2,611,400	EURO	0.0279 €	72,858.06 €
	GLOVES EXAMINATION, S	100	1,233,800	EURO	0.0279 €	34,423.02 €
TRIOMED	GLOVES EXAMINATION, L	98	2,509,700	EURO	0.0300 €	75,291.00 €
	GLOVES EXAMINATION, M	99	2,611,400	EURO	0.0300 €	78,342.00 €
	GLOVES EXAMINATION, S	100	1,233,800	EURO	0.0300 €	37,014.00 €
KOMED	GLOVES EXAMINATION, L	98	2,509,700	EURO	0.0317 €	79,557.49 €
	GLOVES EXAMINATION, M	99	2,611,400	EURO	0.0317 €	82,781.38 €
	GLOVES EXAMINATION, S	100	1,233,800	EURO	0.0319 €	39,358.22 €
MEDICAL GROUP	GLOVES EXAMINATION, L	98	2,509,700	EURO	0.0320 €	80,310.40 €
	GLOVES EXAMINATION, M	99	2,611,400	EURO	0.0320 €	83,564.80 €
	GLOVES EXAMINATION, S	100	1,233,800	EURO	0.0320 €	39,481.60 €
REDONI -HM	GLOVES EXAMINATION, L	98	2,509,700	EURO	0.0330 €	82,820.10 €
	GLOVES EXAMINATION, M	99	2,611,400	EURO	0.0330 €	86,176.20 €
	GLOVES EXAMINATION, S	100	1,233,800	EURO	0.0350 €	43,183.00 €
LIRI MED	GLOVES EXAMINATION, L	98	2,509,700	EURO	0.0500 €	125,485.00 €
	GLOVES EXAMINATION, M	99	2,611,400	EURO	0.0500 €	130,570.00 €
	GLOVES EXAMINATION, S	100	1,233,800	EURO	0.0500 €	61,690.00 €

CONTRACT MH 206-14-022-111 - LOTS 13 AND 14 SUPPLY WITH GOWN SURGICAL STERILE DISPOSABLE, L, M.

In response to tender call 206-14-022-111 Lots 13 and 14 a total of 13 bids were received, and 7 out of these bids were considered irresponsible for the following reasons:

- Bid of Atom Med did not meet the requirement of providing samples of bidded items;
- Bid of Exclusive Pharma did not meet the requirement of providing samples of bidded items;
- Bid of Friends did not have the authorization from producer "Johnsons & Friends";
- Bid of Koslabor did not specify country of origin;
- Bid of Made Kos did not have the authorization from producer Zarys and lacked CE Certificate;
- Bid of Medical Group did not have references as required by Tender Dossier;
- Bid of Proxor Trade did not have products from any of the countries required in the Tender Dossier.

The following table represents all accepted bids for this product:

Initially on 22.08.2014 the Ministry of Health had published announcement for award of contract to Komed company as the cheaper responsible bidder. After the complaint submitted to PRB by "Friends" company on 05.08.2015 (for more see Complaints to PRB), and decision of PRB dated 08.09.2014 with protocol number 283/14, dated 16.10.2014 MH had published announcement for cancelling the contract with Komed and on 14.11.2014 a public framework contract was entered for 24 months with "Friends" company.

COMPLAINTS TO PRB

CONTRACT MH 206-15-025-111, LOT 4- SUPPLY WITH GAUZE ABSORBENT COTTON, ROLL, 90 CM X 100 M, NOT LESS THAN 13 THREADS, WITH WEIGHT FROM 2.4 UP TO 3KG

Regarding contracts 206-15-025-111 Lot 4 supply with GAUZE ABSORBENT COTTON, ROLL, 90 CM X 100 M, there was no complaint submitted to PRB by business operators with regard to tendering, evaluation, and awarding of contract phases.

2 CONTRACT MH 206-14-088-111 - LOTS 98, 99, 100 SUPPLY WITH GLOVES EXAMINATION, L, M, S

Regarding contracts 206-14-088-111 Lots 98, 99, 100 supply with GLOVES EXAMINATION, L, M, S, there was no complaint submitted to PRB by business operators with regard to tendering, evaluation, and awarding of contract phases.

CONTRACT MH 206-14-022-111
- LOTS 13 AND 14 SUPPLY WITH
GOWN SURGICAL STERILE
DISPOSABLE, L, M.

On 06.08.2014, "Friends" company had submitted a complaint to PRB related to announcing of their bid as irresponsible for supplies with materials from Essential List for lots 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13, 14, 15, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28, 29, 30, 31, 32, 33, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46. Based on this complaint, PRB, on 06.08.2014 had made a decision to suspend the given activity. After analysis

TAB. 6 – OVERVIEW OF FINANCIAL OFFERS FOR 206-14-022-111

COMPANY	DESCRIPTION	LOT	QUANTITY	CURR.	PRICE PER UNIT	TOTAL BID AMOUNT
FRIENDS*	GOWN SURGICAL STERILE DISPOSABLE, L	13	62,280	EURO	0.5690 €	35,437.32 €
	GOWN SURGICAL STERILE DISPOSABLE, M	14	67,200	EURO	0.5690 €	38,236.80 €
MADE KOS*	GOWN SURGICAL STERILE DISPOSABLE, L	13	62,280	EURO	0.9500 €	59,166.00 €
	GOWN SURGICAL STERILE DISPOSABLE, M	14	67,200	EURO	0.9500 €	63,840.00 €
KOMED	GOWN SURGICAL STERILE DISPOSABLE, L	13	62,280	EURO	0.9900 €	61,657.20 €
	GOWN SURGICAL STERILE DISPOSABLE, M	14	67,200	EURO	0.9900 €	66,528.00 €
ATOM MED*	GOWN SURGICAL STERILE DISPOSABLE, L	13	62,280	EURO	1.1200 €	69,753.60 €
MEDIOAL	GOWN SURGICAL STERILE DISPOSABLE, M	14	67,200	EURO	1.1200 €	75,264.00 €
MEDICAL GROUP*	GOWN SURGICAL STERILE DISPOSABLE, L	13	62,280	EURO	2.1900 €	136,393.20 €
	GOWN SURGICAL STERILE DISPOSABLE, M	14	67,200	EURO	1.9900 €	133,728.00 €
DRIAR	GOWN SURGICAL STERILE DISPOSABLE, L	13	62,280	EURO	1.2500 €	77,850.00 €
	GOWN SURGICAL STERILE DISPOSABLE, M	14	67,200	EURO	1.2500 €	84,000.00 €
TRIOMED	GOWN SURGICAL STERILE DISPOSABLE, L	13	62,280	EURO	1.3500 €	84,078.00 €
	GOWN SURGICAL STERILE DISPOSABLE, M	14	67,200	EURO	1.3500 €	90,720.00 €
EXCLUSIVE PHARMA*	GOWN SURGICAL STERILE DISPOSABLE, L	13	62,280	EURO	1.2710 €	79,157.88 €
	GOWN SURGICAL STERILE DISPOSABLE, M	14	67,200	EURO	1.2270 €	82,454.40 €
AGANI	GOWN SURGICAL STERILE DISPOSABLE, L	13	62,280	EURO	1.1900 €	74,113.20 €
	GOWN SURGICAL STERILE DISPOSABLE, M	14	67,200	EURO	1.1900 €	79,968.00 €
PROXOR TRADE*	GOWN SURGICAL STERILE DISPOSABLE, L	13	62,280	EURO	0.7300 €	45,462.40 €
	GOWN SURGICAL STERILE DISPOSABLE, M	14	67,200	EURO	0.7300 €	49,056.00 €
MEDICA	GOWN SURGICAL STERILE DISPOSABLE, L	13	62,280	EURO	1.0900 €	67,885.20 €
	GOWN SURGICAL STERILE DISPOSABLE, M	14	67,200	EURO	1.0900 €	73,248.00 €
IQ MEDICAL	GOWN SURGICAL STERILE DISPOSABLE, L	13	62,280	EURO	0.9900 €	61,657.20 €
	GOWN SURGICAL STERILE DISPOSABLE, M	14	67,200	EURO	0.9900 €	66,528.00 €
KOSLABOR*	GOWN SURGICAL STERILE DISPOSABLE, L	13	62,280	EURO	2.2000 €	137,016.00 €
	GOWN SURGICAL STERILE DISPOSABLE, M	14	67,200	EURO	2.0000 €	134,400.00 €

^{*}Companies considered as irresponsible.

from the expert, it was concluded that disqualification of "Friends" company due to lack of authorizations for given lots was groundless and PRB on 08.09.2014 had issued a decision to cancel awarding of contract to KOMED and the case would return for re-evaluation as a result of non-respecting Article 6 and 59 of the LPP. On 25.09.2014 PRB issued a Directive addressed to AK for respecting PRB decision, since AK had not undertaken any activity within the 10-day timeline as required by law. Also, as a punishment for non-respecting PRB decision, AK was fined with 5,000.00€ and procurement officer was stripped of procurement certificate.

mcg, RIBAVIRIN, caps/tbl, 200mg and RIBAVIRIN, sol per inj., 1.2g. Access to contract dossiers for supply with these medicines was initially requests at MH on 04.08.2015 and then again on 13.10.2015, but KDI received documents only related to supply with RIB-AVIRIN, caps/tbl, 200mg, contract with procurement number 206-13-050-111 respectively.

Ribavirin is an anti-viral medicine that is used for serious infections with syncytial virus of breathing channels; infection with Hepatitis C, and often in combination with Peginterferon alfa-2b or Peginterferon alfa-2a for resistant cases; as well as some other viral infections. According to ELM, it is planned that 50,000 units of RIBAVIRIN, caps/tbl, 200mg would be purchased to meet patients' needs.

SUPPLY WITH ANTI-VIRAL (ANTI-INFECTIVE) MEDICINES

NEEDS ASSESSMENT AND PLANNING

According to data from the Agency for Statistics of Kosovo (ASK), during 2014 Infective Clinic was visited by 5,744 patients, from whom 3.074 had received hospital treatment, and the number of deaths at the clinic was 51 ²⁴. One of the main problems in Kosovo is infection of haemodialysis patients with Hepatitis B and Hepatitis C ²⁵. Based on this data, KDI had selected monitoring of procurement of medicines PEGINTERFERON ALFA 2a, filled syringe /sol per inj., 180

PREPARATION OF TECHNICAL SPECIFICATIONS AND TENDER DOSSIER

RIBAVIRIN, caps/tbl, 200mg, is a generic medicine and it is easily accessible in the market. Also, preparation of specifications was general and did not represent any favourable requirement. Minimum qualifying requirements were those for professional suitability, requirements for economic and financial status, requirements for technical and/or professional capacities and securing tender in the amount of 3% of bid amount, but not less than 1,000.00 EUR. Another requirement was that prior to signing of the contract, the successful bidder had to submit the guarantee for execution in the amount of 10% of the contract value. Also, another requirement from the tender dossier was that medicines had to have validity for a least 12 months from the delivery/reception date at the Main Warehouse at MH. This tender 206-13-050-111 was divided in a total of 18 lots, where Lot 10 was allocated for buying RIBAVIRIN, caps/tbl, 200mg, in annual quantity of 22,180 units.

On 14.06.2013 MH notified business operators that had withdrawn the tender dossier that there was a

²⁴ ASK: Seria 5: Statistikat Shoqërore, Publikimi i Statistikave për Shëndetësinë në 2014, fq. 40

²⁵ http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2694791/

change in the Tender Dossier, where Lot 11 for supplies with 3 types of analogues insulin was divided into three lots since "it represents a conflict of interest, since other producers do not possess 3 types of requested insulin" ²⁶. The new list of requested medicines contained 20 lots.

EVALUATION OF BIDS

In response to tender 206-13-050-111 a total of 13 bids were received, from which two offers were for Lot 10, supply with RIBAVIRIN, caps/tbl, 200mg. Both offers had met all qualification requirements and were evaluated as responsible, creating the opportunity for awarding the contract based on the requirement of bid with lower price. The following table shows the bids received for this product:

COMPLAINTS AT PRB

With respect to Contracts 206-13-050-111 Lot 10 supply with Ribavirin, there was no complaint submitted to PRB by business operators regarding the tendering, evaluation, and awarding of the contract.

KDI had submitted a request to MH for access to financial reports, invoices and auditing reports related to supplies on 04 August 2015, 13 October 2015 and 08 February 2016, but until 30 March 2016 did not receive any of the requested documents. One of the complaints of the business operators that participated in the working group organized by KDI related to monitoring of these contracts was the large difference between contracted quantities and quantities requested for delivery according to framework contract requirements, where making available a certain number of contracted items is required, while the requesting units do not request them or request only a very small number of them. Due to lacking of above-mentioned documents, it is impossible to examine whether this complaint from business operators was valid.

TAB. 7 – OVERVIEW OF FINANCIAL BIDS

COMPANY	DESCRIPTION	QUANTITY	CURRENCY	PRICE PER UNIT	TOTAL BID VALUE
AGANI	RIBAVIRIN, caps/tbl, 200mg	22,180	EURO	2.09	46,356.20
Meditech	RIBAVIRIN, caps/tbl, 200mg	22,180	EURO	2.10	46,578.00
		DIFFERENCE	EURO	0.01	221.80

CONTRACT
IMPLEMENTATION,
AND PERFORMANCE
AND PAYMENT
MONITORING

 $^{26\,}$ E-mail from procurement office at MH to business operators dated 6/14/2013 4:02 PM.

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.

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