



CORRUPTION RISK ASSESSMENT IN THE HEALTHCARE SYSTEM OF MONTENEGRO



Stabilitätspakt für Südosteuropa
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ABBREVIATIONS:

CATI – Computer Assisted Telephone Interviewing

CPME – Comité Permanent des Médecins Européens (Standing Committee of European Doctors)

CREE – Central registry of economic entities

SAI – State Audit Institution

EU – European Union

HIF – Health Insurance Fund

INN – International Nonproprietary Name

IT – Information technologies

PHI – Public Healthcare Institutions

CCM – Clinical Center of Montenegro

OECD – Organization for Economic Co-operation and Development

WHO – World Health Organization

DACI – Directorate for Anti-Corruption Initiative

UNODC – United Nations Office on Drugs and Crime

USAID – United States Agency for International Development

SSP – Supreme State Prosecution

INTRODUCTION

Public policy study „Corruption Risk Assessment in the Healthcare System of Montenegro“ was created within the project „Fight against corruption in the healthcare system of Montenegro“ implemented by Center for Monitoring and Research CeMI and supported by the Embassy of Federal Republic of Germany in Podgorica. This is the first initiative of civil society to open the issue of corruption in the healthcare, with the aim to induce more intensive actions of decision makers, as well as actions of all interested parties, civil society and media on suppression of corruption in this area.

Occurrence of corruption in the healthcare negatively influences quality and availability of medical services, decreases number of provided services, increases their cost, and directly jeopardizes lives of patients. The most recent surveys on presence of corruption in Montenegro are showing that, according to the public perception, healthcare sector is one of the most susceptible by this phenomenon. In accordance with the survey which was conducted in 2011 by UNDOC¹, more than one third of citizens of Montenegro uses bribes in order to accelerate procedure of obtaining medical services. Citizens are giving bribe to healthcare workers, especially doctors - in more than 50% of cases. According to the last survey of Directorate for Anti-Corruption Initiative² healthcare sector was recognized as the most corrupted and it is noted that this perception is growing in the last period. Namely, according to the data from this survey, implemented in February 2012, highest number of citizens 18,6% has recognized healthcare sector as the most corrupted, which was higher in comparison to previous years.

Report „Integrity Assessment of Healthcare System in Montenegro“ from 2011, where all results of the, so far most comprehensive research,³ were

¹ UNODC: *Corruption in Montenegro: Bribery as Experienced by the Population*, 2011, pp. 4, available at: http://www.unodc.org/documents/data-and-analysis/statistics/corruption/Montenegro_corruption_report_web.pdf

² DACI: Public opinion survey: Public perception of corruption and awareness of citizens of results of the work of Directorate for Anticorruption Initiative, February 2012, available at: www.antikorupcija.me/index.php?option=com_phocadownload&view=category&id=11:&Itemid=117

³ This report is based on the research, conducted for needs of Ministry of Health and UNDP, by CEED Consulting (available at: <http://www.undp.org/content/dam/montenegro/docs/publications/DG/Corruption/Integrity%20Assessment%20of%20the%20Health%20Care%20System%20in%20Montenegro%20LOC.pdf>)

presented – also confirmed that informal payments are highly present in healthcare system of Montenegro. Within this survey 55, 7% patients has stated that during their stay in the hospital they have given money/presents to medical staff. Report defines recommendations in order to strengthen integrity in healthcare sector, part of which was incorporated in strategic documents of Ministry of Healthcare.

Finally, document of Ministry of Finance „Corruption Risk Assessment in high risk areas“ from July 2011⁴, also identifies healthcare as one of areas especially susceptible to corruption and recommends measures which should be undertaken for its suppression.

All listed researches, as well as recommendations for improvement of the situation in this area, mainly focus on the problem of so-called informal payments and corruption that occurs in relation healthcare worker-patient.⁵ Scarce attention, however, was paid to other levels of healthcare system, such as public procurement procedures, registration and distribution of medicines and medical devices, which are, according to the relevant international studies, very susceptible to different forms of corruption.

Aim of this study is to offer detailed overview of main forms and causes of corruption in healthcare system, examine effectiveness of existing anti-corruption policies in this area, identify risks for occurrence of corruption in healthcare system of Montenegro and recommend measures for its suppression.

Taking in consideration that the healthcare system is very complex, with many involved actors and many decision making levels, research could not encompass all segments of the system, but it was concentrated on areas which are recognized as susceptible to corruption in international and in regional practice. This policy study, except of the analysis of so-called “petty” corruption in relation healthcare worker-patient, also encompasses detailed analysis of the possibility for occurrence of so-called “grand” corruption, through examination of the relations between pharmaceutical and healthcare sector, as well as the public procurement procedures in Montenegrin healthcare.

This policy study is based on results of the research which combined quantitative and qualitative methods. Out of quantitative methods we used public

⁴ Document available at: https://www.google.me/?gws_rd=cr&ei=j0g8UtTDC5HCswakz4GgCg#q=Procjena+rizika+od+korupcije+u+oblastima+od+posebnog+rizika+Ministrstvo+finansija+CG

⁵ Here we can mention as an exception above mentioned document of Ministry of Finances, which partially processes other segments of healthcare sector, but in a reduced manner, taking in consideration that in this document are being analyzed other areas.

opinion survey, done through Computer Assisted Telephone Interviewing, on corruption in the Montenegrin healthcare system, which was conducted on the representative sample of 1005 interviewees, while for qualitative research methods we used Interviews in 6 focus groups with 60 patients from different regional healthcare centers of Montenegro⁶ and 28 in-depth interviews were held with relevant officials, healthcare workers⁷, providers of medicines, medical devices and equipment. The study is also based on analysis of legal, institutional and political framework, monitoring of the work of institutions, obtained responses on Free Access to the Information Demands, analysis of media reports as well as on analysis of examples of good practice and comparative overview of measures, proposed by relevant international organizations for this area.

The study is divided into four chapters. The first chapter contains the definition of the corruption in the healthcare, its most common forms, causes of its occurrence, as well as the negative consequences which might incur for healthcare sector and entire society. The second chapter is related to main forms of corruption occurring in the relation healthcare worker – patient, with analysis of effectiveness of measures for suppression of corruption in this area and with recommendations for improvement of existing situation. Third chapter explains current situation and results in fight against corruption in area of pharmaceutical- healthcare sector relations and offers measures for suppression of possible corruptive actions. Finally, in the fourth chapter are presented risks for occurrence of corruption in the process of public procurement in Montenegrin healthcare system and proposes measures for overcoming of identified deficiencies.

⁶ Focus groups were held in Podgorica, Niksić, Cetinje, Berane, Pljevlja and Kotor. Each focus group counted 9 interviewees. Interviewees were chosen on the basis of the following criteria:

- All interviewees have the medical insurance;
- Half female, half male interviewees (5/4 or 4/5);
- One/two students, three/four employed persons, two unemployed persons, one/two pensioners;
- all interviewees obtained medical services in the last year (had examination, were hospitalized, operated) by a specialist' in the last year;
- interviewee obtained medical service by different specialist.

Guidelines for conducting of focus groups was created and used.

⁷ 20 interviews with health professionals, was conducted in different regional health centers of Montenegro: in Podgorica, Niksic, Kotor and Berane. In all of these centers interviews were led with one family doctor, one nurse and three doctors of various specialties. Interviews were conducted in accordance with @guidelines for interview with medical workers“.

1 CORRUPTION IN THE HEALTHCARE SYSTEM

1.1 Definition and forms

WHO defines corruption in healthcare sector as „use of power and influence by health practitioners, officials and organizations for self-enrichment“⁸. Furthermore, the same organization observes corruption in healthcare through bribery, theft, bureaucratic or political corruption, and misinformation for private gain.⁹

Corruption in healthcare system is usually more susceptible to moral condemnation, than corruption in other parts of the state administration.¹ Often in public we can find more understanding for a corrupt customs officer or tax inspector, than for doctor or surgeon.

Corruption in healthcare system is usually more susceptible to moral condemnation, than corruption in other parts of the state administration.

There are three key reasons, which can be listed as explanations of this attitude towards the corruption in healthcare sector. First of all, corruption in healthcare sector is primarily understood as corruption in relation health practitioner – patient, i.e. on extortion of the bribery by the doctor. Second of all, it is implied that the patient is in a vulnerable position, due to the overall situation, i.e. the fact that doctor disposes with significantly more information than the patient, which puts him into superior position in relation to the patient¹⁰. Finally, strong moral condemn of the public is provoked also by the fact that quality of provided medical services are personal interest of almost each individual. Anyone, regardless of their profession, socio-economic status, can relate to such situations when they are in need of medical service or medical protection, and consequently every citizen easily relates with cases of corruption in the healthcare sector.

⁸ WHO: „A Framework for Good Governance in the Pharmaceutical Sector“ (working draft for field testing and revision), october 2008, pp. 7, available at: <http://www.who.int/medicines/areas/policy/goodgovernance/GGMframework09.pdf>

⁹ Ibid, pp. 11-12

¹⁰ Due to the complexity of the technical data on diagnosis and treatment procedures, and partially due to the state of the patient, he can't collect and process all the information on his medical condition. Thus, the patient has to rely on the doctor and other medical workers to inform him on his illness and possible treatments. In other words, doctor has the monopolistic position over information, which in unregulated conditions creates the atmosphere favorable for occurrence of corruption.

Corruption in the healthcare is far more complex phenomenon than above mentioned simplified picture. Above all, corruption is not present only in relation healthcare practitioner-patient, but it can affect all levels of decision making in the healthcare sector.² Except providers of medical services, there are also regulators, suppliers and users who are facing complex combination of incentives, which can easily lead to corruption. In accordance with relevant researches in this area¹¹, corruption in the healthcare system can be, above others, manifested as:

Corruption can affect all levels of decision making in the healthcare sector

- Embezzlement of healthcare funds, which might take place at the state or local level, as well as in hospitals and other healthcare institutions.
- Corruption in the process of public procurement, which includes bribery, conflict of interests and trade with influence, which leads to more expensive purchase of goods and services and noncompliance with contracted quality standards.
- Corruption in the payment system, which encompasses liberation of payments, or forging of documents for some patients, abuse of healthcare funds for personal use, illegal payment of insurance in order to increase assets, forging of registries, prescriptions or creation of virtual patients.
- Corruption in the process of medicines and medical devices supplying, where products can be diverted, or stolen in different point of distributional chain, or officials can demand “remuneration” for placement of the medicine on the essential/positive list, services could be demanded in return for prescription of certain medicines and trade with counterfeit medicines is possible.
- Corruption in providing medical services, which encompasses extortion or receiving of informal payments for services which are free, payments for special privileges or medicines, extortion or bribery of commissions for licensing of health practitioners etc.

Taryn Vian, one of prominent experts in this area, has created tabular overview of certain processes in the healthcare sector, which are susceptible to corruption, describing problems which might occur as well as their indicators and results¹².

¹¹ Transparency International: *Global Corruption Report 2006: Corruption and health*, available at: http://issuu.com/transparencyinternational/docs/2006_gcr_health-sector_en

¹² Vian T, *Corruption and the Health Sector* (Sectoral Perspectives on Corruption), Washington: USAID & MSI, november 2002, pp.4-6

Table 1: Types of corruption in health sector (T. Vian)

Area or process	Types of corruption and problems	Indicators or results
Construction and rehabilitation of health facilities	<ul style="list-style-type: none"> ▪ Bribes, kickbacks and political considerations influencing the contracting process ▪ Contractors fail to perform and are not held accountable; 	<ul style="list-style-type: none"> ▪ High cost, low quality facilities and construction work ▪ Location of facilities that does not correspond to need, resulting in inequities in access ▪ Biased distribution of infrastructure favouring urban- and elite-focused services, high technology
Purchase of equipment and supplies, including drugs	<ul style="list-style-type: none"> • Bribes, kickbacks and political considerations influence specifications and winners of bids 	<ul style="list-style-type: none"> • Purchase of equipment and supplies, including drugs
Distribution and use of drugs and supplies in service delivery	<ul style="list-style-type: none"> ▪ Theft (for personal use) or diversion (for private sector resale) of drugs/supplies at storage and distribution points ▪ Sale of drugs or supplies that were supposed to be free 	<ul style="list-style-type: none"> ▪ Lower utilization ▪ Patients do not get proper treatment ▪ Patients must- make informal payments to obtain drugs ▪ Interruption of treatment or incomplete treatment, leading to development of anti-microbial resistance;
Regulation of quality in products, services, facilities and professionals	<ul style="list-style-type: none"> ▪ Bribes to speed process or gain approval for drug registration, drug quality inspection, or certification of good manufacturing practices ▪ Bribes or political considerations influence results of inspections or suppress findings ▪ Biased application of sanitary regulations for restaurants, food production and cosmetics ▪ Biased application of accreditation, certification or licensing procedures and standards 	<ul style="list-style-type: none"> ▪ Sub-therapeutic or fake drugs allowed on market ▪ Marginal suppliers are allowed to continue participating in bids, getting government work ▪ Increased incidence of food poisoning ▪ Spread of infectious and communicable diseases ▪ Poor quality facilities continue to function ▪ Incompetent or fake professionals continue to practice

Education of health professionals	<ul style="list-style-type: none"> ▪ Bribes to gain place in medical school or other pre-service training ▪ Bribes to obtain passing grades ▪ Political influence, nepotism in selection of candidates for training opportunities 	<ul style="list-style-type: none"> ▪ Incompetent professionals practicing medicine or working in health professions ▪ Loss of faith and freedom due to unfair system;
Medical research	<ul style="list-style-type: none"> ▪ Pseudo-trials funded by drug companies that are really for marketing ▪ Misunderstanding of informed consent and other issues of adequate standards in developing countries 	<ul style="list-style-type: none"> ▪ Violation of individual rights ▪ Biases and inequities in research
Provision of services by medical personnel and other health workers	<ul style="list-style-type: none"> ▪ Use of public facilities and equipment to see private patients ▪ Unnecessary referrals to private practice or privately owned ancillary services ▪ Absenteeism ▪ Informal payments required from patients for services ▪ Theft of user fee revenue, other diversion of budget allocations 	<ul style="list-style-type: none"> ▪ Government loses value of investments without adequate compensation ▪ Employees are not available to serve patients, leading to lower volume of services and unmet needs, and higher unit costs for health services actually delivered ▪ Reduced utilization of services by patients who cannot pay ▪ Impoverishment as citizens use income and sell assets to pay for health care ▪ Reduced quality of care from loss of revenue ▪ Loss of public trust

In accordance with these premises, it is obvious that the case of corruption in relation between doctor and the patient is just one, specific case of corruption in healthcare. And this specific type of corruption occurs in many different forms. However, specifics of the area of health protection and its financing are leading to different treatment of corruption. If there is existence of corruptive actions, in accordance with the definition of the corruption, i.e. abuse of public function for personal gain, relevant literature doesn't address it as the corruption, but uses euphemisms, such as: informal payment, unofficial payment, or "payments out of the official rules"¹³. Avoiding using

¹³ Vian T, Ibid, pp.3

the term “corruption” could be an indicator that professionals in the area of healthcare still haven’t accepted that problem of corruption exists, and they don’t want to openly discuss about it.¹⁴

One of the aims of this document is to initiate open discussion on the issue of corruption and strategies for its suppression in the Montenegrin healthcare system. Taking in consideration complexity of the healthcare system, mentioned diversity of types of corruption, levels and manifestations of corruptive actions, it is not possible in a single document to examine all parts of the system and all risk areas susceptible to corruption. Thus we decided to examine areas which are in majority of countries recognized as primarily vulnerable and susceptible to corruption. These are:

- (1) Relations among healthcare practitioners and patients, which is often percept as only source of corruption in healthcare ;
- (2) Relation between healthcare sector and pharmaceutical sector; and
- (3) Area of public procurement in healthcare.³

Areas which are in majority of countries recognized as susceptible to corruption are:

- (1) Relations among healthcare practitioners and patients, which is often percept as only source of corruption in healthcare ;
- (2) Relation between healthcare sector and pharmaceutical sector; and
- (3) Area of public procurement in healthcare.

1.2 Causes and consequences

Corruption in the area of healthcare is present in all states and all healthcare systems, whether they’re private, public, poorly or well financed, technically simple or sophisticated. On degree of corruption in healthcare system of the EU countries we can conclude many things from the following statistical data:

- Annual expenses for healthcare in countries of the EU are amounting to one thousand billion euros;
- Between 3% and 11% GDP is being allocated for the healthcare systems in European states;
- In the EU, according to relevant researches, 56 billion euro is being spent due to fraud and mistake;
- The price that the EU daily pays for corruption in healthcare sector amounts to, at least, 80 million euro.¹⁵

¹⁴ Ibid, pp.3

¹⁵ European Healthcare Fraud & Corruption Network, „Did you know?“, available at:

Almost all relevant studies in this area are pointing out that the healthcare is very susceptible to corruption, underlining numerous indicators, which are supporting this statement. Primarily, there is already mentioned problem of asymmetric information, i.e. that stakeholders in the healthcare sector aren't sharing the same level of information: healthcare workers are better technically informed on diagnosis and treatment procedures than patients, pharmaceutical companies know more about their products than doctors who are prescribing them, medical service providers and insurance companies might have better information on health risks that policyholders are facing, etc. This monopolistic position, which various actors in healthcare system have, can be easily abused. Furthermore, the market of medical services is unsecure and unstable (it is impossible to know in advance who will be sick, what and when will be needed for this person, while for users of medical services it is hard to precisely formulate their demands for economic prices and good quality services, bearing in mind that they can't in advance to determine possible expenses, alternatives and true nature of their needs) Malfunctioning of market laws creates possibility for corruptive actions, while uncertainty inherent to the selection, monitoring, distribution and methods of providing of healthcare protection, makes it hard to detect and locate responsibility for abuses. Likewise, large number of involved actors with diverse interests, as well as significant funds being allocated to healthcare sector, contribute to occurrence of corruption in healthcare.^{16 4}

Large number of involved actors with diverse interests, as well as significant funds being allocated to healthcare sector, contribute to occurrence of corruption in healthcare.

These characteristics of healthcare sector, which make him "vulnerable" to corruption, especially are emphasized in underdeveloped countries of third world, but also in developing countries, which still don't have defined and implemented control mechanisms and measures for identification and suppression of this hazardous phenomenon. Of course, different social systems, and each individual country have special characteristics inside of their healthcare system - which can make it prone to corruption to a lesser or greater extent. In this way, in the countries of Western Balkans (hereinafter: region) could be identified several additional factors which contributed to occurrence of corruption in public healthcare. System of healthcare protection inherited

<http://www.ehfcn.org/fraud-corruption/facts-and-figures/>

¹⁶ Savedoff W.D. & Hussmann K. : „Why are health systems prone to corruption“, in Transparency International: *Global Corruption Report 2006: Corruption and health*, pp. 3-7, available at: http://issuu.com/transparencyinternational/docs/2006_gcr_healthsector_en

from the era of socialism has contained structural deficiencies, reflected in irrational spending of available financial and material resources and dysfunctional providing of services. Excessive employment, low utilization of hospital capacities, discrepancy between offered and demanded medical services and lack of efficient control mechanism for work of the healthcare institutions, has limited possibilities of citizens to exercise their right on healthcare protection

Economic decline during eighties, occurred due to the crisis of administrative economy and continued in nineties as consequence of so-called transitional crisis, has incurred deficit to state budget. Decrease of part of state assets intended for healthcare, has inflicted shortages in equipment, medicines and narrowed the extent of public procurement, while pay cuts have deteriorated life standard of doctors and other medical staff. Patients were forced to, besides additional official payments and treatments, resort also to informal payments, i.e. to bribing doctors. Corruption practice in the area of healthcare was supported by tradition rooted in all countries of the region to give small presents to doctors as the gratitude for treatment. This tradition persisted even after introduction of the system of universal healthcare protection, so today it is hard to draw line between bribery and gift.

Despite undertaken reforms, healthcare system of Montenegro still suffers from inherited deficiencies. There still exists “discrepancy between rights granted by the healthcare insurance and financial possibilities to satisfy them”¹⁷, and we often encounter following statements: „large stakes of private funds and existence of informal payments is pointing to unsatisfactory availability of healthcare services in public system”¹⁸; “structure of healthcare workers is inadequate and it’s not corresponding to expectations and needs of citizens”¹⁹; „underdeveloped system of control and safety of healthcare protection lacks quality control and registered data”²⁰; „very low percentage of hospitalization, low number of hospital beds and low level of utilization of hospital beds in comparison with the EU”²¹, etc. If we add to these statements the fact that healthcare budget of Montenegro amounts to 170 million euros, and that we spend 250 euros per capita annually for medical services (in Slovenia it is

¹⁷ Ministry of Healthcare: „Strategy for Optimization of Secondary and Tertiary level of healthcare protection, with Action Plan for its Implementation“, June 2011, page 7, available at: <http://www.mzdravlja.gov.me/biblioteka/strategije>

¹⁸ Ibid, p. 7

¹⁹ Ibid, p. 7

²⁰ Ibid, p. 7

²¹ Ministry of Healthcare: „Master Plan of Development of Healthcare System for the period 2010-2013.“, Podgorica 2010, page 33, available at: <http://www.mzdravlja.gov.me/biblioteka/strategije>

1000 euro, in Croatia 700 euros)²²⁵, then it is not hard to conclude that quality of healthcare services is not on the high level, as well as that direct payments of patients are the only way to close gap between total expenses and low salaries of healthcare practitioners. If there is no possibility to conduct these payments legally, within the official system, it is clear that the corruption represents the only possibility to close this gap.

Healthcare budget of Montenegro amounts to 170 million euros, and we spend 250 euros per capita annually for medical services (in Slovenia it is 1000 euro, in Croatia 700 euros),

Negative consequences of corruption in healthcare sector are numerous. On macroeconomic plan, corruption hinders economic growth, decreases available funds for investments and improvement of healthcare sector. Corruption also can influence to divergence of funds towards projects which are not necessary or needed (e.g. the most recent innovations in medical equipment), and while disregarding key needs of the system (prevention and healthcare protection). Corruption, furthermore have direct negative influence on availability and quality of the healthcare protection.⁶ Already limited budgetary funds are being additionally decreased through e.g. frauds in public procurement processes, than less finances remains for allocation of salaries, work and sustaining of existing capacities. All this leads to unmotivated personnel, low quality of health care and decreased availability of medical services. Finally, unscrupulous work of individual corrupted healthcare experts, motivated by striving to abuse their professional position for illegal enrichment, undermines public trust in entire system of healthcare protection. Small percentage of citizens of the countries in the region is financially able to afford higher quality service in private medical practice. Corruption in public healthcare system decreases accessibility of the healthcare protection for poor people in the society, which can't pay bribe in order to get necessary service. This creates hidden social inequality, and in longer term it jeopardizes entire health condition of the nation.

Corruption has direct negative influence on availability and quality of the healthcare protection.

Therefore it is necessary to identify weaknesses and risk areas for occurrence of corruption in Montenegro, to establish strong anti/corruption mechanisms and to define and continuously implement adequate measures for prevention of corruption.

²² Radio Free Europe: „Healthcare in Montenegro: From lack of finances to corruption“, 02. 11. 2012, available at: <http://www.slobodnaevropa.org/content/zdravstvo-u-crnoj-gori-od-nedostatka-novca-do-korupcije/24758938.html>

2 RISKS OF CORRUPTION IN THE RELATION HEALTHCARE WORKER –PATIENT

Corruption in relation between healthcare worker-patient, usually occurs when there is deficit in certain medical services, i.e. when medical service can't be obtained through regular channels, or it is accessible but it takes long waiting period to obtain it. Incentives for corruption in this relation are especially emphasized when: (1) medical staff is not paid enough for their work (due to limited budgetary funds); (2) their professional and responsible work is not adequately rewarded; (3) adequate regulations and sanctions are not established, or they are not implemented; (4) efficient monitoring and control are lacking²³. Of course, establishing of this corruptive relation is not equally possible in all segments of public healthcare. Degree of its occurrence depends also on nature of the illness and methods of treatment. Less dangerous conditions will hardly create psychological pressure to the patient, enough to extort bribery. In circumstances when elementary existence of the patient is endangered, behavior of the patient and his family is motivated by a single cause – to eliminate threat for patient's life as soon as possible. In those circumstances, possibilities for corruptive activities are increased.

2.1 Types of corruption in relation healthcare professional – patient

In accordance with relevant researches²⁴, the most frequent forms of corruption in this area are informal payments from patients, which are directly linked with long waiting lists for services and insufficiently developed conscience of citizens on rights they have as patients, as well as illegal use of public healthcare institutions for private practice, abuses of contemporaneous work in public and private clinics and absences during mandatory working hours.⁷

The most frequent forms of corruption in this area are informal payments from patients, which are directly linked with long waiting lists for services and insufficiently developed conscience of citizens on rights they have as patients, as well as illegal use of public healthcare institutions for private practice, abuses of contemporaneous work in public and private clinics and absences during mandatory working hours.

²³ Anti-Corruption Resource Center U4: *Corruption in the Health sector*, 2008, pp. 25, available at: <http://www.u4.no/publications/corruption-in-the-health-sector-2/>

²⁴ Ibid, pp.25

2.1.1 Informal payments

Informal payments are defined as “payments to institutions or individuals in cash or in kind, made out of official channels payment for services, which should nevertheless be covered with primary healthcare insurance by public healthcare system” or shorter, as: „remuneration for (medical) services, which are supposed to be free”.²⁵ Taking in consideration that these informal payments are the most frequently given to individual providers of medical services, informal payments can also be categorized as “abuse of public office for personal gain”, i.e. they could be put in the framework of accepted definition of corruption.²⁶ Exception, in certain sense, might be small gifts of patients which are received as a symbol of attention and gratitude for provided service, even though these presents might be considered as a method to provide a certain degree of protectionism for possible future medical needs of the patient.

Informal payments are providing to patients to obtain longer medical care, or medical service of higher quality, to obtain medicines, or simply to access to certain types of services. Therefore, those who can afford to pay additionally, are providing for themselves accessibility and higher quality of medical care, which undermines equality of citizens in the area of healthcare protection, as well as financial sustainability and functionality of entire healthcare system,^{27,28}.

Informal payments undermine equality of citizens in the area of healthcare protection, as well as financial sustainability and functionality of entire healthcare system.

In accordance with results of conducted CATI survey, as well as results of interviews with focus groups²⁸, informal payments are to a great extent present in Montenegro. Namely, in the framework of CATI survey, key findings of which are published separately²⁹, 44% interviewees has stated that they have “gave gift” to a healthcare practitioner in at least one occasion, even though they were not requested to. Out of those who, in the last year

²⁵ Allien, S., Davaki K. & Mossialos E.: „Informal payments for Health Care“, in Transparency International: *Global Corruption Report 2006: Corruption and health*, pp. 62, available at http://issuu.com/transparencyinternational/docs/2006_gcr_health-sector_en_2006

²⁶ Bardhan P.: “Corruption and Development: A Review of Issues,” *Journal of Economic Literature* 35, no. 3, 1997, pp. 1310–1346.

²⁷ Anti-Corruption Resource Center U4: *Corruption in the Health sector*, 2008, pp. 25, available at: <http://www.u4.no/publications/corruption-in-the-health-sector-2/>

²⁸ Transcripts of focus groups, held in the period: February-March 2012.

²⁹ Available at: <http://www.cemi.org.me>

(2012/13) made an unofficial, additional payment for healthcare service (7.6%)⁹, 53.3% has paid with money and 21.1% gave smaller gifts. One of interviewed patients, from focus groups held in Podgorica, stated that his mother gave 300€ for operation in the Clinical Center of Montenegro, which is covered by primary healthcare insurance.³⁰

In the conducted survey 7.6% interviewees has stated that they have once (5.1%), or several times (2.5%) informally paid to the healthcare practitioner for a service which is covered by the mandatory healthcare insurance

In focus groups, among others we had following statements of the patients:

Interviewee from Kotor: „My neighbor had tumor, and when she went for a regular check-up, she gave 600-700€ to the doctor who operated her. Doctor took the money, although he didn't remember who she was. He did a routine procedure and forgot all about the patient, but still he accepted the money.“³¹

Interviewee from Kotor 2: „My brother was heavily ill and three times he gave money to the doctor, and doctor took it all three times, while knowing that my brother will die. My brother eventually died, but it didn't stop the doctor from taking the money“³².

Interviewee from Cetinje: „I know for the case of a woman who had esthetic operation in the public hospital at the department for general surgery. She had liposuction, which she paid from her own pocket, which was cheaper than to go to the private plastic surgeon. Another woman, who was hospitalized, was dismissed earlier from the hospital immediately upon the operation, in order to hospitalize the woman who paid for this esthetic surgery.“³³

Interviewee from Pljevlja: „My uncle gave 250€ (in Clinical Center of Montenegro), but I am not sure whether he gave it in order to be hospitalized or in order to receive more attention and more effective treatment from the doctor“³⁴.

Interviewee from Podgorica: „I personally paid for medical opinion on the basis of which I could take sick leave from job. Also, I was recently operated and I gave to the doctor a bottle of whiskey and a perfume, as a sign of gratitude, which was really gladly accepted“³⁵.

Interviewee from Berane: „I was hospitalized for 30 days and for me it

³⁰ Transcript of the focus group in Podgorica, held: 05/03/2013

³¹ Transcript of the focus group in Kotor, held: 11/03/2013

³² Transcript of the focus group in Kotor, held: 11/03/2013

³³ Transcript of the focus group in Cetinje, held: 20/03/2013

³⁴ Transcript of the focus group in Pljevlja, held: 25/03/2013

³⁵ Transcript of the focus group in Podgorica, held: 05/03/2013

became normal to give everyday something to the hospital staff. Every day nurses are coming to change sheets, let somebody inside out of the visit hours and series of other reasons. They are not asking for gifts, but they are not rejecting them. I was satisfied I could do that, because it was useful for me.”³⁶

Interviewee from Niksic: „My father was operated two days ago, the doctor didn't ask for anything, but my father insists that we give him something, because he has to go to surgery in half of the year again, with the same doctor”³⁷.

On the other hand, in the interview with healthcare practitioners, one interviewee stated that his cousin was asked to pay 1000 € for admission to the hospital treatment in Clinical Center of Montenegro.³⁸

2.1.2. Waiting for healthcare services and corruption

Long waiting period for a medical service is one of possible causes of informal payments, bribery and corruption in healthcare sector. Due to limited capacities of healthcare system, waiting lists are being created for procedures and interventions, which are not urgent, and implementation of which is slow due to lack of human resources and equipment (e.g. some specialist examinations, surgeries, scanning, etc.).³⁹ If there is a large number of patients interested for such services, i.e. if the waiting lists are long, these procedures might be affected by the corruption, because wealthier patients and patients with influence will strive to accelerate this procedure. The longer waiting period is, the harder pressure on healthcare practitioner becomes. Having in mind that ranking of patients on waiting lists depends on discretionary decision of persons in charge of deciding upon urgency of treatment, it is hard to prove that moving of a patient towards the top of the list is a consequence of corruption. Long queues, i.e. long waiting time in waiting rooms, are also somewhat inducing corruption.

Although certain measures were taken in order to decrease waiting times

³⁶ Transcript of the focus group in Berane, held: 16/03/2013

³⁷ Transcript of the focus group in Niksic, held: 25/02/2013

³⁸ Transcripts of interviews held with healthcare professionals in period April-May 2013.

³⁹ Borowitz M., Moran V. & Siciliani L.: „Waiting times for health care: A conceptual framework“ in Siciliani L., Borowitz M. & Moran V.: *Waiting time Policies in the Health Sector: What Work?*, OECD 2013, pp. 20-21, available at:
http://www.keepeek.com/Digital-Asset-Management/oecd/social-issues-migration-health/waiting-time-policies-in-the-health-sector/waiting-times-for-health-care-a-conceptual-framework_9789264179080-4-en#page1

for medical services in Montenegro, CATI survey has shown that the problem in this area still persists. For example, 7,4% of interviewees has stated that they waited longer than three months to be examined

7,4% of interviewees has stated that they waited longer than three months to be examined by the specialist

by the specialist.⁴⁰ Same m was pointed out by interviewees in focus groups, which mentioned concrete cases of informal payments in order to avoid long waiting for some medical services. For example, one of interviewees on focus groups in Niksic has stated that her cousin gave 500€ in order to get necessary surgery earlier.⁴⁰ We will list several similar experiences mentioned in diverse focus groups:

Interviewee from Pljevlja: „My son-in-law had an accident and he was hospitalized in the Clinical Center in Podgorica, he needed urgent surgery but doctors kept delaying, until he paid and he was immediately operated. He paid 1000 €. “⁴¹

Interviewee from Pljevlja: „I know a woman who needed a surgical intervention and she was placed on the waiting list. She was on 30th place, she paid 300€, and she was promoted to third place on the waiting list. “⁴²

Interviewee from Niksic: „One family from Niksic was requested to pay 200 € for surgery. Surgery was scheduled in a month. Doctor took 200€ and told them to come next morning “⁴³.

2.1.3 Additional work and service providing in the private practice

Contemporaneous work in public and private sector provides opportunity for abuses of official position of the doctor, which reflects in the fact that this position, obtained in the state service is being used for recruiting patients for private practice of the same doctor, or his family and friends. In other words, certain medical service is not being provided in the public sector, although the expenses are at least nominally covered by their insurance, but it is being provided in private sector where it is covered by direct payment of the patient. In such manner patients are paying double for the medical service: once- through contributions for medical insurance, and second time directly in private practice. Additional work in private sector can increase number of absences of healthcare professionals during mandatory working hours, and influence duration of waiting for healthcare services in public sector.⁴⁴

⁴⁰ Transcript of the focus group held in Niksic 25/02/2013

⁴¹ Transcript of the focus group held in Pljevlja, 25/03/2013

⁴² Transkript razgovora sa fokus grupe u Pljevljima, održane 25.03. 2013.god.

⁴³ Transscript of the focus group from Niksic, held: 25/02/2013

⁴⁴ Anti-Corruption Resource Center U4: Corruption in the Health sector, 2008, pp. 26,

In the framework of the mentioned CATI survey, 37% of interviewees in Montenegro have stated that healthcare professionals advised them to go to a private clinic, where they paid for examination, which is free in the public institution.¹¹ Problem of „referral to private practice“ for services covered by medical insurance, was pointed out during interviews in focus groups that we held as well.⁴⁵

37% of interviewees in Montenegro have stated that healthcare professionals advised them to go to a private clinic, where they paid for examination, which is free in the public institution.

2.1.4 Violation of patients' rights

Underdeveloped conscience of citizens on rights they have as patients, as well as poor protection of patients' rights, could also be listed as cause of occurrence and spreading of corruption. Namely, if patients are unaware of their rights, they are not aware when those rights are being violated, and due to complexity and specifics of medical services provision, they are not able to identify individual forms of corruption.

Concerning data, obtained through public opinion survey that CeMI conducted, is that 66,1% interviewees in Montenegro doesn't know to whom he/she would report violation of their patients' rights.¹²

66,1% interviewees in Montenegro doesn't know to whom he/she would report violation of their patients' rights.

Interviewees in groups have also shown that they are not familiarized with their rights.⁴⁶ On the other hand, healthcare professionals claim that patients know their rights and that they reportedly complain without any basis that their rights are being violated. Medical staff also claims that there should be a mechanism which would protect them from unfounded complaints of patients.⁴⁷

2.2 Legal, institutional and political framework

In the aim of suppressing of mentioned irregularities and abuses which are occurring in the doctor-patient relation, legislative framework was changed in the last years, and measures for improvement of institutional and administrative capacities in these areas were defined. Despite these changes, certain

available at: <http://www.u4.no/publications/corruption-in-the-health-sector-2/>

⁴⁵ Transcript of focus groups, held in period: February – March 2013

⁴⁶ Transcript of focus groups, held in period: February – March 2013

⁴⁷ Transcript of focus groups, held in period: February – March 2013.

deficiencies are evident, especially in the implementation, which are leaving the space for corruptive actions.

2.2.1 Legal regulations

In order to improve the quality of healthcare services and healthcare protection in total **Law on Healthcare Protection**⁴⁸ foresees obligation of institutions to, within their regular activities, conduct quality monitoring and evaluation processes.¹³ This system sets two types of evaluation: internal, i.e. process of self-evaluation, conducted by the healthcare institution itself and external quality control done by the external body in cooperation with Ministry of Healthcare. Quality control encompasses, in accordance with Article 112 of the Law on Healthcare Protection, assessment and measuring of following factors: (1) fulfillment of prescribed conditions for work of healthcare institutions; (2) implementation of adopted standards in healthcare; (3) decrease of unwanted, unnecessary and inadequate processes and (4) undertaken measures of education and professional training of healthcare practitioners. Implementation of standards and procedures foreseen by the quality control system, are primarily under jurisdiction of commissions for quality control, which are established in all public healthcare institutions. One of important obligations of established commissions is to plan and conduct anticorruption measures in healthcare institutions.⁴⁹

Mandatory quality control process introduced

In order to address the issue of contemporaneous work of doctors in public institutions and private practices, amendments and supplements of the Law on Healthcare Protection⁵⁰ were adopted, as well as the **Regulation on Additional Work of Healthcare Workers within the Network of Healthcare Institutions**⁵¹. These regulations are limiting simultaneous work in public and private sector and they are defining additional responsibility of healthcare institutions' management in this area¹⁴. Article 74 paragraph 1 of the Law on Healthcare Protection are stipulating that healthcare practitioner employed with full working hours can conduct additional work, only with consent of

Amendments and supplements of the Law on Healthcare Protection were adopted, as well as the Regulation on Additional Work of Healthcare Workers within the Network of Healthcare Institutions.

⁴⁸ „Official Gazette of Montenegro“, No.39/04 and „Official Gazette of Montenegro“, No.14/10

⁴⁹ Article 111a, paragraph 2, Law on Healthcare Protection

⁵⁰ Law on Amendments and Supplements to the Law on Healthcare Protection „Official Gazette of Montenegro“, No.14/10

⁵¹ „Official Gazette of Montenegro“, No.09/11

the director and only in the healthcare institutions within the Network of Healthcare Institutions.⁵² Also, in mentioned Regulations on Additional Work of Healthcare Workers, conditions and criteria under which a director of a healthcare institution can approve additional work to his employee in another institution, were more precisely defined.

The Law on Healthcare Insurance⁵³ stipulates that Health Insurance Fund every year should conclude contracts with both private and public healthcare institutions in order to provide for policyholders services which they can't obtain within the Network of the Healthcare Institutions, or they have to wait long time for these services.¹⁵ In the **Rulebook on Criteria for Conclusion of Contracts on Provision of Medical Services and Methods for Payment for Medical Services**⁵⁴, availability of medical services was set as one of criteria for conclusion of contracts among Health Insurance Fund and medical service providers, i.e. that policyholder shouldn't wait longer than 30 days on services of specialist consultation⁵⁵, diagnostic and specialist medical rehabilitation⁵⁶ and she/he shouldn't wait on hospitalization⁵⁷ longer than 15 days.

Health Insurance Fund every year concludes contracts with both private and public healthcare institutions in order to provide for policyholders services which they can't obtain within the Network of the Healthcare Institutions, or they have to wait long time for these services.

Patients' rights are regulated both by the Law on Healthcare Protection and by the **Law on Rights of the Patients**^{58, 16} Law on Healthcare Protection in Articles 3-6 prescribes available healthcare protection under equal conditions, and bans any kind of discrimination (racial, gender, national, social, religious and ethical) during provision of medical services. The same Law in Articles 18-25 defines rights and obligations of citizens in implementation of their right to healthcare protection. By adoption of the Law on Rights of Patients, rights of the patients were more precisely defined

Patients' rights are regulated both by the Law on Healthcare Protection and by the Law on Rights of the Patients

⁵² In next chapters of the study we will elaborate on the method of establishment and functioning of the Network.

⁵³ „Official Gazette of Montenegro“, No. 39/40, 23/05, 29/05 and Official Gazette of Montenegro“, No. 12/07, 13/07, 73/10, 40/11, 14/12

⁵⁴ “Official Gazette of Montenegro“, No. . 09/11

⁵⁵ Article 8 of the Rulebook

⁵⁶ Article 13 of the Rulebook

⁵⁷ Article 10 of the Rulebook

⁵⁸ “Official Gazette of Montenegro“, No. 40/10 i 40/11

and procedures for their protection were regulated. In accordance with the Article 31 of this Law, patient who was deprived of his right on healthcare protection, or the patient who is not satisfied with provided medical service or conduct of an employee of the healthcare institution, can file a complaint. Complaint is being filed to the Director of the healthcare institution or to the Protector of Patients' Rights in verbal or written form.⁵⁹ Patient, who is not satisfied with decision regarding his complaint, can refer to the healthcare inspection.⁶⁰ Articles 37 and 38 of the Law are foreseeing sanctions for violations of these legal provisions.

2.2.2 Institutions

Ministry of Healthcare and Health Insurance Fund are primarily responsible for establishment of legal provisions in this area and their implementation.

Ministry of Healthcare prepares draft laws and strategic documents in this area, prepares and adopts bylaws (regulations, ordinances), establishes and organizes institutions in the healthcare system and determines conditions regarding facilities, resources and equipment of healthcare institutions; it formulates policies in the area of control over the legality of the work of healthcare institutions, as well as other relevant duties⁶¹.

Healthcare Insurance Fund determines criteria for conclusion of contracts with providers of medical services; concludes contracts and controls implementation of execution of contractual obligations; sets criteria and indicators for pricing of medical services encompassed by obligatory medical insurance; sets prices and methods of payment, conducts control of spending of funds by the medical service providers, etc.⁶²

Besides mentioned institutions, special role in implementation and control of implementation of regulations in this area have directors of healthcare institutions, protectors of patients' rights, commissions for quality control of healthcare protection, healthcare inspection of the Directorate for Inspection, Medical and Pharmaceutical Chamber.

In accordance with the Law on Rights of Patients, **director of the healthcare institution** appoints the Protector of Patients' Rights.⁶³ The same Law, furthermore, sets that the director or the protector of rights of patients, shall

⁵⁹ Article 32, Law on Rights of the Patients

⁶⁰ Article 32 Law on Rights of the Patients

⁶¹ Regulation on the organization and operation of state administration,"Official Gazette of Montenegro", No. 5/12 and 25/12

⁶² Article 88 Law on Health Insurance

⁶³ Article 31 Law on Rights of Patients

determine all circumstances and important facts related to a complaint of a patient and they shall inform the patient on their findings in the within three days of submission of the complaint.⁶⁴ In addition the Director of the healthcare institution will submit quarterly and annual reports on received complaints of patients to the Ministry of Healthcare.⁶⁵ According to the Law on Healthcare Protection, the director of a healthcare institution appoints Commission for the Quality Control of the Healthcare Protection which has at least 5 and the most 7 members⁶⁶, and he/she undertakes responsibility for quality of professional work in the healthcare institution.⁶⁷ Besides mentioned duties, director is also in charge of control of additional work of healthcare practitioners.

Protector of Patients' Rights is in charge of processing of patients' complaints, together with the director of a healthcare institution. In accordance with the Article 31 of the Law on Rights of Patients, protector can be a person with a medical degree, or degree in psychology, sociology or law. The same article of the law stipulates that two, or more, healthcare institutions, which operate in the same geographical area can appoint a common protector of patients' rights.

Law on Healthcare Protection in the Article 111a stipulates that all healthcare institutions established by the state, shall appoint Commission for Control of Healthcare Protection. The Commission is in charge of monitoring and evaluation of quality of healthcare protection. It also proposes to the director of the healthcare institution measures for improvement of the quality of work of the healthcare institution, as well as proposals and opinions in relation to organization of work and conditions for development of healthcare. In addition this body also plans and conducts anticorruption measures and other activities set in the Statute of the healthcare institution.

The Directorate for Inspection, i.e. relevant healthcare inspection is in charge of processing complaints from patients who are not satisfied with primary decision of the director of the healthcare institution or its protector of patients' rights. The same body is in charge of inspection control of implementation of laws and other regulations related to: conditions for functioning of healthcare institutions; quality of work; organization of work; legal changes and changes in status of healthcare institutions; registry keeping and their management; etc.⁶⁸

⁶⁴ Article 32 Law on Rights of Patients

⁶⁵ Article 33 Law on Rights of Patients

⁶⁶ Article 111a Law on Healthcare Protection

⁶⁷ Article 113 Law on Healthcare Protection

⁶⁸ „Report on the work of the inspection for 2012 “, available at: www.gov.me/ResourceManager/FileDownload.aspx?rId=126710&rType=2

Medical Chamber⁶⁹ and Pharmaceutical Chamber⁷⁰ are professional associations also in charge of patients' rights as well as of establishment and implementation of professional standards and ethical principles and codes.⁷¹ These bodies should define criteria for evaluation of professional training and licensing of healthcare practitioners, etc.

2.2.3 Policies, strategies and action plans

National Action Plan and the Healthcare Action Plan for Fight against Corruption⁷² foresee implementation of many activities aimed at suppression of corruption in relation healthcare worker-patient. However, scarce number of these activities was completely implemented, while majority of them remained partially implemented or unimplemented.⁷³ Ministry of Healthcare has adopted in January of 2012 "National Strategy for Improvement of the Healthcare Protection Quality and Safety of Patients with Action Plan 2012-2017"⁷⁴.¹⁷ In this strategic document, the problem of informal payments and possible corruptive practices wasn't addressed, although the prevention of corruption represents one of the important preconditions for quality of healthcare protection.

Ministry of Healthcare has adopted in January of 2012 "National Strategy for Improvement of the Healthcare Protection Quality and Safety of Patients with Action Plan 2012-2017".

2.3 Effectiveness of anticorruption measures

In the following pages we will expose some of deficiencies which we encountered in legal, institutional and political framework, as well as in implementation of adopted regulations and measures aimed at suppression of corruptive action in relations between healthcare practitioner-patient.

⁶⁹ www.ljekarskakomora.co.me

⁷⁰ <http://www.fkcg.org>

⁷¹ Code of Medical Ethics and Deontology was adopted in 2005, while Code of Ethics for Pharmacists was adopted in 2011

⁷² Strategic framework for the fight against corruption and organized crime is composed of the Strategy for the Fight against Corruption and Organized Crime and two consequently adopted action plans for its implementation. (available at: www.antikorupcija.me/index.php?option=com_phocadownload&view=category&id=7:&Itemid=91)

Action Plan for Fight against Corruption in the Healthcare is adopted in 2009 available at: <http://www.mzdravlja.gov.me/biblioteka/dokument?pagerIndex=2>

⁷³ Refer to the Annex: Report on Implementation of the National Action Plan and Action plan for Fight against Corruption In Healthcare Sector

⁷⁴ Document available at: <http://www.mzdravlja.gov.me/biblioteka/strategije>

2.3.1 System of quality control and suppression of corruption

System of quality control in the healthcare, defined by the Law on Healthcare Protection, is not adequately implemented in Montenegro. In regards to implementation of healthcare standards and better processing of complaint, it is important to mention that adequate bylaws are still not adopted, on the first place the rulebook for conducting and of internal and external evaluation,¹⁸ which would define procedures of monitoring, methods of implementation of healthcare standards and obligations of participants in all these processes. As already pointed out, commissions for quality control are established in all public healthcare institutions, but we can conclude on the basis of answers to Free Access to the Information Demands⁷⁵ that their work is inconsistent and that they are not active enough in planning and implementation of anticorruption measures. Reason of this inactivity lies in lack of understanding of the fact that suppression of corruption improves quality of healthcare protection, so these commissions are more dedicated to other activities from their jurisdiction.

Adequate bylaws are still not adopted, on the first place the rulebook for conducting internal and external evaluation.

2.3.2 Equal access to healthcare protection and waiting lists

Equal access to healthcare for all patients is one of main preconditions for adequate implementation of the reform of healthcare system, but also for the suppression of corruption which occurs due to difficult access to certain medical services⁷⁶. National Action Plan for Fight against Corruption and Organized Crime foresees measures for improvement of institutional and

⁷⁵ In Free Access to the Information Demands, sent to all healthcare institutions in the country on 17/06/2013, following data were requested:

Number of quarterly and annual reports submitted by the Commission for the Quality Control of Healthcare, for the period since the establishment of the Commission until June of 2013;

Number and type of planned and conducted anticorruption measures proposed by the Commission for the Quality Control of Healthcare, for the period since the establishment of the Commission until June of 2013;

Number and type of implemented anticorruption measures proposed by the Commission for the Quality Control of Healthcare, for the period since the establishment of the Commission until June of 2013.

⁷⁶ For example: according to reporting of the media, for operation of cataract at the Clinical Center is currently waiting 780 patients. (Daily Vijesti: „ for operation of cataract at the Clinical Center is currently waiting 780 patients“, 18/07/2013, available at: <http://m.vijesti.me/vijesti/na-operaciju-katarakte-klinici-ocne-bolesti-ceka-780-pacijenata-clanak-139470>

administrative capacities in the healthcare sector, through introduction of the IT system and establishment of procedures and daily updating of waiting lists. IT support was introduced into 18 health centers, 7 general hospitals, Health Insurance Fund, Institute for Public Health, PHI Pharmacies of Montenegro „Montefarm“⁷⁷, Ministry of Healthcare and Agency for Medicines and Medical Devices „Calims“⁷⁸. Since the beginning of 2009, electronic prescriptions are in use, along with the electronic referral, electronic remittances for sick leave and fully electronic invoicing for services at the level of primary health care, which means that all work processes in health centers are supported electronically. However, IT system is not introduced in 3 special hospitals, as well as in the biggest healthcare institution in Montenegro – Clinical Center in Podgorica, and this represents a significant weakness in analysis and evaluation of functioning of all subjects inside of the healthcare system and it impedes monitoring of the quality control over work of mentioned healthcare institutions. Also, the measure of regulating procedures for placement on waiting lists is only partially implemented. Waiting lists are created for cardio-surgical procedures, interventional cardiology, radiotherapy, neurology (EMNG), as well as for the hip surgery and ophthalmological surgeries⁷⁹, which are only a part of medical services.¹⁹ Apart from the fact that waiting lists system is not fully implemented, procedure of placement on waiting lists is also not transparent, i.e. criteria on the basis of which are determined urgency and ranking on the relevant waiting lists are not clear. Finally, there is no information which employees have access to created waiting lists.⁸⁰

IT system is not introduced in 3 special hospitals, as well as in the biggest healthcare institution in Montenegro – Clinical Center in Podgorica, and the measure of regulating procedures for placement on waiting lists is only partially implemented.

⁷⁷ Information obtained through Free Access to the Information Demand No.85/13, sent on 15/02/2013 to the Ministry of Healthcare

⁷⁸ Report of the Ministry of Healthcare for the National Commission on implementation of measures from the Action Plan for Fight against Corruption and Organized Crime in the first half of 2013, available at:
http://www.antikorupcija.me/index.php?option=com_phocadownload&view=section&id=2:&Itemid=91_

⁷⁹ Information obtained through Free Access to the Information Demand No.78/13, sent on 15/02/2013 to the Ministry of Healthcare

⁸⁰ Similar remarks regarding waiting lists were exposed in the document of Ministry of Finance: „Corruption Risk Assessment in Vulnerable Areas“, Podgorica, July, 2011 page. 66

2.3.3 Additional work

According to valid regulations, healthcare workers have the right to additional work, with certain limitations: healthcare worker should work full time in the public healthcare institution, he/she should have the consent of the director of the healthcare institution, and additional work should be conducted in the institution within the Network of Healthcare Institutions. Ordinance on precise conditions for conducting of additional work of healthcare practitioners is adopted, but there is no unique registry of additional work, nor the registry of private practice of healthcare practitioners from public sector.²⁰ Lack of these registries leaves possibility of abuse, i.e. for sending patients to private clinics for services covered by the insurance of the patient, as well as for “exchange of patients”, i.e. referral of patients to private practice of a colleague and vice versa. Additional work is characterized by a particular conflict of interests, taking in consideration that the person is employed in public and private sector.⁸¹

There is no unique registry of additional work, nor the registry of private practice of healthcare practitioners from public sector.

2.3.4 Low remunerations of healthcare workers

Due to limited budget for the healthcare, remunerations of healthcare workers in the public sector are low, which can also be an incentive to complement incomes by informal payments by patients. In the interviews we conducted with healthcare workers, low salaries were mentioned as one of the main causes of corruption.⁸² Citizens interviewed through public opinion survey have similar opinion. Namely in the survey every second citizen (50.2%), has stated that low salaries are the principal cause of corruption in healthcare. Action Plan for Fight against Corruption in Healthcare has set measures for “providing financial incentives for workers and associates”.⁸³ Criteria for rewarding of healthcare practitioners are regulated by the collective contract for healthcare. This collective contract stipulates that remunerations of employees in healthcare institutions could be increased on the basis of obtaining of academic title, professional title and mentorship; as well as that these remunerations could be increased only by one of these criteria. Results of work are evaluated by the employer, in accordance with general acts of the institution. Employee, who during a month achieves results, which are higher by scope and quality than average, has the right to increase of the salary by 15% in proportion with the achieved result.

⁸¹ Ibid, page. 66

⁸² Transcripts of interviews held in period April/May 2013 with healthcare practitioners.

⁸³ Action plan for Fight against Corruption in the Healthcare System, page 11

Financial funds for implementation of this right are amounting to 1.85% out of funds intended for salaries of employees in public healthcare institutions. These funds are being allocated in accordance with the criteria settled jointly by employer and representatives of relevant syndicates.⁸⁴

Even though the Action plan for Fight against Corruption in Healthcare has foreseen submission of periodical reports on numbers of rewarded healthcare professionals, ministry of Health doesn't have this information in their possession.⁸⁵ Ministry of Healthcare has informed us that chosen doctors are the most afflicted by limited budget of healthcare and that doctors on secondary and tertiary level of healthcare protection have higher remunerations and additional incomes⁸⁶. On the other hand, healthcare workers claim that they are overloaded with work, that they spend many overtime hours working, that the number of conducted examinations is way too high and that they are not properly rewarded or financially stimulated.

Financial remunerations of healthcare workers are low and there are no data on financial incentives and rewarding

2.3.5 Lack of effective detection and penalization of corruption in the healthcare

16 criminal charges were filed against healthcare practitioners in the period January 2010 – March 2013, to the Department for Suppression of Organized Crime, Corruption, Terrorism and War Crimes, by civil society organizations and citizens, on the basis of the suspicion in corruptive activities. Ten reports were archived as groundless, because prosecutors concluded that there is no reasonable suspicion for corruption, and no charges on the basis of any criminal act could be filed. Five reports were referred to general prosecutors, while one charge was dropped after conducted investigation. In the mentioned period this department has initiated ex officio investigation against seven persons on grounds of bribery in the healthcare. Acting upon these indictments, Higher Court in Podgorica has brought one decision and sentenced the perpetrator to three months in jail, while other six indictments are still in procedure.⁸⁷ The Ministry of Healthcare⁸⁸ has released information

⁸⁴ Information obtained through Free Access to the Information Demand No. 182/13 sent to the Healthcare Insurance Fund, sent on 11/03/2013.

⁸⁵ Information obtained through Free Access to the Information Demand No. 182/13 sent to the Ministry of Healthcare, sent on 11/03/2013

⁸⁶ Meeting in the Ministry of Healthcare, held on 9/10/2013

⁸⁷ Information obtained through Free Access to the Information Demand No. 279/13 sent to the Supreme State Prosecution - Department for Suppression of Organized Crime, Corruption and War Crimes, sent on 27/03/2013.

⁸⁸ Daily Vijesti: "Citizens reported 16 doctors, but they're afraid to support accusa-

for the media that in 2011/12/13 they have received 23 reports of corruption, but the Ministry doesn't have the information if any of the perpetrators were suspended after initiation of the court procedure. In the same press release it is stated that Medical Chamber so far hasn't revoked any medical license.

2.3.6 Implementation and control of implementation of Codes of Ethics

Measures from the National Action plan for the Fight against Corruption, related to organizing of trainings on implementation of provisions of ethic codes, as well as monitoring of compliance with codes of ethics, were not implemented. One Round table with participation of 150 doctors from throughout the country was organized⁸⁹, which is not enough, taking in consideration that the Action Plan has foreseen periodic organization of trainings. Moreover, measure foreseeing implementation of discipline procedures wasn't implemented until the end, was not conducted, taking in consideration that not one discipline procedure was conducted until the end, nor the one sanction was imposed against doctors for violation of the Code of Ethics.⁹⁰ Also, it is important to emphasize that "Code of Ethics and Deontology of Healthcare Workers wasn't available on the website of the Medical Chamber and Ministry of Healthcare, so that this code is not available to citizens and medical service users. This all speaks about very visible weakness in the system, which prevents users of medical services to clearly identify obligations healthcare practitioners and to recognize when their rights are being endangered."²²

There was no trainings on implementation of Codes of Ethic, and no monitoring of the implementation of ethical norms of standards either.

2.3.7 Patients' Rights

The Law on Rights of Patients doesn't adequately define the institutional mechanisms of protection of patients' rights. Although there is similarity in names of the Protector of the Patients' Rights and Protector of Human Rights (Ombudsman), they are not very similar, as Protector of Patients' Rights is only an internal body appointed by the director of the healthcare institution.

tions";05/07/2013., available at: <http://www.vijesti.me/vijesti/gradani-prijavili-16-ljekara-ali-se-plase-da-stanu-iza-optuzbi-clanak-137229>

⁸⁹ Information published on the website of the Medical Chamber: www.ljekarska-komora.co.me

⁹⁰ Pharmaceutical Chamber has, however, since adoption of Ethical Code, processed one case of irregularity in the work of a pharmacist and sanctioned him by written warning.

Therefore, director of the healthcare institution has the discretionary right to appoint the Protector from the circle of already employed medical and administrative staff. In such way, protectors of patients' rights are in the conflict of interests, as they are employed in the healthcare institution where they should protect patients' rights, by processing appeals on the work of the same institution.²³

Protectors of patients' rights are in the conflict of interests, as they are employed in the healthcare institution where they should protect patients' rights, by processing appeals on the work of the same institution

Also, powers of the protector are very narrow. We have pointed out that, in accordance with the Article 32 of the Law, the director or protector should immediately, and not later than three days upon reception of the appeal, determine through investigation all circumstances and relevant facts in relation to the appeal and notify the appellant. This legal deadline is too short for gathering of all the relevant information and serious processing of the appeal, especially if we take into consideration all specifics of the work of healthcare practitioner, such as: work in different ambulances, sick leaves, various absences, replacement of the doctor in another ambulance, etc. In the Law also wasn't stipulated independence of the Protector in decision making. Moreover, taking in consideration that the protector could be replaced at any given time, it means that he is not enough legally protected to confront the director in cases when they don't have the same opinion on the matter of complaint, so the question arises whether the protector could be of actual use to the patient?

Special problem is also lack of bylaws which would more precisely define methods of implementation of the Law on Protection of the Rights of Patients. For example, there is no regulation or ordinance on methods of processing of complaints from patients, which in induces different processing practice in similar cases.²⁴

There is no regulation or ordinance on methods of processing of complaints from patients, which in induces different processing practice in similar cases.

Finally, the problem arises from the fact that appointed protectors are not passing additional trainings upon their appointment. Performing the function of the Protector by persons who are not qualified for this job, is nullifying effects of existence of this body (e.g. if the Protector is lawyer, it means that he can't be in charge in cases of complaints regarding professional mistake).

Certain number of campaigns was conducted in order to inform citizens on their patients' rights, and complaint boxes were placed inside of the healthcare institutions (which also serve for reporting the corruption). However, mentioned results of public opinion survey are showing that this is not enough,

i.e. that citizens are still scarcely familiarized with their patients' rights and mechanisms of their protection.

It is necessary also to stress that, according to the information obtained through Free Access to the Information Demands⁹¹, the number of disciplinary procedures conducted in the public healthcare institutions is negligible.⁹²

Summarizing all these deficiencies, we could extract following basic problems in functioning of the institute of Protector of Patients' Rights:

- fact that protectors are employed in the institution where they control work of other employees might influence their independence and objectivity in their decision making;
- protectors are not independent in their decision making, as the director of the healthcare institution holds discretionary right to discharge them;
- performing of other duties in addition to the duties of the Protector might create conflict of interests, and except that it might endanger the quality of the work of the protector, due to increased scope of duties;
- citizens are still not enough familiarized with their patients' rights, and violations of these rights are not being adequately sanctioned

2.4 International standards and comparative practice

Experts of the Anti-Corruption Resource Center U4, in their relevant studies,⁹³ are encompassing strategies and measures based on examples of good practice, which can be applied in order to suppress informal payments and corruption in the relation healthcare practitioner-patient. We will list here the most important ones:

- Monitoring the performance of health practitioners, associated with higher incomes, can reduce the risk of corruption. This strategy im-

⁹¹ Information for 2010, 2011 and 2012, was obtained through Free Access to the Information Demand, which was referred to all public healthcare institutions in Montenegro on 19/03/2013

⁹² Graphic display of all imposed sanctions in 2010, 2011 and 2012 could be found in the Annex to this study

⁹³ Anti-Corruption Resource Center U4: *Corruption in the Health sector*, 2008, available at: <http://www.u4.no/publications/corruption-in-the-health-sector-2/>, kao i Anti-Corruption Resource Center U4: *Adressing corruption in the health sector*, available at: <http://www.u4.no/publications/addressing-corruption-in-the-health-sector-securing-equitable-access-to-health-care-for-everyone/>

plies that expected results should be precisely defined, as well as the scope of work of health practitioners. Also, transparent and applicable rules and standards of behavior should be set, with clear criteria for implementation of the policy of professional advancement. This strategy also requires effective monitoring instruments, internal and external monitoring, unannounced inspection visits to health facilities, as well as the evaluation of the quality of the services by users and clients. Modern information technology and procedures within healthcare facilities can also increase the efficiency and quality of service delivery, and reduce long waiting and opportunities for bribery. External monitoring could be improved by provision of channels for whistleblowers and legal assistance to citizens who feel they have been unfairly treated or damaged by corrupt activities of health workers.

- Introduction of norms of professional behavior through codes of ethics can reduce corruption and induce healthcare workers to provide better care. Ethical codes can increase internal motivation of healthcare workers to better perform their duties. Besides of the promotion of codes of ethics, promotion of evidence based guidelines of good clinical practice, can also decrease possibilities of abuse.
- In their demand of healthcare services, citizens should be in a position to choose adequate services, based on adequate prices and quality standards, on the basis of reliable information. Therefore, users of health services should be adequately informed about their rights, availability of services, prices and conditions of their use. The public availability of this information hinders possibility of abuse and corruption.
- Involvement of the wider community in the process of decision making and monitoring in the healthcare area, has shown to be very effective in regulation of the healthcare services delivery. Participation of the community can be ensured through constitution of local healthcare committees, where civil society should be represented and participate in decision making at all levels, as well as in the monitoring of implementation of foreseen activities. Efficient appeal procedure should also be ensured, in order to provide effective reporting and processing of reported abuses.
- Patients' rights must be clear and very well known, the procedure of filing appeals and its processing should be simple and precisely defined, regulatory bodies should be strong and reliable, in order for anti-corruption policies to be efficient and effective.

2.5 Proposals for improvement

Although certain changes of legal and institutional framework in Montenegrin healthcare system were introduced and measures for suppression of informal payments, bribery and corruption were defined, there are still evident deficiencies in this area. In order to overcome these deficiencies, we consider that following steps should be undertaken:

- It is very important to improve the system of quality control in healthcare system and provide participation of civic associations and civil society in control of the work of healthcare institutions. It is necessary to commit commissions for quality control and protectors of patients' rights to regularly report on implementation of anti-corruption measures in public healthcare institutions. Introduce mechanisms of regular survey of medical services users on their satisfaction with quality of provided medical services, which represents one of obligatory types of quality control, but also one of main instruments for identification of possible corruption in healthcare sector.
- It is necessary to define national waiting lists and to update them regularly (to create unique database of waiting lists for specialist' examinations and surgeries). Also, it is necessary to decrease workload of those institutions with longest waiting lists, by transferring patients into institutions with shorter waiting lists, when possible. It's important to have clear procedures for setting of waiting lists and to monitor decisions on setting priorities for waiting lists.
- Central registry of additional work within the Network of Healthcare Institutions should be created along with registry of private practice of healthcare workers, in order to establish more effective control and prevention of abuses of simultaneous work in public and private sector.
- Human capacities of deficient medical professions should be enhanced, as well as human capacities of sectors which are overloaded with patients'. Healthcare workers, who on the basis of clearly set criteria are showing special quality in their work and dedication, should be financially rewarded, and registration should be kept on number of these rewards.
- It is necessary to intensify work of state bodies in identification of corruptive activities in healthcare system, and accordingly sanction discovered cases of bribery in this area.
- It is necessary to promote Codes of Ethic of Healthcare workers, and to organize education on their implementation, which is one of main

preconditions for strengthening of integrity of healthcare workers. In that sense, it is necessary that relevant chambers (Medical Chamber and Chamber of Pharmacists) consistently sanction violations of provisions of ethic codes. Code of Ethics for doctors should be made available for medical services users (e.g. by publishing them on the site of the Medical Chamber, Ministry of Healthcare and on sites of Public Healthcare Institutions), in order to provide clear identification of ethical principles of medical profession to citizens. This would also help citizens to recognize cases where their patients' rights are endangered and violated.

- Existing legal provisions which define the institute of the Protector of Patients' Rights, should be amended and defined more precisely, in order to strengthen independence of this institution. The Protector should be independent from healthcare institution where he works. The best concept for his independence would be if the Protector wouldn't be paid by the healthcare institution and if he would be out of the jurisdiction of the Ministry of Healthcare. Protectors of the patients' rights should be organizationally allocated under jurisdiction of the Ombudsman or local self-government, and they should conduct their work in several different institutions. Salary of the Protector should come from the budget of the Health Insurance Fund.
- Bylaws, which would more precisely define procedure of dealing with appeals by patients, should be adopted. These bylaws should, besides methods of processing of appeals, also define manner in which decisions upon appeals are being made, in order to provide unified practice and to establish more efficient sanctioning of serious violations of patients' rights.
- Protectors of patients' rights should attend additional trainings, and acquire necessary qualifications in area of legislative related to patients' rights, in order to adequately and effectively act in cases of breaches of these rights.
- Campaigns for public awareness rising on patients' rights should be intensified, as well as campaigns against corruption. Waiting rooms in hospitals and medical centers should be provided with informative materials, which closer explains phenomenon of corruption in healthcare to patients. It is necessary to inform citizens, in simple language, on all forms of corruption and instruct them how to act in cases them to the private clinic, if he/she prescribes the medicine in inadequate manner, etc. It is necessary to warn patients that offering of a bribe is a criminal act as well. Also common opinion that "you don't go to see a doctor empty handed" should be eradicated.

3 CORRUPTION RISKS IN RELATION HEALTHCARE SECTOR - PHARMACEUTICAL SECTOR

According to statistic WHO and IMS HEALTH, 4.1 trillion dollars are being spent each year on healthcare services⁹⁴, out of which 750 billion dollars are being spent on world pharmaceutical market⁹⁵. On the other hand, researches of *Transparency International* are showing that 10 to 25% of public procurement processes (including procurement of medicines and medical products) are lost due to corruption.⁹⁶ Medicines are going through several diverse instances, before they reach the patient. Numerous procedures in the process of procurement of medicines (production, registration, promotion, distribution, consuming) are providing numerous opportunities for unethical and corruptive actions.²⁵ Albeit in practice there are processed cases of corruption in this area, numerous cases of corruption are remaining unrevealed.

Numerous procedures in the process of procurement of medicines (production, registration, promotion, distribution, consuming) are providing numerous opportunities for unethical and corruptive actions.

3.1 Types of corruption in relation healthcare – pharmaceutical sector

Corruption in the process of procurement of medicines and medical products appears in different forms and it can endanger functioning of the entire healthcare system. Taking in consideration standard methods of regulation of this process, relevant international organizations in their researches⁹⁷ usually

⁹⁴ WHO *Fact Sheet: spending on health: a global overview*, 2007, available at: <http://www.who.int/mediacentre/factsheets/fs319.pdf>

⁹⁵ *IMS Health lowers 2009 global pharmaceutical market forecast to 2.3-3.5 percent growth*, IMS New Releases, available at: <http://www.imshealth.com/portal/site/ims/menuitem.d248e29c86589c9c30e81c033208c22a/?vgnnextoid=1e61fa8adb ec0210VgnVCM100000ed152ca2RCRD>

⁹⁶ Transparency International: *Handbook for curbing corruption in public procurement*, 2006, pp. 13, available at: http://www.transparency.org/whatwedo/pub/handbook_for_curbing_corruption_in_public_procurement

⁹⁷ Transparency International: *Global Corruption Report 2006: Corruption and health*, available at http://issuu.com/transparencyinternational/docs/2006_gcr_health-sector_en, kao i

Anti-Corruption Resource Center U4: *Corruption in the Health sector*, 2008, available at: <http://www.u4.no/publications/corruption-in-the-health-sector-2/>

underline six key processes particularly prone to corruption: (1) production, (2) registration, (3) selection, (4) public procurement (5) distribution (6) promotion of medicines and medical products. Taking in consideration that we are separately analyzing process of public procurement in the next chapter, due to its complexity and significance, in this chapter we will concentrate on the corruption risks in remaining processes.

3.1.1 Production and counterfeit medicines

Production of medicines and medical devices demands adoption, and strict implementation, of good manufacturer's practice principles, which foresee that medicines and medical devices are regularly produced and controlled in accordance with quality standards corresponding to their purpose⁹⁸. This means that manufacturers should satisfy all necessary technical and professional requirements, and follow precisely defined rules and procedures of production (including mode of operating with rough materials, laboratory analysis, mode of storage, packing and labeling), in order to make their products safe and induce foreseen clinical effect on the patient. Lack of precise regulation and control mechanisms in this area can lead to diverse forms of corruption, such as:

- Bribing of bodies authorized to license pharmaceutical manufacturers;
- Bribing officials in charge of inspection and quality control;
- Falsification of the data on medicine substances, its identity and origin;
- Bribery of custom officers and illegal import/export of unverified medicines⁹⁹.

Such forms of corruption are contributing to appearance of substandard and counterfeit medicines¹⁰⁰ which represent serious threat for health of the

⁹⁸ WHO *good manufacturing practice for pharmaceutical products*: main principles, WHO Technical Report Series, NO. 961, 2011, available at: http://www.who.int/medicines/areas/quality_safety/quality_assurance/GMPPharmaceuticalProducts-MainPrinciplesTRS961Annex3.pdf

⁹⁹ Cohen J. C, Mrazek M. & Hawkins L.: *Corruption and Pharmaceuticals: Stenghtening Good Governance to Improve Acess*, February 2007, pp.10.

¹⁰⁰ SZO defines counterfeiting of medicines as „intentional mislabeling of produced medicines, or ingredients used in its production regarding their identity, structure and/or orgin. (...) Counterfeit medicines could contain accurate or incorrect ingredients, they could be without active ingredients, with insufficient active onredients, or have a falsified package“. (WHO media centre: *General information on counterfeit medicines*, available at:

<http://www.who.int/medicines/services/counterfeit/overview/en/>)

Besides counterfeit medicines, there are substandard medicines, which are actu-

people. According to the data of American Center for Medicine in Public Interest, global turnover of counterfeit medicines in 2010 amounted to 75 billion of dollars and it is estimated that this market grows at the rate of 13-15% annually, which shows that this business is very financially lucrative¹⁰¹. WHO researches are showing that to 10% of medicines present on global market, are counterfeit (in developed countries about 1%, in developing countries' around 30%)¹⁰².²⁶ Acknowledging increasingly present practice of sale of medicines through internet, WHO has conducted a research which has shown that in more than 50% cases of internet sold medicines, those medicines were substandard or counterfeit¹⁰³.

WHO researches are showing that to 10% of medicines present on global market, are counterfeit (in developed countries about 1%, in developing countries' around 30%)

3.1.2. Registration or obtaining of the license for placing the medicine on the market

Registration represents important element of the regulatory control of trade with medicines and medical devices. This is a prescribed procedure, in which produced medicine (regardless of its origin and features), has to undergo certain verification procedures by relevant institution/agency, in order to obtain license for sale of medicine, i.e. its placement on the market of medicines. This procedure foresees estimation of quality, safety and efficiency of the medicine, as well as estimation of accuracy of presented data on its ingredients, features, origin and identity. However, pharmaceutical companies

ally original products, but they are not corresponding to published specification of quality, which makes them inefficient. Substandard medicines could appear due to negligence, human error, and inadequate human and financial capacities. Substandard medicines can be treated as counterfeit medicines if a legal manufacturer is included in criminal activities and intentionally and consciently produces these medicines in order to gain profits. Counterfeit medicines represent a part of wider phenomena of substandard medicines. (WHO media centre: *Substandard and counterfeit medicines*, available at:

<http://www.who.int/mediacentre/factsheets/2003/fs275/en/>)

¹⁰¹ Center for Medicine in the Public Interest: *Counterfeit Drugs and Chine NEW*, available at: <http://www.cmpi.org/in-the-news/testimony/counterfeit-drugs-and-china-new>

¹⁰² WHO media centre: *Counterfeit medicines: an update on estimates*, november 2006, available at: <http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf>

¹⁰³ WHO media centre: *Growing treat from counterfeit medicines*, available at: <http://www.who.int/bulletin/volumes/88/4/10-020410/en/>

can bribe or influence authorities, in order to provide certificate of accuracy and executed quality control. In such manner, pharmaceutical companies are providing secure profit, regardless of quality of the product, or market trends. Corruption occurs in different phases of medicine registration, and it can have following forms:

- Bribing of relevant officials to register or accelerate registration of medicines and medical devices without necessary verifications;
- Officials can intentionally slow down registration procedures for medicines and medical devices in order to extort bribery from manufacturers;
- Selection of members of the commission for registration of medicines, based on clientelism, instead of merit based criteria;¹⁰⁴
- Offering lucrative jobs, consultancy engagements, and fellowships to employees and members of commission for registration of medicines, by pharmaceutical companies, in order to ensure favorable decisions by this bodies;¹⁰⁵

3.1.3 Selection or placing the medicine on the essential/positive list

Majority of contemporary healthcare systems and healthcare insurance systems define mechanisms for rationalization of medicine procurement and expenditure for medicaments, by comparing and selecting among different kinds of medicines on the market. This step leads to creation of National list of essential medicines. List of essential medicines represents a published document which contains identified basic medicines used for treatment of key pathological conditions and health problems in a country, and which should be available within the primary healthcare insurance. This is a national drug policy which, if implemented correctly, could help to the Government and other stakeholders to rationalize expenses and provide citizens with essential medicines. On the basis of essential list of medicines, all other lists are being created. Most important of these lists is the list of the medicines which are being financed by state Healthcare Insurance Fund, i.e. basic or positive list. Procurement of medicines from the positive list is a process particularly prone to corruption, due to the fact that contracts, made with public healthcare funds,

¹⁰⁴ WHO media centre „WHO sets up network to combat corruption in medicines procurement“, available at: <http://www.who.int/mediacentre/news/notes/2006/np31/en/>

¹⁰⁵ Anti-Corruption Resource Center U4: *Corruption in the Health sector*, 2008, pp. 16 available at: <http://www.u4.no/publications/corruption-in-the-health-sector-2/>

are very lucrative, and that the amount of purchased medicines is very large.²⁷ Thus, in this process can occur bribery of officials to place a medicine on the positive list, as well as overpayment of medicines produced with significantly lower expenses, false presentation of ingredients, origin and identity of medicines, or selection of unnecessary, low-grade and expensive medicines.¹⁰⁶ For example, 2005 research of USAID on corruption in Bulgarian pharmaceutical system has discovered that national list of medicines contains new, costly medicines, of problematic quality, while older, cheaper and reliable medicines were excluded, as well as the fact that this list contained many alternative versions of the same medicine (e.g. five types of statin, eight brands of ibuprofen etc.)¹⁰⁷.

Procurement of medicines from the positive list is a process particularly prone to corruption, due to the fact that contracts, made with public healthcare funds, are very lucrative, and that the amount of purchased medicines is very large.

3.1.4 Abuses in the chain of distribution

Distribution system in pharmaceutical sector should provide for medicines and medical devices to be allocated, transported, stored and delivered safely, with maximal preservation of their quality. Bad conditions of transport and storage of pharmaceuticals, along with inefficient monitoring and control, could lead to decrease of their quality, as well as to diverse abuses, such as thefts for personal practice, personal use, or further trade on the black market. Certainly, these abuses include series of other illegal and corruptive behaviors, such as bribery of custom and inspection officers, forging of documentation on quantity of received and delivered products, inadequate registries or forging of registries, distribution to inexistent patients or inexistent documentation on distribution, etc.¹⁰⁸

3.1.5 Advertising, promotion and imposing of medicine use

Advertising and promotion of medicines, especially new ones, presents a contribution of pharmaceutical industry to every healthcare system and it is important part of daily, continuous education and informing of healthcare workers, patients and public. However, some pharmaceutical companies are stimulating use of medicines by unethical promotion, nepotism or corruption.

¹⁰⁶ Phil Matsheza, Anga R Timilsina and Aida Arutyunova: *Fighting Corruption in the Health Sector: Methods, Tools and Good Practices*, UNDP 2011.

¹⁰⁷ Meagher P., Azfar O. & Rutherford D.: *Governance in Bulgaria's pharmaceutical system: A synthesis of research findings*, College Park MD: USAID, August 2005.

¹⁰⁸ Cohen J. C., Mrazek M. & Hawkins L.: *Corruption and Pharmaceuticals: Stengthening Good Governance to Improve Acess*, February 2007, pp.10.

Research of international organization for protection of consumers “Consumers International” has shown that pharmaceutical companies are spending twice more money on convincing doctors and pharmacists to prescribe/sell their medicines, than on research of new medicines.²⁸ This research has encompassed is stated largest pharmaceutical companies, such as “GlaxoSmithKline” and “Johnson&Johnson”. In the same study it is stated that 60 billion dollars are spent in the world, annually, on legal promotion of new pharmaceutical products. Of course, it is assumed that this number in the grey zone is several times higher¹⁰⁹.

Research of international organization for protection of consumers “Consumers International” has shown that pharmaceutical companies are spending twice more money on convincing doctors and pharmacists to prescribe/sell their medicines, than on research of new medicines

One of concrete examples of illegal inducement of healthcare workers to prescribe/sell medicines of certain manufacturer is the affair “Hipokrat”, which happened last year in Croatia. Namely, Croatian Bureau for Suppression of Corruption and Organized Crime USKOK has ordered initiation of investigation against 76 persons and one pharmaceutical company on the basis of suspicion for following criminal acts: „receiving and giving bribery, abuse of the authority and position, and incitement to abuse of position and authority“¹¹⁰. According to USKOK investigative documentation, it is being doubted that management and employees of a certain pharmaceutical company have continuously given money, gift shopping cards and flight tickets to doctors and personnel of a certain healthcare institution in exchange for prescribing/ordering of their products.

3.2 Legal, institutional and political framework

Above mentioned steps in the process of medicine policy are governed by numerous regulations in the healthcare system of Montenegro, and their implementation is divided among numerous institutions, bodies and agencies. In accordance with reform activities which are being implemented in Montenegrin healthcare system, this segment of healthcare protection is changed as well, both in legislative and in institutional part. During implementation of mentioned reforms, however, scarce attention has been paid to defining of

¹⁰⁹ Consumers International: *Branding the Cure: A consumer perspective on Corporate Social Responsibility, Drug Promotion and the Pharmaceutical Industry in Europe*, June 2009, pp. 5-7

¹¹⁰ USKOK: OA „HIPOKRAT“, dostupno na: <http://www.dorh.hr/13112012>

effective anti-corruption mechanisms and especially to their effective implementation.

3.2.1 Legal regulation

Basic laws which are governing this area Law on Medicines and Law on medical devices¹¹¹.

Law on Medicines sets, among other, conditions, methods and procedures for licensing manufacture, distribution and import of medicines, prohibits trade with unauthorized medicines or medicines without permission for procurement or import. It also prohibits sale of medicines separate from the pharmacy, trade with counterfeit medicines, medicines which are not labeled in accordance with this Law, expired medicines or medicines which are not aligned with quality standards. Law also defines that legal entity that supplies medicines should comply with Directives of the Good Distribution Practice and that it has to fulfill conditions regarding human resources, equipment and space, prescribed by this Law and bylaws adopted by relevant ministry. Law sets conditions under which licensed traders with medicines can advertise medicines to professional and general public, as well as the conditions under which advertising can be banned¹¹².

On the other hand, the **Law on Medical Products** sets conditions and methods of manufacturing of medical products. This law defines conditions for manufacturer and medical product, which need to be fulfilled in order to be registered. This Law also foresees conditions of conducting of clinical ex-

¹¹¹ "Official Gazette of Montenegro", No.79/04 i "Official Gazette of Montenegro", No.53/09 i 40/11

¹¹² In order to adequately implement this Law, so far, following bylaws were adopted:

- **Rules on detailed conditions on issuing of the trading license for medicines** ("Official Gazette of Montenegro", No.30/09);
- **Rules on detailed content of pharmaceutical testing of medicines** ("Official Gazette of Montenegro", No.38/09);
- **Rules on detailed content of pharmaco-toxicological examination of the medicine** ("Official Gazette of Montenegro", No.68/09);
- **Rules on content and methods of conduct of pharmaceutical examination of the medicine in order to determine its quality** ("Official Gazette of Montenegro", No.04/10);
- **Rules on form, content, period of the reporting on medicine trade and methods of reporting** ("Official Gazette of Montenegro", No.2/13);
- **Directives of Good Practice In Distribution of Medicines Smjernice dobre prakse u distribuciji lijekova**, available at: (<http://www.search.ask.com/web?o=41647997&l=dis&tpr=1&gct=hp&q=smjernice+dobre+distributivne+prakse>)

amination of medical products and devices and it prohibits trade with medical products which don't have valid registration documents or permission for procurement and import. This law also prohibits trade with medical products to legal entities and entrepreneurs, who are not registered for this type of work.²⁹

Law on Medicines and Law on Medical Products are aligned with international standards to the great extent.

Besides mentioned legal solutions, it is necessary to mention provisions of the **Law on Healthcare Insurance**, Article 17¹¹³, which define methods of adoption of lists of medicines and medical products, which are being prescribed and issued at expense of the mandatory healthcare insurance; as well as provisions from Articles 105, 106, 145, 146 of the **Law on Healthcare Protection**¹¹⁴ that are related to organization of work of Medical Chamber and Pharmaceutical Chamber. Taking in consideration the significance of inspection control in this area, following laws should be observed as well: **Law on Inspection Control**¹¹⁵, **Law on Healthcare Inspection**¹¹⁶ and **Law on Sanitary Inspection**¹¹⁷ which are regulating area and methods of work of relevant inspection controls.

3.2.2 Institutions

Control over implementation of regulation in this area, primarily is conducted by: the Government of Montenegro and Ministry of Healthcare, Agency for Medicines and Medical Devices „Calims“, Healthcare Institution Pharmacy of Montenegro „Montefarm“ and Health-Sanitary Inspection.

In accordance with Article 5, item 1 Law on medicines, **the Government** sets criteria for creation of maximum prices of medicines used in human medicine, which are prescribed and issued at expense of the mandatory healthcare insurance. Also, according to the article 17 items 2 and 3 of the Law on Healthcare Insurance, the Government, on the proposal of Ministry of Healthcare, sets list of essential medicines, which contains medicines of special significance for health of policyholders, which are prescribed and issued at expense of the mandatory healthcare insurance, supplementary

¹¹³ “Official Gazette of Montenegro”, No.39/40, 23/05, 29/05 i “Official Gazette of Montenegro”, No.12/07, 13/07, 73/10, 40/11, 14/12

¹¹⁴ “Official Gazette of Montenegro”, No.39/04 i „Sl. list CG“, br.14/10

¹¹⁵ “Official Gazette of Montenegro”, No. , br. 39/03, “Official Gazette of Montenegro”, No.76/09, 57/11

¹¹⁶ “Official Gazette of Montenegro”, No.78/08, 40/11

¹¹⁷ “Official Gazette of Montenegro”, No.14/10

list of medicines, which contains list of medicines which are not on the list of essential medicines and list of medical devices which are built in human body, as well as their standards. The Government is obliged to prescribe the criteria for conclusion of mentioned lists, on proposal of the relevant ministry.

Ministry of Healthcare in accordance with provisions of the Article 6 Law on medicines sets measures for rational usage of medicines; determines detailed conditions for: licensing of medicines, production and trade of medicines for human use, control, monitoring of adverse effects, announcing and labeling of medicines; prescribes content and methods of registry keeping on issued licenses, permissions, certificates and receipts. Ministry also prohibits trade with drugs which are not correspondent to standards of quality, safety and effectiveness of medicines and it proposes criteria for forming of maximum medicine prices. Ministry of Healthcare is, according to provisions from the article 6 of Law on Medical Devices, obliged to: adopt regulation for implementation of this Law; give their consent on the act on forming of commission and expert lists; prescribe content and method of registry keeping of following registries: accredited legal entities for assessment of alignment with standards; registry of manufacturers; registries of legal entities and entrepreneurs who are trading in wholesale; registries of import and export of medical devices; registry of specialized shops, as well as registry of medical devices. Ministry also decides on complaints in second instance procedures.

Agency for Medicines and Medical Devices „Calims“ was established by the decision of the Government of Montenegro in 2008¹¹⁸. Agency started working in January 2009, and during 2008 it was organized as Directorate for Medicines and Medical Devices. In accordance with the Law on Medicines and Law on Medical Devices, this Agency was formed as a national regulatory body, i.e. as expert scientific institution which has numerous competencies in the area of protection of public healthcare. Among other competencies, the Agency is authorized to: issue licenses for placing medicine on the market, issue permits for manufacturing and trade of medicines in wholesale, for use in human medicine; issue certificates on implementation of Directives of Good Manufacturers- Practice, Good Clinical Practice and other certificates in accordance with the Law on medicines; approve clinical examination of medicines in human and veterinary medicine; issue permits for import-export of medicines; collect and process the data on trade and use of medicines; control quality of medicines and issue quality certificates; form maximum prices of medicines used in human medicine, in accordance with criteria set by the Government; enroll, erase and keep registry of manufacturers and legal

¹¹⁸ „Official Gazette of Montenegro“, No.62/08

entities that are conducting wholesale trading, import and export of medical devices, keep registry of medical devices which could be on the Montenegrin market; monitors adverse effects of medicines and medical devices through the system of vigilance, etc.

Management of the Agency is constituted of: Governing board, Supervisory board and Director. Governing and Supervisory board are appointed and dismissed by the Government on the four-year term, on the proposal of the Minister of the Healthcare. Director of the Agency is being appointed and dismissed by Governing board, on the basis of public tender, for a period of five years with a possibility of reelection. Funds for functioning of the Agency are provided from its own incomes and other sources on accordance with the Law. Agency prepares annual report, which is adopted by the Parliament of Montenegro¹¹⁹.

Healthcare Institution Pharmacy of Montenegro „Montefarm“ is founded by the Decision of Parliament of Montenegro in 1991¹²⁰, with the aim to supply citizens and healthcare institutions with medicines and other therapeutic products. “Montefarm” has the status of legal entity and it is independent in legal trade. This institution conducts its activities through 3 sectors: sector of pharmaceutical health protection, consisted of 41 pharmacies in all municipalities of Montenegro; wholesale pharmacy, consisted out of commercial service and storage; and sector for legal, economic and general business. This institution conducts procurement and distribution of medicines and medical materials for all public healthcare institutions, and for citizens, through the chain of its pharmacies¹²¹.

New Decision of the Government on Network of Healthcare Institutions from April 12th, 2013, besides “Montefarm”, **Galenika Crna Gora d.o.o.** is marked as a service provider which ensures access to prescription medicines and medicines, medical devices and materials which can be purchased without prescription. This is a private pharmaceutical company, which encompasses 13 pharmacies¹²². This process of integration of private sector in the public healthcare system is problematic for widely set criteria and disputable method of choice of private companies and institutions which are listed in the Network of Healthcare Institutions, but this will be further elaborated in the chapter dedicated to public procurement processes.

¹¹⁹ „Report on the work of Agency for Medicines and Medical Devices for 2012“, available at: www.skupstina.me

¹²⁰ “Official Gazette of Montenegro”, No.21/91

¹²¹ Information available at www.montefarm.co.me

¹²² Information available at: www.galenikacg.me

Health-sanitary inspection is a special department within the Directorate for Inspection which is relatively new administrative body formed by amendments to the Law on Inspection Control¹²³ and Decision of the Government on organization and methods of operation of state administration¹²⁴. Health-sanitary inspection department has various authorities and competencies. This department is in charge of: inspection control over implementation of laws and other regulations regarding fulfillment of conditions for functioning of healthcare institutions, quality of work, organization of work, organization and legal status change of medical institutions, methods of keeping records and their usage, control over safety and health acceptability of medicines and medical devices, cosmetic products, toys, detergents, tobacco products, materials that are coming into contact with food, poisons; control over production and trading with dangerous substances, transport of dangerous substances, as well as control over safety and health acceptability of food, etc. Total number of employed inspectors in this department is 38: chief inspector, 34 sanitary inspectors and 3 health inspectors (professional dentists)¹²⁵.

Besides mentioned institutions and bodies, important role in implementation of regulation in this area is played by private healthcare institutions as well as Medical and Pharmaceutical Chamber.

3.2.3 Policy, strategies and action plans

Problem of large public expenditures for procurement of medicines and medical devices is underlined in almost all main strategic documents, where Montenegrin healthcare policy is defined. In the „Strategy for optimization of secondary and tertiary level of healthcare protection with the Action plan for implementation“ it is stated that, in Montenegro, 25% of total healthcare budget is being spent on medicines, while in the in countries of the Western Europe, with defined policy and strategy in area of medicines procurement, expenditures in this area are limited to 15% of total healthcare budget^{126, 30}.

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¹²³ “Official Gazzette of Republic of Montenegro”, No.39/03, “Official Gazzette of Montenegro”, No.br.76/09, 57/11

¹²⁴ “Official Gazzette of Montenegro”, No. 7/11

¹²⁵ „Report on work of the Directorate for Inspection for 2012 “, available at: www.gov.me/ResourceManager/FileDownload.aspx?rId=126710&rType=2

¹²⁶ Ministry of Healthcare: „Strategy for optimization of secondary and tertiary level of healthcare protection with the Action plan for implementation“, June 2011, p.10,

These significant costs of medicines, Ministry of Healthcare mainly explains with lack of control of prescribing and issues of medicines, as well as with lack of usage control in stationary healthcare institutions. Not a single state document attributes these irrational expenditures to corruptive practices¹²⁷. In the new “National plan for rational use of medicines in Montenegro for period 2012 -2016 “ activities for improvement of the situation in this area are defined, some of which are: adoption of bylaw which regulates proclamation and advertising of medicines; creation and adoption of Code which regulates relation and cooperation among medical workers and pharmaceutical industry; adoption of Regulation on criteria for placing of the medicine on the positive list; creation and adoption of the bylaw which defines establishment and keeping of registry on conflict of interests of members of the Commission for essential/positive list; amendments and supplements to the Law on Health Insurance in sense of defining of competencies and methodology of work for Commission for placing medicines on the List; etc.¹²⁸. Although some of these activities, with adequate implementation, obviously can have effects in decreasing of corruption, in document they are planned only in the context of decrease of irrational use of medicines. On the other hand, in sector Action Plan for fight against corruption, only two measures, which target relation of pharmaceutical and medical sector, are introduced: (1) forming of teams of pharmacists and doctors in healthcare institutions, which would conduct rational pharmacotherapy and (2) pharmaco-economic monitoring and research of therapy programs. These measures can be a part of the plan for the fight against corruption if they are primarily conducted with an aim to identify and curb cases of exaggerate and therapeutically undue prescription of medicines of certain manufacturer. In mentioned Action Plan - however, they are defined as a measure for achievement of the aim “provision of financial incentives for continuous improvement of quality of healthcare protection and safety of patients”¹²⁹.

available at: <http://www.mzdravlja.gov.me/biblioteka/strategije>

¹²⁷ Ministry of healthcare: „ Strategy of Development of Healthcare system of Montenegro until 2020 “, September 2003, p.20, and “National plan for rational use of medicines in Montenegro for period 2012 -2016 “, 2012, p.4, available at: <http://www.mzdravlja.gov.me/biblioteka/strategije>

¹²⁸ Ministry of Healthcare: „National plan for rational use of medicines in Montenegro 2012 -2016 “, 2012, p.38-39, available at: <http://www.mzdravlja.gov.me/biblioteka/strategije>

¹²⁹ Ministry of Healthcare: „ Action Plan for Fight against corruption in the healthcare sector “, September 2009, p.11, available at: <http://www.mzdravlja.gov.me/biblioteka/dokument?pagerIndex=2>

3.3 Effectiveness of anticorruption measures

Through the analysis of the legal, institutional and political framework, monitoring of the work of institutions, demands for the free access to information, interviews with healthcare workers and relevant functionaries, we have identified some of deficiencies of the healthcare system, which are leaving the space for occurrence of corruption. Deficiencies are found in following areas: control of production and trade of medicines and medical devices, establishing of essential and positive list of medicines and relations among healthcare workers and pharmaceutical companies.

3.3.1 Control of production and trade of medicines and medical devices

Despite the fact that the legal framework in the area of medicines and medical devices is partially aligned with the EU and international standards and regulations, numerous bylaws which would decrease possibilities of arbitrary decision making and corruption, are missing. Thus, e.g. regulations which would define conditions for obtaining licenses for production, export and import of medicines, clinical tests, in more detail, are missing: regulations on classification and registration, Guidelines of Good Manufacturers Practice, Guidelines of Good Clinical Practice, good pharmaceutical practice, etc.¹³⁰.

Agency for medicines and medical devices „Calims“ has, in accordance with Atciles 12 and 13 of the Law on medicines, formed Commission for Placing the Medicine on the Market, and it has established the list of experts who are giving professional advices on quality, safety and effectiveness of the medicine, in process of its registration (licensing). This Commission, as well as the list of experts is approved by the Ministry of Healthcare, or Ministry of Agriculture, in cases of registration of veterinary medicines.³¹ Through the interview with Director of “Calims” Mr. Milorad Drljević¹³¹, we were informed that the Agency has introduced written procedure of evaluation of external consultants who are chosen on the basis of professional and scientific references, as well as

Agency for Medicines and Medical Devices “Calims” generally follows procedures and standards set by the European Agency for Medicines and Medical Devices

¹³⁰ Agency for medicines and Medical Devices „Calims“ has, according to the information available on their website (www.calims.co.me), created drafts of some bylaws in this area, but they are still not adopted.

¹³¹ Transcript of the interview with the Directors of the Agency for medicines and Medical Devices, Mr. Milorad Drljevićem, held on June 19th, 2013

compulsory signing of the Statement on conflict of interests for all entities included in the process of licensing of the medicine. However, in the Statement on conflict of Interests, no sanctions are implied for concealing of existing conflict of interest. “Calims” has already implemented one of the recommendations of CeMI, i.e. to publish names of the members of Commissions in question, relevant officials who are licensing the medicine, or producers and legal entities who are manufacturing and trading with medicines in Montenegro, on the website of the Agency, in order to verify allegations from signed statements on conflict of interests, and identify eventual interest connection between persons responsible for licensing of a medicine and pharmaceutical company which produces the medicine.³²

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Procedure of registration of medicines was initiated by “Calims” in 2009 (for medical devices in 2010)¹³², and in the last 4 years this agency has reviewed large number of applications of manufacturers for authorization of sale of a medicine (in 2009 - 379 applications, in 2010 - 929 applications, in 2011 - 581 applications, u 2012 - 335 applications)¹³³. Taking in consideration changes of regulations in this area, and its alignment with European standards, manufacturers which merchandized their medicines in Montenegro, before adoption of new regulation, were obliged to initiate registration procedure in order to maintain their products on the market¹³⁴. Large number of those manufacturers has, however, submitted incomplete documentation, which could be seen from 379 demands for supplementing documentation issued by the Agency in 2012¹³⁵. This data implicates that the market of medicines is still not adequately regulated, i.e. that this market still contains products

¹³² Enrollment in the registry of medical devices has started in 2010, in accordance with amendments and supplements of the Law on medical devices which was the first step in alignment of regulations in the field of medical devices with Directives 90/385/EEC, 93/42/EEC, 98/79/EEC i 2007/47 of the European Commission.

¹³³ Reports on work of CALIMS for 2009, 2010, 2011, 2012, available at: www.skupstina.me

¹³⁴ Report on work of CALIMS for 2012, available at: www.skupstina.me

¹³⁵ Ibid

which haven't passed entire necessary procedure of quality check, verification of safety and effectiveness¹³⁶ and which could be substandard.

Limited capacities of sanitary and especially health inspection are bringing in question efficiency of the inspection control in this area. Namely, three health inspectors, besides their other numerous jurisdictions, are in charge of revealing of errors in production, quality and distribution of medicines and medical devices. They are also in charge of processing of illegal activities such as reselling of medicines or trade with substandard and counterfeit medicines.¹³⁷ Taking in consideration the fact that currently engaged health inspectors are dentists¹³⁸, issue of their competence in disclosing of irregularities in sphere of medicines and medical devices arises, as this area demands excellent knowledge of pharmacology.³³ In the response to our Free Access to the Information Demand, this inspection stated that there were no discovered cases of counterfeit medicines in the period 2010-2012,¹³⁹ despite of mentioned global trend of growing market of these medicines.

Limited capacities of sanitary and especially health inspection are bringing in question efficiency of the inspection control in this area.

3.3.2 Establishment of basic or essential list of medicines

We have already stated that the Government, on the basis of provisions contained in the Article 17 of the Law on Healthcare Insurance, upon the proposal of Ministry of Healthcare, defines criteria for establishment and establishes basic list of medicines which are prescribed and issued at expense of the mandatory healthcare insurance, additional list of medicines which contains medicines which are not on the basic list¹⁴⁰ and the list of medical devices. These provisions are part of amendments and supplements to the Law on Healthcare Insurance, adopted in the February of 2012.¹⁴¹ The Government

¹³⁶ The process of evaluating the submitted documentation includes the analysis of quality data: pharmaceutical-chemical and biological documentation, safety: pre-clinical documentation and efficiency: clinical documentation.

(CALIMS: „Brošura“, page 8, available at: www.calims.me)

¹³⁷ „Report on the work of the inspection for 2012“ pages 90-91, available at: www.gov.me/ResourceManager/FileDownload.aspx?rId=126710&rType=2

¹³⁸ Ibid, page.90

¹³⁹ Free Access to the Information Demand, No. 520/13, issued 20/06/2013.

¹⁴⁰ Additional list of medicines or B list is Dopunska lista lijekova ili B list is being established on the basis of consiliar proposals of competent clinics and special hospitals (Ministry of Health, “National Plan for the rational use of drugs in Montenegro for the period 2012 -2016., p.10, available at: <http://www.mzdravlja.gov.me/biblioteka/strategije>)

¹⁴¹ „Official Gazzette of Montenegro“, No. 14/12

however still hasn't adopted mentioned criteria, nor has it established mentioned list.¹⁴² Instead, Ordinance on establishment of list of medicines prescribed and issued at expense of the Health Insurance Fund, adopted in January of 2012, is still in force.^{143,144}

Procedure of placement to the essential or basic list of medicines is not fully defined.

Common practice so far in this area was to commit Commission for List of Medicines to determine contents of the List of Medicines Issued on Prescription or Positive List. This Commission was composed out of pharmacologists, doctors, economists and pharmacists, appointed by the governing Board of the Healthcare Insurance Fund. There was no prescribed procedure for methods of appointment of members of the Commission, nor there were written criteria for placement of the medicine on the Positive List. Also, the members of the Commission weren't obliged to sign the statement on the Conflict of Interests.¹⁴⁴

3.3.3 Relation between healthcare practitioners and pharmaceutical companies

By provisions of the Article 131 of the Law on Medications – to manufacturers of medicines, their representatives and legal entities trading with medicines is forbidden to offer financial, material, or any other benefit to persons who prescribe or dispense medicines, or their families (sanctions for this offense are between 10000 and 20000 €). However, the same article of the Law prescribes that manufacturers of medicines, their representatives and legal entities trading with medicines could be sponsors of scientific and promotional assemblies with participation of professionals. Sponsoring could be done through reimbursement of travel expenses, covering of meals and mandatory fee on scientific assemblies.³⁵

Manners of interaction among healthcare professionals and pharmaceutical companies is not adequately regulated.

Through interviews with healthcare practitioners we were notified that they are obliged to attend specialized courses as a prerequisite for extension of their working license, but that there are also privileged healthcare work-

¹⁴² Only "Regulation on the scope of rights and standards of health care, originated from the compulsory health insurance in the secondary and tertiary levels of health care" („Official Gazzette of Montenegro", No. 5/13) was adopted

¹⁴³ „Official Gazzette of Montenegro", No. 4/12

¹⁴⁴ Ministry of Health, "National Plan for the rational use of drugs in Montenegro for the period 2012 -2016.", p.10, available at: <http://www.mzdravlja.gov.me/biblioteka/strategije>

ers (usually those deciding or participating in decision making in healthcare institutions) who have various consultancies with pharmaceutical companies, and they are participating on international congresses at the expense of these companies. Through interviews we were also notified that representatives of pharmaceutical companies often advertise their products in healthcare institutions during working hours and that they are directly or indirectly trying to promote their medicines, in order to achieve higher market turnover¹⁴⁵.

3.4 International standards and comparative practice

Numerous relevant international organizations are dealing with corruption risk assessment in the relation between pharmaceutical and healthcare sector and a series of international standards and guidelines were adopted which should be followed in order to suppress corruption in this area. WHO has developed assessment tools for measuring of transparency in pharmaceutical sector, in the frames of which are set benchmarks and indicators which should be completely fulfilled in each level of medical services, in order to be proclaimed as transparent and the least liable to corruption. In each phase, including manufacturing, trading, distribution and dispensing of medicines, WHO demands strictly defined regulations, public accessibility of all relevant information and effective sanctioning of illegal and corruptive actions.¹⁴⁶

Following WHO, experts of the Anti-Corruption Resource Center U4 are suggesting acceptance of following general principles for prevention of corruption in the supply chain of medicines and medical devices:

- harmonization of regulations governing the national pharmaceutical market, with the regulations governing the international markets;
- national authorities shall promote transparency in the regulation of drugs, legally regulate and sanction aggressive promotion of drugs, introduce strict limitations to excessive prescribing of drugs and ensure effective monitoring of the relationship between healthcare institutions and the pharmaceutical industry;
- drug registration and selection of essential drugs / positive list should be based on transparent criteria in order to avoid conflict of interest, abuse and various kinds of impact on the decision-making process;

¹⁴⁵ Transcripts of interviews with healthcare workers, held in the period April-May 2012

¹⁴⁶ WHO: *Measuring Transparency in the public pharmaceutical sector*, March 2009, available at: www.who.int/entity/medicines/areas/policy/goodgovernance/AssessmentInstrumentMeasTranspENG.PDF

- regulatory policies, procedures and decision-making criteria should be published and made easily accessible to the public¹⁴⁷.

Standing Committee of European Doctors (CPME), from its side has adopted principles with the aim of more transparent regulation of relations between medical profession and pharmaceutical industry¹⁴⁸. They demand from the industry to: provide accurate and new information on their products, which precisely describe their advantages and disadvantages on the basis of contemporary scientific evidences; to provide clinically relevant scientific data on their product; to monitor scientific and clinical reports in relation with their products upon their placement on the market; to restrain of advertising of medicines before their licensing; to refrain from offering unjustified hospitality and expensive gifts to healthcare practitioners. On the other hand, CPME demands also health practitioners to refrain from demanding of gifts from representatives of pharmaceutical companies, not to accept unjustified hospitality and expensive gifts, and to always regularly report on adverse effects of the drug.

In order to prevent of corruptive relation between pharmaceutical industry and healthcare practitioners, different countries are introducing different provisions. For example, the Sweden has forbidden any contacts among pharmaceutical companies and doctors who re prescribing medicines¹⁴⁹. In Serbia, through contract between healthcare institutions and Fund for Healthcare Insurance, it is regulated that familiarizing of doctors with new medicines can't be done in working hours.¹⁵⁰

3.5. Recommendations for improvement

On the basis of the previous analysis we can conclude that, in order to decrease possibility of corruption in relation between pharmaceutical and healthcare sector in Montenegro, we need to implement following measures:

¹⁴⁷ Anti-Corruption Resource Center U4: *Approaches to corruption in drug management*, December 2009, available at: www.u4.no/publications/approaches-to-corruption-in-drug-management/

¹⁴⁸ CPME: *Declaration on the Cooperation between the Medical Profession and the Pharmaceutical Industry*, June 2005, available at: http://www.cpme.eu/cpme_-_efpia_joint_declaration_on_the_cooperation_between_the_medical_profession_and_the_pharmaceutical_industry/

¹⁴⁹ Cohen J. C, Mrazek M.& Hawkins L.: *Corruption and Pharmaceuticals: Stenghtening Good Governance to Improve Acess*, February 2007, pp.8.

¹⁵⁰ HIF Serbia: „Pravilnik o uslovima, kriterijumima i merilima za zaključivanje ugovora sa davaocima zdravstvenih usluga“, available at: http://www.rfzo.rs/download/pravilnici/ugovaranje/Pravilnik_ugovaranje_izmene_27052013.pdf

- It is necessary to adopt all missing bylaws for the Law on Medicines and the Law on Medical Devices, which would determine conditions which would clearly set conditions for licensing of production, clinical examinations, export and import of medicines, regulations on methods of classification and enrollment into registries of medical devices, guidelines of good production practice, good clinical practice, good pharmaceutical practice, in order to decrease possibility of arbitrary decision making and corruption in this important area;
- It is essential to provide that all medicines, which were in Montenegrin market before the latest change of regulations, possess adequate license by the Agency for Medicines, i.e. those medicines need to pass entire prescribed procedure of evaluation of their quality, efficiency and security;
- Capacities of healthcare inspection should be significantly strengthened, and a department for pharmaceutical inspection should be established, which would conduct controls only in area of medicines and medical devices;
- The Government and Ministry of Healthcare should adopt regulation which would precisely define criteria for placement of medicines on the Positive List. It is important to establish Commission for Positive List, members of which would be appointed on the basis of clearly determined procedure. Members of the Commission should officially report on existence of any kind of conflict of interests, and these cases should be filed into a database, which would be publicly accessible. Reported conflicts of interests should encompass paid consultancies for pharmaceutical companies, payment or sponsoring of clinical examinations or research of medicines, as well as sponsorships for participation in conferences and educational assemblies;
- Regulation on relation of healthcare professionals and pharmaceutical companies should be adopted. It is necessary to limit the number of scientific and promotional assemblies, which could be attended by an individual health worker, who would be sponsored by a pharmaceutical company. Also, promotion and advertising of pharmaceutical products to doctors, by representatives of pharmaceutical companies, should be banned during working hours. All this measures would decrease possibility of illegal incentives for healthcare professionals, given in order to prescribe medicines of certain producer.
- Additionally amend existing mode of licensing of issuing different medical diplomas by pharmaceutical companies, which additionally stimulate doctors to participate on conferences and lectures, paid by

those companies. Additional education should be provided by regular lectures organized by Medical Chamber, Institute for Public Health, Health Insurance Fund . On this kind of conferences would be presented most significant information (newest medicines, orthopedic devices, protocols), and in such manner health professionals could obtain points necessary for working license. In such manner, participation on conferences organized by pharmaceutical companies would be facultative, without obtaining of points, which are mandatory condition for getting and extending of the working license. Doctors who have referent works for presentation on international congresses, should be paid by their institution, relevant ministry, or Healthcare Insurance Fund

4 CORRUPTION RISKS IN THE AREA OF PUBLIC PROCUREMENT IN THE HEALTH CARE SECTOR

The system of public procurement in the health care sector is subject to corruption because it represents a very complex process with a twist of a significant funds through the series of stages where interests of pharmaceutical companies, manufacturers of disposable medical supplies, international humanitarian organizations, competent officials, officials of health institutions in charge of implementing procurement and health professionals (doctors, pharmacists and paramedical staff) are overlapping.

Within the public procurement procedures in the healthcare, there is a wide variety of economic entities. First of all, there are economic entities specialized in the production and sale of medicines, medical supplies, medical equipment, as well as specific non-medical equipment (e.g., hospital beds). In addition to these, all other economic entities that produce or sell all other services and goods are encountered, from contractors to manufacturers of food and hygiene products. Their motive is simple - to maximize the profit that is achieved if the contract is signed. This is achieved by eliminating competition in the public procurement and by violating other basic principles of public procurement.

Corrupt activities in the public procurement in general, and in public procurement in the health care sector, lead not only to losing taxpayers' money, but also to the fact that procurement of the goods, services and works with its quality, characteristics and delivery does not correspond to actual needs of clients. Poor implementation of public procurement further increases the negative effects of corruption in public procurement, because there is a possibility to deliver only part of the contracted or that delivery is not executed. Effects of corrupt activities are ultimately borne by citizens, because contracting authority for public procurement are institutions mostly funded by their money, for which they receive a low or questionable quality.

The health care sector has certain characteristics that made it even more vulnerable to corruption. These are in addition to the complexity of the procurement system

The health care sector has a certain characteristics that made it even more vulnerable to corruption. These are in addition to the complexity of the procurement system (especially medicines), with a many actors involved: (1) aggressive marketing campaigns of pharmaceutical companies that will eventually increase demand for products, (2) information asymmetry, which means that only a small circle of experts knows the true value of pharmaceutical innovation and (3) emergency situations that require a quick decisions about procurement.

(especially medicines), with many actors involved: (1) aggressive marketing campaigns of pharmaceutical companies that will eventually increase demand for products, (2) information asymmetry, which means that only small circle of experts knows the true value of pharmaceutical innovation and (3) emergency situations that require a quick decisions about procurement.³⁶

4.1. The greatest risks for corrupt activities in different stages of public procurement

The process of public procurement consists of many phases, which we can divide into:

1. Planning of public procurement;
2. Preparation of tender documents (with conditions for participation in the process of selective criteria) and public announcement;
3. Submission and evaluation of bids;
4. Contracting and implementation of the contract.

The risks of corruption are the greatest in the second and third phases - preparation of tender documents and evaluation of bids.³⁷

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4.1.1 Planning of public procurement

According to Article 38 of the Law on Public Procurement¹⁵¹, until January 31 of the current fiscal or financial year, the ordering party is required to prepare the procurement plan and to submit it to the competent authority for the publication on the Public Procurement Portal. Under the provisions of this Law and Regulations on the forms of public procurement procedures¹⁵², the public procurement plan includes the following:

- The subject of public procurement;
- The name, and description of the subject of public procurement;
- The estimated value of the public procurement;
- Type of the procedure of public procurement;
- Approximate time of the proceedings;
- Account and budget position;

¹⁵¹ "Official Gazette of Montenegro", no 42/2011

¹⁵² "Official Gazette of Montenegro", no 62/2011

- The amount of the account or the budget position and
- Funding sources.

The publication of public procurement plan provide transparency and inform potential bidders on the customers' needs for procurement of goods, works and services for the current fiscal year.

In the planning phase, ordering party must specify the goods, works or services that meet their needs, as well as how much funding is needed to meet these needs. In both cases, there are opportunities for corruption.³⁸

Preparation of public procurement, determining the needs of contracting authorities and preparation of tender documents, in particular technical features or specifications, are equally exposed to corruption, because the certain corruptive acts that will appear later in the procurement process can be planned even at this stage.

Preparation of public procurement, determining the needs of contracting authorities and preparation of tender documents, in particular, technical features or specifications, are equally exposed to corruption, because the certain corruptive acts that will appear later in the procurement process can be planned even at this stage.

Potential risks for corruption in the phase of planning of public procurement appear in cases of inadequately prepared plan of public procurement – without in advance prepared analysis based on the research of the market conditions, wrong and unnecessary investment which has no value for society, failure to adopt and non-disclosure of public procurement plan, the overpriced required amount of goods and contracting of unnecessary amounts¹⁵³. The funds allocated to certain public procurement can be planned in artificially high amount in order to alienate or redirect the excess funds.

In determination of the needs of contracting authority, current or future needs may be falsely justified, falsely increasing the actual needs, in order to create a surplus that can be used for corrupt purposes. Thus, for example, according to the media in the region, the Ministry of Health of Serbia bought radiological devices to the certain health care institutions that did not have radiologist or adequate room for radiology device, so the same remained unpacked for months. The same article states that the equipment was procured by double prices¹⁵⁴.

¹⁵³ Institute Alternative: Corruption and public procurement in Montenegro, June 2012, p 18, available at:

¹⁵⁴ Daily Blic: „Good news: Millions for new x-ray machines! Bad news: Nobody uses it”, June 16, 2013, available at: <http://www.blic.rs/Vesti/Drustvo/388220/Dobra-vest-Milioni-za-nove-rendgene-Losa-vest-Niko-ih-ne-koristi>

The need for public procurement can be formulated in a way to put a provider in a privileged position, or vice versa, and the most in the cases of selection of public procurement.

Last but not least, the appearance of corruption may be affected by the selection of the type of the procedure of public procurement, especially when these procedures are less transparent, such as the negotiated procedure without prior publication of a call for tender, the restricted procedure as well as through the conclusion of the contract based on the outline agreement.

4.1.2 Preparation of the tender documentation and public announcement with eligibility criteria for participation in the public procurement procedure and criteria for tender awarding

In the phase of preparation of tender documentation and publishing of the call for tender, eligibility criteria for participation in tender can be especially sensitive to corruption, along with definition of criteria for awarding the tender, and defining of technical characteristics and specifications of subject of public procurement. Corruption mainly occurs in the form of discriminating treatment of potential bidders.

Obligatory conditions for participation in the process of public procurement, according to the Law on Public Procurement, are committing a bidder:

1. to be registered for providing of services or goods which are demanded by the announced public procurement tender;
2. to have a license for performing the activity which is demanded by the public tender, in accordance with the Law;
3. to fulfill all his tax and administrative duties in accordance with the Law, or in accordance with regulations of the state where the company is registered;
4. not to be convicted for any criminal act in the period of two years before publication of the tender and not to be banned from performing of the activity in relation to the criminal act.

Contracting authority can demand facultative conditions in the tender or tender documentation, from the bidder. Those facultative conditions can be related to:

1. economic-financial eligibility and/or
2. professional, technical and human capacities.

By setting of the eligibility criteria, contracting authority can provide preferential treatment for the desired bidder, by setting of conditions which are favorable for this bidder.³⁹

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Criteria for awarding the tender in public procurement are:

1. lowest offered price or
2. economically most favorable offer.

Choice of criteria is made by the contracting authority, depending on the type of the procedure and procured item. Criteria and sub criteria for awarding the tender are influencing intensity of competition in the public procurement procedures. Decision on criteria is relevant not only for the procedure, but also for maintaining a group of potential credible bidders, with continuous interest to participate in future tenders.¹⁵⁵ Criteria and sub criteria for awarding of the tender can be formulated in a way to provide preferential treatment for one bidder, or to point out deficiencies of other bidders.¹⁵⁶

Conditions and demands regarding quality, performances, safety and dimensions of goods and services are being determined by technical characteristics or specifications, in order to provide quality, terminology, labeling testing and packing.¹⁵⁷

Technical characteristics or specifications are, in accordance with the public procurement's item, obligatory part of the tender documentation.

Contracting authority determines technical characteristics or specifications¹⁵⁸:

- 1) in accordance with technical regulations;
- 2) referring to standards, which are in use in Montenegro, and which are

¹⁵⁵ Commission for Protection of the Competition of Serbia Komisija: Guidelines for detection of the fraudulent offers in the public procurement processes, June 2011, page 9, available at: <http://www.kzk.org.rs/kzk/wp-content/uploads/2011/08/Uputstvo-za-otkrivanje-nameštenih-ponuda-u-postupku-javnih-nabavki.pdf>

¹⁵⁶ For example, if one of bidders can relatively faster deliver public procurement item, tender will demand very short deadlines, which can be achieved only by preferential bidder, even though the time is not the relevant factor for that procurement. .

¹⁵⁷ Law on Public Procurement "Official Gazette of Montenegro", No. 42/2011, Article 52

¹⁵⁸ Law on Public Procurement "Official Gazette of Montenegro", No. 42/2011, Article 56

aligned with European standards. When there are no Montenegrin standards, contracting authority refers to European, or internationally recognized standards, technical provisions or norms;

- 3) as necessary functional characteristics or demands for implementation of the contract, which have to be precise and clear, so the bidders can accordingly prepare their offers.

Contracting authority is prohibited to use technical characteristics or specifications, brands, patent or type, or special origin and production of the goods and services, if those characteristics are unduly excluding other bidders.

When contracting authority is unable to describe item of the public procurement in an understandable manner to bidders, without these details, contracting authority can use brands, patent or type, or name of producer, with reference “or equivalent”.

Aimed or adjusted specification for individual bidder can occur as a potential jeopardy in the process of determination of specifications. Also, information on desired specifications can be revealed to preferential bidder significantly before publishing of the call.¹⁵⁹

This kind of adjustment of specifications of the procurement item, criteria and sub criteria are especially feasible in the healthcare, due to the fact that healthcare procurement are procurements of highly sophisticated products, where only one condition could be detrimental for disqualification of all bidders except the privileged one.⁴⁰

Adjustment of specifications of the procurement item, criteria and sub criteria are especially feasible in the healthcare, due to the fact that healthcare procurement are procurements of highly sophisticated products, where only one condition could be detrimental for disqualification of all bidders except the privileged one.

It is important to emphasize high risk for corruptive behavior, which exists in the procedures when awarding of contract and negotiation procedures are done without published tender (Article 25 of the Law on Public Procurement). This risk is especially related to processes of public procurement in healthcare.

These are the cases when:

- a) In at least two open or limited public procurement procedures, there were no eligible bids, provided that public procurement item or contents of the tender documentation weren't altered – contracting authority consciously poses conditions which make any bidder ineligible, which leads to nullification of tenders.

¹⁵⁹ Mujević, M. Z., *Public procurement*, Podgorica: September 2012, p. 56-59.

- b) When, due to technical demands, criteria could be met only by a single bidder. This is done mainly due to lack of knowledge of technical regulations and standards, and contracting authority adjusts legal situation, only to conduct desired procurement.
- c) when there are additional supplements to the contracts of the same bidder, intended for partial replacement of the product, materials or installations and expanding of the scope of existing deliveries of these products , provided that value of additional deliveries is not higher than 15% of concluded contract.

4.1.3 Submission and evaluation of bids

Review, assessment of validity and evaluation of bids is done by the commission for opening and evaluation of bids on a closed session. Bids are evaluated by verification of compliance of the bid content with tender announcement and tender documentation. Commission for opening and evaluation of bids can, during the process, ask for additional clarifications from bidders, in order to eliminate doubts regarding the validity of the offer. Offers evaluated as invalid are being rejected. During assessment and evaluation of bids, contracting authority is obliged to use only criteria published in the tender and tender documentation.

Among others, as major violations of the law are considered: omissions in the procedure of review assessment, comparison and evaluation of bids, and especially lack of arguments on the basis of which the decision was taken; choosing of the bid, value of which is higher than estimated value of public procurement; choosing of the bid which is not the most economical one, and choosing of the bid which is invalid.

The practice has shown that in public procurement in healthcare sector, main omissions and violations were made exactly in this phase of the procedure. In the phase of evaluation of bids parts of the bid can be disproportionately assessed – exclusion of the bidder and bids which are complying to conditions, or acceptance of the bid which would be rejected.^{160 41}

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¹⁶⁰ Institute Alternative, *ibid*, p.22.

4.1.4 Contracting and implementation of contracts

Contracting authority is concluding the contract on public procurement with bidder whose offer was chosen as the best. Public procurement contract has to be in accordance with conditions determined in public tender announcement, tender documentation and decision on awarding of the contract. The price, set in the contract, can't exceed price which was listed in the decision on awarding the contract. The public procurement contract can't be concluded before the deadline for submission of appeals, and before decision on the submitted appeals, unless the Law has stipulated differently. The bidder, who won the tender, is obliged to sign contract on public procurement within 8 days from delivery of the contract, and to return signed contract to the contracting authority, along with the guarantee for full implementation of the contract. If the bidder fails to sign the contract, or to provide the guarantee for implementation of the contract, the contracting authority may close the contract with the next best bidder, if the price difference is not bigger than 10% in relation to the previously chosen offer, or it may nullify the public procurement procedure. Contracting authority should submit the contract to the Directorate for Public Procurement, in order for this contract to be published on the web site of public procurements.

This phase of public procurement provides numerous possibilities for corruption.

There are numerous techniques of concealing corruption actions in the process of contract execution. We can list following situations as examples: the bidder has offered in his bid goods or services of high quality, in order to fulfill requirements from the tender, while in implementation phase bidder replaces these items, with items of less quality; chosen bidder in the bid offers unrealistically low price, hoping that the contractor will later consent to amendments of the contract due to increase of expenses; also it is possible to conclude contracts which are very divergent in relation to the conditions prescribed by tender documentation, in order to increase quantity of delivery of ordered goods and services, fictional deliveries, extension of deadlines, etc.

The application of the Law on Public Procurement stops upon signing of the contract. Relations arising from the contract are governed by the laws on obligations. Monitoring of implementation of contracts is not part of the Law on Public Procurement. However, contracting authorities have to provide monitoring of contractual obligations through their departments. In this process is very significant role of internal and external controls.⁴²

In the process of implementation of public procurement, especially important is the role of departments for internal audit, as well as the role of the state Audit Institution

4.1.5 Internal agreements among bidders

The highest risk for corruptive actions on the side of bidders, lies in the possibility of cooperation among bidders, as well as in agreements of bidders not to compete with each other – cartel agreements. This agreements might be very concealed and hardly recognizable. The most common types are:¹⁶¹

- Fictional bid (bid designed to represent a competitive bid in the procedure, however it contains high price, or intentional mistake, or it is insignificantly more expensive than the offer of the preferred bidder;
- Splitting of the market (bidders are sharing the market among themselves, in the way that they don't compete on tenders of the certain contracting authority, or in the certain geographical area);
- Restraining from bidding;
- Rotational bidding (bidders are submitting their bids in the procedure with the determined winner, and taking turns).

Highest risk from the occurrence of cartel agreements exists in the repeated procedure of public procurement (when first procedure is stopped or nullified by the State Commission for Control of the Procedure of Public Procurement).⁴³

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4.2 Legal, institutional and policy framework

Area of public procurement in Montenegro's health care sector is defined by the general provisions regulating the overall public procurement in Montenegro. There are, however, certain shortcomings or gaps of the certain legal provisions and regulations in the areas of health care and public procurement, which as we shall see, leave no room for ambiguity and arbitrary of interpretations that undermine or impede the implementation of anti-corruption measures and mechanisms whose effectiveness, in any sector of public procurement is very much needed.

4.2.1 Legal framework

Current Law on Public Procurement was adopted in July 29, 2011, and entered into force in January 01, 2012¹⁶². This Law, which is one of the system-

¹⁶¹ OECD, *Guidelines For Fighting Bid Rigging In Public Procurement*, pp. 2, available at: <http://www.oecd.org/competition/cartels/42851044.pdf>

¹⁶² "Official Gazzete of Montenegro", no. 42/11

atical anti-corruption laws, regulates the conditions, way and procedure for procurement of goods, services and cession, protection of rights in the public procurement procedures and other matters relevant to public procurement. The Law on Public Procurement is largely in line with the relevant regulations (directives) of the EU, additional anti-corruption measures, which were not foreseen by previous legal solutions, are introduced, and specific procedures for public procurement procedures are fully and clearly defined. Further division and positioning of the jurisdiction and powers of institutions in this area is done.

The Law introduced the possibility of integrating procurement¹⁶³, and the step forward was made towards the improvement of transparency and monitoring of the entire process, the obligation of clients to adopt and publish a reasoned plan of public procurement, as well as the obligation to publish calls and requests, the decision on the choice of the best bid on the portal of public procurement, as well as overall public procurement contracts. This Law has also improved the control of the procurement procedures by introducing the inspection controls for the procurements of the value less than 500.00 of Euros and mandatory controls for procurements which value is over the mentioned amount. When it comes to regulating the possible occurrence of corruption and conflicts of interest on both sides, of the procurement commissioners and bidders, Articles 15, 16 and 17 of the Law prescribe an anti-corruption rule and prevention of conflicts of interest, which provides an invalidity of the contract and sanctions in the case of corruption and existence of the conflict of interest^{164, 44}.

The Law on Public Procurement is largely in line with the relevant regulations (directives) of the EU, additional anti-corruption measures, which were not foreseen by previous legal solutions, are introduced, specific procedures for public procurement procedures are fully and clearly defined, and further division and positioning of the jurisdiction and powers of institutions in this area is done.

¹⁶³ In accordance with the regulation of the Government of Montenegro (**Regulation on the organization and functioning of public administration**, "Official Gazette of Montenegro 38/03 and "Official Gazette of Montenegro", no.7/11) or competent body authority of a local government, and other procurement commissioner as a legal entity in certain administrative areas has enabled the establishment of central bodies of public procurement. This centralization of the public procurement process, ie transfer of authority from more individual taxpayers to one relevant ministry (the local authority or procurement commissioner as a legal entity), is significantly simplified method of supervision over the system of public procurement.

¹⁶⁴ By law acts are also adopted, necessary for appropriate implementation of this Law:

It is necessary, of course, to further improve the Law, particularly in these areas: shopping process and control of its implementation control of the planning process of public procurement, independence of the body which monitors the implementation of the Law and so on¹⁶⁵. It is necessary to introduce in the Law the provisions that would further specify the way of procurement of the goods of special importance to human life and health, which will be discussed below.

In addition to the Law on Public Procurement, for the area of public procurement in the health sector provisions of Article 16 of the Law on Health Care Insurance¹⁶⁶ are also important, which define the basic types of services that include the right to health care, the provisions of Article 99 and Article 103 of the same Law which regulate the procedure of concluding the contract between health care services providers and Healthcare Insurance Fund. In the same sense, the Regulation on criteria for the conclusion of the contract on the provision of health care services and the way of payment for health care services¹⁶⁷ is particularly important as well as the provisions of Article 9 item 8 and Article 12 p 3 item 6 and page 4 of the Law on Health Care¹⁶⁸, which define the Network of Health Institutions and the method of determination, as well as the decision of the Government on the Network of Health Institutions¹⁶⁹.

- **Regulation on forms in public procurement procedure**, „Official Gazzete of Montenegro“, no 62/11
- **Regulation on on the methodology of presenting the sub-criteria in the appropriate number of points, way of evaluating and comparing bids**, „Official Gazzete of Montenegro“, no 63/11;
- **Regulation on the record in the public procurement procedure**, „Official Gazzete of Montenegro“, no 63/11;

Also, it is adopted the **Regulation on the Programme and Method of Taking the Professional Exam for Work in public procurement**, „Official Gazzete of Montenegro“, no 28/12.

¹⁶⁵ About deficiencies of the Law on Public Procurement to see the study by Institute Alternative, *ibid.*, p. 59-60, as well as UAI: *Information: Proposed measures to improve, strengthen and further specification of the modalities of coordination in the field of prevention*, January 2013, available at: http://www.antikorupcija.me/index.php?option=com_phocadownload&view=category&id=12:&Itemid=117

¹⁶⁶ „Official Gazzete of Montenegro“, no 39/40, 23/05, 29/05 and „Official Gazzete of Montenegro“, no „Official Gazzete of Montenegro“, no 12/07, 13/07, 73/10, 40/11, 14/12

¹⁶⁷ „Official Gazzete of Montenegro“, no 09/11

¹⁶⁸ „Official Gazzete of Montenegro“, no 39/04 and „Official Gazzete of Montenegro“, no 14/10

¹⁶⁹ „Official Gazzete of Montenegro“, no 18/13

4.2.2 Institutions

The institutional framework in the area of public procurement, including public procurement in the health care sector includes the Ministry of Finance, Directorate for Public Procurement, State Commission for Supervision of Public Procurement Procedures, Directorate for Inspection, Administrative Court of Montenegro and the State Audit Institution.

Ministry of Finance prepares strategic documents in the area of public procurement and draft Law on Public Procurement in cooperation with the Directorate for Public Procurement. In cooperation with the Directorate, also prepares and adopts by-laws (regulations) in the area of public procurement, for which has the authority, decides upon the complaints against the administrative/individual acts adopted by the Directorate, approves the public procurement plans of contracting authorities, supervise the legality of the Directorate, reports to the Government of Montenegro on the state of the public procurement system, as well as other activities within the framework defined by regulation of the Government of Montenegro, which regulates the organization and operation of public administration¹⁷⁰.

Directorate for Public Procurement is founded in 2006 with responsibilities defined in direction of monitoring the implementation of the Law on Public Procurement. Current Law provides that Directorate, among other things, monitors the implementation of the public procurement system; maintains a public procurement portal; gives approval to procurement commissioner on the fulfillment of requirements for the implementation of the certain public procurement procedure, etc. Directorate for public procurement has the status of an independent state authority, in accordance to Article 32 of the Regulation on the organization and functioning of public administration. The Directorate for public procurement prepares an annual report on public procurement which adopts the Government.

State Commission for Supervision of the Public Procurement Procedure, is also founded in 2006. The Commission reviews and decides on appeals in public procurement procedures, decides on the requirements related to the cost of the procedure, does control on the public procurement procedures worth more than EUR 500 000¹⁷¹. The Commission has a president and four members which are working professionally. The President and members of the Commission cannot perform any other public function, or professionally perform other activities. The president and members of the Commission are

¹⁷⁰ Regulation on the organization and operation of public administration („Official Gazette of Montenegro”, no 5/12 and 25/12)

¹⁷¹ Article 139 of the Law on public procurement

appointed by the Government, on the basis of an open competition. They can be appointed for a term of five years and may be reappointed. The Commission decides on appeals and other matters from its authority by majority of votes of all members. The Commission prepares annual report and submits it for consideration to the Parliament of Montenegro.

Directorate for Inspection - Department for Inspection of Public Procurement, or relevant public procurement inspector performs inspection in relation to the regularity of implementation of the public procurement from EUR 3,000 to 500,000. Also, it is in charge to control the timeliness of submission of public procurement plans, calls for tender, decision on the public procurement procedures; public procurement contracts; etc.¹⁷² Prior to the establishment of the Inspection Directorate, workplace of the inspector for the public procurement was positioned within the Directorate for Public Procurement. Directorate for Inspection prepares an annual report and submits it to the Government.

Judicial protection in the public procurement procedures is provided in the administrative proceedings before the competent **Administrative Court**. Namely, Article 146 of the Law on Public Procurement provides that decisions of the State Commission for Supervision of Public Procurement can start an administrative dispute in order to review the justification of the decision.

State Audit Institution (SAI) conducts review of the legality and efficiency of the management of state assets and responsibilities, budgets and all financial affairs of subjects whose financial resources are public or arise by using state assets. The subjects of the audit are required to carry out the purchase of the goods and services, and cession of implementation of work in accordance with the provisions of the Law on Public Procurement. SAI, in accordance with the Law on the State Audit Institution, on its activities reports to the Parliament and the Government.

Within the public procurement in the health care sector, the leading role has: the Ministry of Health, Healthcare Insurance Fund and “Montefarm”, as the largest procurement commissioners, but also the rest of health care institutions in Montenegro, as well as subjects to the Law on Public Procurement are active participants of the system of public procurement.

4.2.3 Policy, strategies and action plans

In the strategic documents of the Ministry of Health public procurements are considered primary in the context of rationalization of expenditures,

¹⁷² Article 148 of the Law on public procurement

especially in the part of budgetary expenditures for medicines which are, as we have underlined in the previous chapter, very high¹⁷³, but the measures which will improve transparency, equality, competition and responsibility in the process of implementation of public procurement in the Montenegrin health care system are not being considered. In the Sector Action plan for the Fight against Corruption¹⁷⁴ it is foreseen to question the system of public procurement in the health care institutions through the consideration of annual report on public procurement which is being submitted to the Ministry of Health and Directorate for Public Procurement. However, based on these reports an estimation of the quality of public procurement in the area of health is still not presented neither were suggested the mechanisms for combating possible irregularities.

4.3 The effectiveness of anti-corruption measures

In the following analysis we will point out some of the factors that endanger the effectiveness and transparency of the system of public procurement in the health care sector, and create possibility for corporative actions. Noticed disadvantages are related to regulative which regulates this area, as well as the work of institutions which are in charge for its implementation.

4.3.1 Inconsistency of regulations

We have already pointed out that provision from the Article 99 to Article 103 of the Law on Health Care Insurance manages the procedure for concluding the contact between the provider of the health services and the Healthcare Insurance Fund. The aim of this procedure is, to ensure the exercise of rights to health protection to insured persons of the Fund, through determined procedure, or to enable them to obtain the services included in this rule¹⁷⁵. Article 16 of the Law on Health Care Insurance, determines the package of the basic services including: (1) medical measures and procedures for improvement of the health, prevention, combating and early detection of the sickness and

¹⁷³ In the „Strategy for optimization of the secondary and tertiary level of the health care“, June, 2011 (available at: <http://www.mzdravlja.gov.me/biblioteka/strategije>) are defined priorities for the public procurement of medicines and investment in health institutions.

¹⁷⁴ Ministry of health: „The Action plan for the fight against corruption in the area of health“, September 2009, available at: <http://www.mzdravlja.gov.me/biblioteka/dokument?pagerIndex=2>

¹⁷⁵ Article 100, p.1 of the Law on Health Care Insurance

other health disorders; (2) medical examinations and other medical help in order to determine, monitor and check the health condition; (3) treating the sick and injured persons and other medical help; (4) treatment outside of Montenegro; (5) prevention and treatment of dental diseases; (6) medical rehabilitation; (7) medicines and medical devices; (8) medical - technical devices (prostheses, orthopedic and other devices, dental prosthetic assistance and dental materials and compensations). In order to ensure this type of services, the Fund conducts the procedure for conclusion of the contract with its providers, i.e., with the institutions which can provide those services.

Within the listed procedure, it is foreseen, among others, that Fund announces every year two public calls for providers of the health services for the submission of the bids in order to conclude the contract. The first call is addressed to providers who are determined by the Network, for services that cannot be provided within the Network, or as the Minister of the Health explained, for services and activities „in which were recorded unjustified waiting lists“¹⁷⁶. However, what is the Network of Health Institutions, i.e., what is its role in the area of health care protection?

In the master plan of the development of the health care system of Montenegro for the period 2010 -2013, it is stated that the Network of Health Institutions is: „spatial and temporal distribution of the capacity of public health institutions and concessionaires, including human, material, space, and other resources in order to ensure an optimal availability of health services for the entire population and the care in the primary, secondary and tertiary level of the health protection. The Network includes primary, secondary and tertiary level of the health protection and it needs to provide geographic access to health services“¹⁷⁷. By article 9, item 8 of the Law on Health Protection, definition of the Network of Health Institutions is expanded from the public to private sector, so here the Network is determined as „type, number and distribution of public and private health institutions in Montenegro“, while in the Article 12 p 3 item 6 and p 4 of the same Law foresees that the state, or Government determines the Network of Health Institutions. Therefore, the Network of Health Institutions does not include only public health institutions, but involves the private health institutions, which is regulated by a special act

¹⁷⁶ Statement of the Minister of Health prof. dr Miodraga Radunovic MD, given to the MINA Agency, May 2nd, 2013, broadcasted by the RTCG: „Radunovic: We will expand the network of services“, available at: <http://www.rtcg.me/vijesti/drustvo/11051/radunovic-prosiricemo-mrezu-usluga.html>

¹⁷⁷ Ministry of Health: „Master plan of the development of the health care sector in Montenegro for the period of 2010 – 2013, p. 35, available at: <http://www.mzdravlja.gov.me/biblioteka/dokument?pageIndex=2>

of the Government. Thus, the government's latest decision on the network of health institutions includes some providers of the health services from the private sector in the Network, such as: General hospital „Meljine“¹⁷⁸, „Galenika Crna Gora“ I.L.c¹⁷⁹ and „Rudo Montenegro“ I.L.c¹⁸⁰.

The main problem of involvement of the private sector in the Network of Health Institutions reflects in the broad set of criteria on which is based the implementation of the procedure. In the mentioned decision of the Government it stands that the Network is established based on the: (1) total number of population in Montenegro, (2) total number of insured people by the Healthcare Insurance Fund, (3) demographic characteristics of the population, (4) public health, (5) gravitating population, (6) characteristics of a certain areas and (7) availability of health resources¹⁸¹. These generally set criteria leave the wide space for the discrete decision making, and preferential treatment of the certain providers from the private sector, which by entering the Network obviously receive numerous advantages in regard to competitors which offer the same type of services in the market^{182, 45}. For example, why is in the Network of the health institution included „Galenika Crna Gora“ I.L.c which according the media reports is in big financial problems¹⁸³, and some other chain of private

Criteria for inclusion of private companies in Network of Healthcare Institutions leave the wide space for the discrete decision making, and preferential treatment of the certain providers from the private sector, which by entering the Network obviously receive numerous advantages in regard to competitors which offer the same type of services in the market

¹⁷⁸ Article 11 and Article 12 of the Decision on the network of the health institutions

¹⁷⁹ Article 15 of the Decision on the network of the health institutions

¹⁸⁰ Article 15 of the Decision on the network of the health institutions

¹⁸¹ Article 2 of the Decision on the Network of health institutions

¹⁸² Additional problem to this establishment of the Network of health institutions and determination of precise criteria for including the private sector in providing the rights of insured persons from the mandatory health care insurance, represents the fact that in Montenegro are still not adopted standards for accreditation of health institutions which set clearly defined and measurable system of generated indicators of the quality and safety during provision of the health care protection. In accordance with the National strategy for improvement of the quality of the health care protection and safety of patients, establishment of the internationally recognized procedure of accreditation in the health is projected until 2017 (Ministry of health: „National strategy for improvement of the quality of the health care protection and safety of patients with the Plan of actions 2012 – 2017“, p 13, available at: <http://www.mzdravlja.gov.me/biblioteka/strategije>).

¹⁸³ Vijesti: „Farmegra seeks bankruptcy in Galenka“, Septemebur 21, 2012, available at: <http://www.vijesti.me/vijesti/farmegra-trazi-stecaj-galenici-clanak-92607>

pharmacies are not included? Why is the general hospital „Meljine“, which has no permanently employed ophthalmologists¹⁸⁴, determined to, among others, provides a hyperbaric chamber and cataract surgery (up to 150 cataract surgeries per year) in the entire gravity area of Montenegro¹⁸⁵, although in Podgorica, for example, there is a Daily hospital „Optimal“ – specialized ophthalmological microsurgery, with the latest equipment and permanently employed ophthalmologists?¹⁸⁶ Finally, why the Network of the health care institutions includes „Rudo Montenegro“ l.l.c which is not a health care institution, but in the Central Registry of Economic Entities¹⁸⁷ it is registered as a company for the manufacture of medical and dental instruments and materials? To recall, the Article 9 of the Law on Health Care Protection states that health institution is legal entity registered to perform health care activities, which has appropriate approval in accordance with this Law, while Article 39 of the same Law explicitly states that health institutions are: health center, ambulance, laboratory, pharmacy, hospital, institute, natural health resort, clinics, clinical center, Institute for Public Health. “Rudo Montenegro“ can’t be included in any of these categories according the current status. Because of these irregularities, we initiated before the Constitutional Court of Montenegro a procedure for assessment of the constitution and legality of the Decision on the Network of health institutions^{188, 46}

CeMI has initiated before the Constitutional Court of Montenegro a procedure for assessment of the constitution and legality of the Decision on the Network of Health institutions

Besides the previous decision of the Government, which as we can see in disputable way is selecting providers of health services from the private sector for inclusion into the Network of Health Institutions, the Healthcare Insurance Fund is conducting two more selections between providers of the health services¹⁸⁹ through the public calls for submission of the bids in order to conclude

¹⁸⁴ In General hospital Meljine is engaged as expert consultant prof. dr Nikica Gabrc MD, founder and director of the special hospital for ophthalmology „Svjetlost“ in Zagreb (<http://www.nacionalni-forum.hr/default.aspx?id=34>), while during his absence the work at the clinic is performed by residents doctors, not specialists in ophthalmology (<http://www.bolnica-meljine.me/>).

¹⁸⁵ Public call for health institutions within the Network (Special conditions of the call, item 2), May 27, 2013, available at: [http://fzocg.me/index.php#sadrzaj\(55,5\)](http://fzocg.me/index.php#sadrzaj(55,5))

¹⁸⁶ <http://www.optimal.co.me/>

¹⁸⁷ <http://www.crps.me/>

¹⁸⁸ The initiative was submitted before the Constitutional Court in July 04, 2013.

¹⁸⁹ Certain bidders or providers of the health services with who we have talked are questioning who the Network of health institutions does not include all registered health institutions which are accepting the price list of the Fund, in order to ensure

the contract with the providers of services that belong to the Network, as well as with those who does not belong to the Network of services which can not be provided within the Network¹⁹⁰. Although the criteria according to which the Fund¹⁹¹ is obliged to make the selection in these cases are more concrete from the listed criteria which are pointed out in the Decision of the Government¹⁹², because it is required to take into consideration, among others „specific prices by the type of health services“ and „other objective indicators of expenditures for health services“¹⁹³, these two public calls of the Fund are not in the right sense tenders, nor it is about the procedure which is following procedures of public procurement determined by the Law on Public Procurement.⁴⁷ In fact, although the procedure regulates the way of closing

Annual public calls of the Health Insurance Fund are not actual tenders, nor these are the procedures which follow provisions of the Law on Public Procurement. Namely, although this procedure regulated methods of contract conclusions with service providers, it is governed by the Law on healthcare, without any reference to valid regulations from the area of public procurement.

the equal conditions and competition in providing services and so the insured person can choose the institution and doctor for his examination and treatment. (Transcript of the interview with the executive director of the company „Osmi red – D“ from Podgorica, Angelina Vukovic, held on June 21, 2013)

¹⁹⁰ Article 101 of the Law on the Health Care Insurance foresees that the Fund exceptionally, without the public call, signs the contract „with the health institutions which are performing activities of public health, blood transfusion, taking, typing and transplantation of human body parts, emergent medical aid, clinical center and the institute for public health, for the part of activities which are financed from the Fund intended for the mandatory health care insurance, as well as accredited health institutions and health institution outside of Montenegro“.

¹⁹¹ According the Article 100 of the Law on the Health Care Insurance, the Governing Board of the Fund every year appoints the Commission for the estimation of the fulfillment of conditions for the conclusion of the contract, on which report is based the decision of the Governing Board on proposal of the director of the Fund on the selection of provider of health services with whom it will conclude the contract. Provider of the service which did not conclude the contract with the Fund has the right to appeal to the Ministry of Health as secondary organ.

¹⁹² In the newest decision of the Governing Board of the Fund on selection of providers of the health services which are included by the decision of the Government on the Network of health institutions, it has not been concluded the contract with the „Galenikom Crna Gora“ I.L.C. ([http://fzocg.me/#opsirnije\(823\)](http://fzocg.me/#opsirnije(823))). Therefore we have a paradox situation that Galenika, next to „Montefarm“, by decision of the Government is determined as a provider of services which provides medicines, medical devices and materials, but „Galenika“ will not ensure listed services at least in the next year. Than why is „Galenika“ included in the Network of health institutions at all?

¹⁹³ Article 99 p 2 item 4 and 6 of the Law on Health Care Insurance

the contracts with the providers or suppliers of services (goods, activities), it is completely defined by the Law on the Health Care Insurance and related by-laws in the field of health¹⁹⁴ within which nowhere is referred to the applicable provision from the public procurement field. During the interview with the representatives of the Directorate for Public Procurement, about this problem was stated that the Law on Public Procurement is *lex generalis*, and that neither one individual sector, nor the sector of health, can prescribe a special procedure for public procurement which is not in accordance with this Law¹⁹⁵. On the other side, representatives of the Healthcare Insurance Fund believe that the Law on Public Procurement is not *lex generalis*, that Ministry of Health and Fund have constitutional obligation¹⁹⁶ to provide a health care protection to all citizens, as well as availability of services from the mandatory health care insurance to all insured persons and that listed procedures must be clearly regulated by relevant regulations in the area of health¹⁹⁷.

Previous inconsistency of legal acts leads, not only to different interpretations but in certain cases to unadjusted, as we will see, arbitrary procedures in the practice.

¹⁹⁴ In addition to mentioned decision on the Network of health institutions and Regulation on criteria for conclusion of the contract on providing the health services and the way of paying for health services, during the implementation of this procedure the following by-laws acts are taken into consideration:

- Regulation on the scope of rights and standards of the health care protection from the mandatory health care insurance on the secondary and tertiary level of protection („Official Gazzete of Montenegro“, no.18/13);
- Regulation on conditions for the implementation of health activities in the hospitals and natural health resorts („Official Gazzete of Montenegro“, no. 74/08);
- Regulation on the way and procedure to exercise the rights to specialized medical rehabilitation („Official Gazzete of Montenegro, no. 74/06 and „Official Gazzete of Montenegro, no. 30/10);
- The Regulation on the way and procedure of exercise of the rights to medical-technical devices („Official Gazette of Montenegro“, no. 74/06 and „Official Gazette of Montenegro“, no. 28/08);
- Program of the health care protection in Montenegro for 2013.

¹⁹⁵ Transcript of the interview with the director of the Directorate for public procurement pdh Mersad Mujevic, held in June 21, 2013.

¹⁹⁶ Article 69 of the Constitution of Montenegro („Official Gazette of Montenegro“, no. 1/07)

¹⁹⁷ Script of the interview with the representatives of the Fund for the Health Care and Insurance, held in July 26, 2013.

4.3.2 Procurement of orthopedic devices and calls for tender

Representatives of the Montenegrin company „Montenegro Business Solutions“ (MBS) owned by the „Bauerfeind AG“, is one of the leading world manufacturers of orthopedic, prosthetic and rehabilitation devices, informed us that since 2008 in Montenegro has not been open call for tender for procurement of orthopedic-technical devices¹⁹⁸. Namely, back in the end of 2008, the Commission for the control of procedures of public procurement has canceled the tender no 10/08 for the procurement of medical-technical devices for the needs of the Republican fund for health care insurance because of the numerous procedural irregularities in the process of opening the call for tender¹⁹⁹. Since then the call for tender for the same needs (at least when it comes to orthopedic devices) was not open despite the order of the Commission to repeat the procedure in the certain timeline²⁰⁰. Explaining the above, representatives of the Fund for the Health Care Insurance point out that procurement of orthopedic devices is done based by the concluded contracts with the company „Rudo Montenegro“ I.l.c with whom they have a long standing business cooperation, and the contracts are concluded in accordance with the Law on the Health Care Insurance, and that delivery of devices to insured persons is by the agreed prices, according the Regulation on the way and procedure of exercise of the rights to medical-technical devices and the List of medical-technical devices which is included in the Regulation. As the new Government Decision on the Network of health institutions, made the company Rudo Montenegro a part of the Network, the further procedure of ensuring the rights of insured persons to orthopedic-technical devices will be implemented based on the public call and review of the conditions for concluding the contract with the providers of health services which are within the Network of the health institutions²⁰¹. Similar explanation of the procurement gives the Ministry of Health which claims that „Rudo Montenegro“ is long standing business partner of Healthcare Insurance Fund, and therefore because of the good cooperation and the quality of services is included in the Network of the Health Institutions²⁰². However, “long lasting and good

¹⁹⁸ Minutes of the meeting with the representative of MBS held in June 14, 2013.

¹⁹⁹ Solution of the Vommission for the control of the procedure of public procurement, no 1127-3/2008 from December 19, 2008, available at: http://www.kontrola-nabavki.me/1/index.php?option=com_wrapper&view=wrapper&Itemid=124&lang=mne

²⁰⁰ Within 15 days from the day of received Rjesenja on cancelation of the procedure (ibid, p 1)

²⁰¹ Minutes of the meeting with representatives of the Fund for Health Insurance, held on July 26, 2013.

²⁰² Response of the Ministry of Health to the journalist from Daily „Vijesti“ about including the company „Rudo Montenegro“ in the Network of Health institutions, published in the article „Mopney from the budget for private health care companies“,

cooperation” with some of providers of services, according to the Law on Public Procurement, or according to the Law on Health Insurance upon which calls the Healthcare Insurance Fund²⁰³, is not prescribed as criteria based on which should be done the selection of the most favorable offer and made decision on concluding the contract.⁴⁸ Representatives of the company „Rudo Montenegro“ have pointed out one important quality of this company, that it is the only company of this kind in the market which provides services in a different regions of Montenegro, in their premises in Podgorica, Bijelo Polje, Berane, as well as in the health care institutions in Pljevlja, Riasan, Herceg Novi, Bar and Niksic. In this way the place of providing services (delivery/ takeover of orthopedic aids) is closer to the place of residence of the insured person, which is very important in this case because usually persons with reduced mobility or persons with special needs are those who need aids to be developed according to their measures, etc. Representatives of this company have also stated that “Rudo Montenegro” is not a formal health care institution, only because it does not have hospital beds and accommodation, but that this condition is not fulfilled by the Healthcare Insurance Fund either which is recognized as a health institution by the Law²⁰⁴.

There is a discrepancy between normative solutions which are treating provision / procurement of this kind of healthcare services.

From the above examples it is clear not only that there is non-compliance and lack of precision in the legal provisions which deal with the provision/ procurement of this kind (health) of services, but that the procedure of procurement in recent years took place in closed, non-transparent manner, without conducting an adequate procedure of public procurement, and the arbitrary and selective interpretation and (non) implementation of the provisions of the Law on Public Procurement and Law on Health Insurance.

4.3.3 Nullification of tenders in healthcare and shortages of medicines and medical devices

Since January 1st of 2012, when the new Law on Public Procurement came into force, until July 15th of 2013, state Commission for Supervision of Procedures of Public Procurement has nullified significant number of public procedures in the area of healthcare. Precise statistical data weren't available²⁰⁵, partially

available at: <http://www.vijesti.me/vijesti/novac-budzeta-privatne-zdravstvene-firme-clanak-140481>

²⁰³ Criteria for selection of the most favorable bid, prescribed by the Articles 92 - 96 of the Law on Public Procurement.

²⁰⁴ Minutes of the meeting with Aleksandar Miranovic, Director of the company “Rudo Montenegro”, held on July 26, 2013.

²⁰⁵ Response to the Free Access to the Information Demand No. 158/13 from

due to the fact that State Commission doesn't have electronic database with systematized and classified decisions by areas²⁰⁶, but with simple calculation of adopted complaints and decisions of the State Commission, published on the web page of this institution²⁰⁷, we have determined that in the observing period was nullified partially or totally, at least 40 procedures of public procurement in healthcare sector. Highest attention of the public was attracted by cases of nullification of tenders for procurement of medicines for annual supply of healthcare institutions²⁰⁸ and for procurement of insulin²⁰⁹, announced by the Healthcare Institution Pharmacies of Montenegro "Montefarm, and in this year cases of nullification of tenders for procurement of RTG films and consumables for necessities of the healthcare institutions²¹⁰, which was announced for Healthcare Insurance Fund, as well as nullification of series of parties within the „Montefarm“ tender for procurement of medicines and medical devices.²¹¹

Competent officials in the healthcare, starting with Minister of the Health²¹², director of the Healthcare Insurance Fund²¹³ and director of „Montefarm“²¹⁴

05/03/2013..

²⁰⁶ This information was given to us in conversation with Suzaan Pribilovic, President of the State Commission.

²⁰⁷ <http://www.kontrola-nabavki.me>

²⁰⁸ Decision of the State Commission No. UP. 0905-304/4 -2012 from 25.05.2012 available at: http://www.kontrola-nabavki.me/1/index.php?option=com_wrapper&view=wrapper&Itemid=124&lang=mne

²⁰⁹ Decision of the State Commission No. 0903-174/4 -2012 from 27.04.2012. available at: http://www.kontrola-nabavki.me/1/index.php?option=com_wrapper&view=wrapper&Itemid=124&lang=mne

²¹⁰ Decision of the State Commission No. UP. 0903-25/2 -2013 from 15.02.2013. available at: http://www.kontrola-nabavki.me/1/index.php?option=com_wrapper&view=wrapper&Itemid=124&lang=mne

²¹¹ For procurement of medicines for this year is foreseen 26.5 million euros. In the framework of mentioned tender, divided by parties, out of 881 parties, disputable was 100 of parties, with value of 2.5 million of euros. (Decision of the State Commission No UP. 0903-125/1 -2013 od 12.04.2013. available at: http://www.kontrola-nabavki.me/1/index.php?option=com_wrapper&view=wrapper&Itemid=124&lang=mne)

²¹² Daily Pobjeda: „Shortage of medicines threatens, Radunović to Katnić: Insulin is not the cement“, 24 May 2012, available at: <http://www.pobjeda.me/2012/05/24/prijeti-nestasisa-ljekova-radunovic-katnicu-insulin-nije-cement/#.UhKVlpJBM-c>

²¹³ Daily Pobjeda: „Hrapović: Shortages of medicines were caused by the Law on Public Procurement“, 25 December 2012, available at: http://www.pobjeda.me/2012/12/25/hrapovic-zbog-zakona-o-javnim-nabavkama-bilo-je-nestasisa-ljekova/#.UhKZ_5JBM-c, as well as Notes of the interview with representatives of the Healthcare Insurance Fund, held on 26/07/2013

²¹⁴ Daily Dan: „New tender until Friday“, 01, June 2013, available at:

have the common opinion that nullification of tenders in healthcare occurs for complicated tender procedure, and that it is necessary to amend the Law on Public Procurement in order to simplify procedure, shorten of deadlines for submission of complaints, restrict possibilities of submission of complaints in each individual procedure of the public procurement, and prescribe possibility of faster and simpler procedure of procurement of medicines and specific medical devices, in order to avoid situations in which shortages directly jeopardize lives and health of citizens.⁴⁹

Frequent nullification of tenders in healthcare causes shortages of medicines, medical devices and equipment

On the other hand, representatives of the Directorate for Public Procurement²¹⁵ state that shortages of medicines in the market are not occurring due to deficiencies of the Law on Public Procurement, but due to lack of knowledge on opportunities that this Law provides, inadequate planning and untimely initiation of procurement procedures, discriminatory conditions se in tenders for public procurement etc. Representatives of the State Commission for Control of the Public Procurement Procedures²¹⁶ also state that contracting authorities are making serious mistakes in implementation of the procurement procedures, that provisions of the Law are not being respected and that invalid tenders are being announced. In consequence, mentioned public procurement procedures in healthcare were nullified due to many various reasons: lack of estimated value of the public procurement, failing to provide to all interested bidders individual parties of the tender, possible conflict of interests of members of commission for evaluation of bids, different texts of the publicly announced bid, conclusion of procurement contracts with companies which are not registered for the type of services they are providing, etc.²¹⁷ Furthermore, due to the suspicion that there are certain abuses in implementation of tender procedures in the area of medicines procurement,

[http://www.dan.co.me/?nivo=3&datum=2013-06-01&rubrika=Povodi & najdatum=2013-07-10&clanak=388293&naslov=No%ADvi%20ten%ADder%20do%20pet%ADka](http://www.dan.co.me/?nivo=3&datum=2013-06-01&rubrika=Povodi%20i%20najdatum=2013-07-10&clanak=388293&naslov=No%ADvi%20ten%ADder%20do%20pet%ADka), as well as Notes of the interview with Budimir Stanišić, director of the „Montefarma“, held 21 June 2013

²¹⁵ Daily Pobjeda: „Directorate for Public Procurement: Medicines have to wait for the procedures as well“, May 25, 2012, available at: <http://www.pobjeda.me/2012/05/25/direktor-uprave-za-javne-nabavke-mujevic-i-ljekovi-moraju-da-cekaju-procedure/#.Uhl4pJBM-c>

²¹⁶ Expose of Tomo Miljić from State Commission at the Round table “Implementation of the Law on Public Procurement” organized by Chamber of Commerce on 15/05/2013 available at: <http://www.privrednakomora.me/poslovni-ambijent-javne-rasprave/primjena-zakona-o-javnim-nabavkama>

²¹⁷ Data exposed in clarifications of mentioned decisions of the State Commission.

according to the press, inspectors of the criminalist police have recently²¹⁸ seized documentation of the PHI Pharmacies of Montenegro „Montefarm“ for detailed examination. Also, police has announced hearings of relevant officials from Montefarm, State Commission and Healthcare Insurance Fund. Directorate of Police is conducting an investigation on procedure of public procurement of X-ray machines and ultrasound machines and chamber for development of films, since the last April. Police suspects that these tenders were fraudulent. These tenders were announced by the Ministry of Health and they are worth 440 000 €, while entire procurement was funded by the World Bank credits²¹⁹.

Whether shortages of medicines, medical devices and equipment are consequences of the deficiencies of the current Law on Public Procurement, or due to violations of the legal provisions and possible abuses in procurement procedures will be the subject of the control hearing, which will take place in the end of October, before the Parliamentary Committee for Healthcare, Labor and Social Welfare.²²⁰ On the Committee will be held hearing for the Minister of Health, Director of the Healthcare Insurance Fund, Director of the Clinical Center of Montenegro, Director of „Montefarma“, and Head of the Directorate for Public Procurement.

4.3.4 Splitting of unique subject of the public procurement and monopolies on the market

In conversation with representatives of the company „Eight Row – D“, which is one of providers of goods and services in healthcare sector,²²¹ a serie of objections was presented regarding announcement and implementation of tender procedures in healthcare. Representatives of this company are pointing out that certain tenders are being designed for already known bidder, that technical specification of the procurement items are sometimes locked, i.e.

²¹⁸ Daily Vijesti: „Police seized business documentation of Montefarm“, July 27, 2013, available at: <http://www.vijesti.me/vijesti/policija-uzela-poslovnu-dokumentaciju-montefarma-clanak-141039>

²¹⁹ Daily Vijesti: „Police verifies the tender of Ministry of Healthcare in the value of 440.000 euros“, 24.04.2013, available at: <http://www.vijesti.me/vijesti/policija-provjerava-tender-ministarstva-zdravlja-440-000-eura-clanak-125148>

²²⁰ Decision on control hearing for public procurement in the healthcare sector was adopted on the 15th session of the Committee 24/07/2013 available at (<http://www.skupstina.me/index.php/me/odbor-za-zdravstvo-rad-i-socijalno-staranje/sjednice>)

²²¹ Transcript of the interview with Angelina Vukovic, Executive Director of the Company „Osmi red – D“, held on June 21, 2013.

they are suitable for just one particular bidder, and that there is no possibility of the equivalent offer in accordance with Articles 50 and 51 of the Law on Public Procurement.

Representatives of the „Eight Row“ are questioning purposes and efficiency of the individual procedures of public procurement in healthcare. They have listed cases²²² in which the tender for medical equipment was published, but not the tender for consumables for this equipment. Problem occurs when equipment of one producer is procured and consumables of those producers are only ones corresponding to the bought equipment.²²³ Therefore, for these kinds of procurement it is necessary to announce linked tenders for the equipment and consumables, in order to prevent future monopolies in procurement of consumables. Otherwise, main principles of the Law on Public Procurement are being violated.

Representatives of the „Eight Row“ also claim that, in the last years, biggest tenders for supplying of healthcare institutions with medical devices and equipment are always won by same privileged companies, which didn't possess even the valid registration within CREE, i.e. they were not registered for wholesale of pharmaceutical products.

4.3.5 Insufficiently effective control over procedures of the public procurement in healthcare

We have already that the State Commission for Control of the Procedures of Public Procurement is in charge of the control of conducted procedures of public procurement, value of which exceeds the amount of 500 000€. Therefore, in accordance with the Article 144 of the Law on public Procurement each contracting authority on the tender, value of which exceeds 500 000€ is obliged to submit entire documentation relevant for that procedure, to the State Commission for Control of Public Procurement Procedures. In the interview with state Commission we have asked what should be undertaken when the contracting authority doesn't submit relevant documentation, taking for

²²² Executive director of “Osmi Red-D” in an interview stated the open public procurement procedure no. 25/12 from October 23, 2012, in which was performed the procurement of plasma sterilizers and decontamination devices for general hospitals in Bar, Berane and Pljevlja.

²²³ The same problem arises during donations of various medical devices and supply. For example, donated is the equipment that requires service, accessories, consumables, parts, software etc, which produces only the company that donated the equipment, in which case the company may dictate the price of the equipment. If the equipment was in use, the donor would eliminate any competition that manufactures such equipment.

example Health Insurance Fund which conducts procurements of orthopedic devices in amount far higher than 500.000 Euros on the annual level, without open procedure of public procedure since 2008, failing to provide documents for compulsory control to the State Commission. Representatives of the State Commission that this institution is not obliged to conduct the field control and that reporting of the documents is the sole legal responsibility of the contracting authority.²²⁴

The problem of effective controls occurs in the procurement processes under 500 000€. For the control of public procurement procedures whose value does not exceed 500 000€, as we have noted, is in charge the Directorate for Inspection, namely the Department for Inspection of Public Procurement. Considering that in this department is employed only one (main) inspector who inspects at the entire territory of Montenegro²²⁵, it is obvious that an adequate and effective control of the accuracy of implementation of the above procedures cannot be achieved, especially if we take into account that the number of such procedures is annually close to 62 000, and that in Montenegro there are over 650 subjects to the Law on Public Procurement²²⁶. Also, jurisdiction and powers of the newly formed Direction for Inspections are not clearly normatively defined in relation to the Public Procurement in terms of decision making and giving instructions.⁵⁰

Inconsistency and ambiguity of certain legal norms in the area of healthcare and public procurement, underdeveloped function of internal audit and insufficient number of inspectors decreases possibility for effective control of the processes of public procurement in healthcare sector.

Finally, State Audit Institution still has no developed capacities to conduct regular controls of audit subjects. In such manner, SAI has conducted one of the audit of the financial management of subjects from healthcare sector, and that is audit of HI Pharmacies of Montenegro („Montefarm“) for 2010, which has discovered some deficiencies and irregularities.²²⁷ There were no other individual audits in the healthcare sector. Also, except in the Health Insurance Fund, in institutions of the public healthcare there is no adequate organizational unit for internal audit.

²²⁴ Minutes of the conversation with Suzana Pribilovic, President of the State Commission for Supervision of Public Procurement Procedure, held on June 27, 2013.

²²⁵ „Report on the work of Directorate for Inspection for 2012“, p.88, available at: www.gov.me/ResourceManager/FileDownload.aspx?rId=126710&rType=2

²²⁶ Ibid, p. 13

²²⁷ „Audit Report on the Annual Financial Report of the Pharmaceutical Institute of Montenegro, Podgorica in 2010“, available at: <http://www.dri.co.me/1/doc/Izvjestaj-o-reviziji-Godisnjeg-finansijskog-izvjestaja-Apotekarske-ustanove-Crne-Gore-za-2010.godinu.pdf>

4.4 International standards and comparative practice

In addition to the OECD universal guidelines for the fight against corruption in public procurement procedures²²⁸ which are designed in such way to represent the starting point and basis for the implementation of the international instruments to combat fraud and irregularities in the area of public procurement in general, WHO has identified the concrete strategic objectives and operational principles for good, efficient and transparent procurement of pharmaceutical products in the health sector²²⁹. WHO, in fact, points out that in this area should strive to supply economically most profitable products in appropriate amounts, that should select reliable suppliers of high-quality products, which means that it should conduct prior checking and testing of the quality of products and suppliers, to ensure accurate and timely delivery and seek to ultimately achieve the lowest possible total cost. Based on this set of general goals, the WHO defines a set of operating principles, among which are the following:

- Different functions and responsibilities in the procurement (selection, quantification, product specification, review sellers' reliability and product quality, scheduling and implementation of tender) should be divided between different expert services, committees and individuals (so all decision-making power will not be concentrated in the one place);
- Public procurement procedures should be transparent, and it is necessary to follow formal written procedures during the whole process and to define clear and explicit criteria for the award of the contract;
- Procurement should be adequately planned and their implementation should be under constant monitoring and control that must necessarily include periodic external audits;
- Procurement in the public health care sector should be implemented according the essential, national lists of medicines and medical devices;
- In the tender documents, medicines should be classified according to their International Nonproprietary Name (INN)²³⁰, ie generic name (in order to be able to immediately identify their composition);
- Procurement quantities should be based on reliable analysis and assessment of current needs;
- Procurement must be implemented in the largest necessary quantities in order to achieve a higher degree of effectiveness;

²²⁸ *OECD Principles for Integrity in Public Procurement*, OECD, 2009.

²²⁹ WHO: „Operational principles for good pharmaceutical procurement“, Geneva 1999, dostupno na: <http://www.who.int/3by5/en/who-edm-par-99-5.pdf>

²³⁰ International Nonproprietary Name

- Procurement in the public health care sector should be based on competitive processes and procedures, except for a very small or urgent orders;

According to experts of the Anti-Corruption Resource Center U4²³¹, the basic precondition of combating corruption in public procurement in the health care sector consists in defining clear and transparent rules and guidelines to reduce the possibility of discretionary decision-making and increase the possibility that corrupt actions will be detected and sanctioned. In this regard, the adoption and application of the above principles of the WHO is recommended, which undoubtedly contribute to the transparency and efficiency of procurement in the health care sector. In order to increase the transparency of the process, we further recommend publishing of the list of suppliers of medicines, medical supplies and equipment involved in tenders, to make publicly available the results of conducted tenders, as well as involving civil society in all stages of the process. It is particularly pointed out the importance of establishing a list of reliable suppliers of pharmaceutical products with information on the prices of products that would be available publically, which would contribute to the comparison, control and reduce of the price of the products, and thus to suppress opportunities for corrupt activities.

One of the good examples of a transparent, cost-effective and efficient system of public procurement in the health care sector is example of Denmark. Namely, the only adopted procedure of procurement and sale of medicines in this country²³², has led to fact that medicines dispensed by prescription in the period from 2000 to the first half of 2012 on average got cheaper for 42%. Thus, for example, in the period from the first half of 2011 to the first half of 2012, prices of medicines fell by 7%. This means that during this period the value of sales of medicines (with prescription) at pharmacies fell for 56 million of DKK, while the number of defined daily doses (DDD) increased for 27 million. Generic medicines which are subject to the recipe today in Denmark are among the cheapest in Europe. At the same time (during 2010-2012), the prices of medicines which are being sold in the free market have risen for 23%. This success was achieved through the simple system of public bidding, which is repeated every two weeks. All interested suppliers in a fierce competition submit their bids for certain medicines (or generic equivalents) from a list of approved medicines. The offered price is automatically published on the

²³¹ Anti-Corruption Resource Center U4: *Corruption in the health sector*, 2006, available at: <http://www.u4.no/publications/corruption-in-the-health-sector-2/>

²³² Kaiser U., Mendez S. J., Ronde Th. & Ullrich H.: „Regulation of Pharmacheuthical Prices: Evidence from a Reference Prices Reform in Denmark“, february 2013, available at: <http://ftp.iza.org/dp7248.pdf>

Internet. Pharmacies shall offer to the patient with a prescription the cheapest medicine that are currently on the list (from the publicly available portal: medicinpriser.dk), even though the doctor prescribed an expensive medicine. The patient is the one who, in general, pays for the medicine, but with a larger or smaller contribution from the public fund. Certain categories of patients receive a 100% contribution.

Thus, on average, for 18 million prescriptions annually, less expensive medicines are issued than the medicines prescribed by doctors. In practice this means that the supplier which offers the lowest price in 14 days has practically the whole Danish market of that medicine, until the next auction. Pharmacies have no interest in selling more expensive medicines, because their profit is fixed, and does not depend on the price of the medicine.

4.5 Recommendations for improvement

In order to eliminate exposed weaknesses, and to improve the situation in the area of public procurement in the health care system in Montenegro, we believe that the following measures and actions should be taken:

- It is necessary to reconsider provisions from Articles 99-103a of the Law on Healthcare Insurance, which regulate procedure of conclusion of contracts among service providers and Healthcare Insurance Fund, and to align those provisions with general regulations in area of public procurement. More precisely, in the Law on Healthcare Insurance should be clearly defined services, which would be subjected to Law on Public Procedures, in order to avoid arbitrary interpretations of legal provisions and to decrease possibility of irregularities and abuses in practice;
- It is necessary to additionally amend procedures and criteria, according to which the private service providers are being integrated into Network of Healthcare Institutions, and to reconsider current Decision of the Government on the Network of Healthcare Institutions. In this sense, there are two solutions: either all public and private institutions which fulfill legal criteria²³³ should be included in the Network of Healthcare Institutions, or Network should encompass only public healthcare institutions founded by the state. In the first case patients could choose institution and doctor out of funds from

²³³ They are registered as medical service providers and they are accepting prices of Health Insurance Fund

their mandatory healthcare. In second case, for services that are not available in public healthcare institutions, on the annual level should be published tenders with clearly defined procedure and criteria, and service providers should be chosen on the basis of assessment of their quality and the best price for the service;

- Detailed control of all concluded contracts of higher value should be conducted by relevant institutions, especially for contracts in which there are indications of possible abuses and irregularities. In such manner it could be determined whether contracts were concluded in accordance with prescribed legal procedures, or whether there were avoiding of regulations and monopolizing of the market by individual subjects.
- It is necessary to strengthen capacities of Department for Inspection of Public Procurement and increase number of inspection controls of public procurement procedures in healthcare sector;
- Relevant authorities should regularly control transactions and management of companies that are repeatedly winning on public tenders, and are occurring as the biggest suppliers of devices, goods and services for healthcare institutions, in order to detect existence of possible abuses and corruption;
- It is necessary to create publicly available databases of the biggest suppliers of medicines, medical devices and equipment, containing also average prices of their goods and services (current market prices and previous market prices), in order to increase transparency and control in this area;
- Function of internal audit in the institutions of public healthcare should be strengthened, and its results should be made available to interested parties and to general public;
- It is necessary to reconsider introduction of new provisions into the Law on Public Procurement, which would provide more efficient procurement processes in the area of medicines and specific medical devices, taking in consideration that shortages of these items directly jeopardizes lives and health of citizens;
- Also, the Law on Public Procurement should prescribe special controls for urgent procurement procedures, in order to prevent possible abuses and irregularities in practice;
- It is necessary to additionally develop and strengthen education of the staff of contracting authority that participates in preparation and implementation of the public procurement procedures, in order to

avoid irregularities identified by the State Commission for Control of the Public Procurement Procedures;

- It is necessary to clearly define status and organization of work of all participants in the public procurement procedures, including the phase of monitoring of implementation of concluded contracts;
- It is necessary to decrease formalism and unnecessary bureaucracy – public procurement process should be simplified and participation of higher number of bidders should be facilitated (e.g. originals proof of eligibility should be requested only from the winner; allow correction of formal mistakes in the bid within a certain legal deadline etc.);
- It is necessary to develop manuals for contractors and bidders, on their rights and obligations , but as well as with warning of type and kind of sanctions which will be applied in cases of corruptive behavior;
- In the practice, in accordance with the conditions set by this Law, contract awarding procedure, by implementation of the framework agreement, should be more frequent. This would contribute to more efficient procedure of public procurement, as it would provide the possibility to conclude several contracts (up to 4 years of duration) with the same bidder(s), within one public procurement procedure, in order to avoid complicated and expensive procedure with uncertain result.

Regulations on conducting of unified procurements should be adopted, in the manner set by the Law on Public Procurement. Before that, it is necessary to prepare adequate analysis of justification of unified procurement procedures (explaining to which public procurement procedures it could be applied and which is the responsible authority for implementation of this kind of procedures).

CONCLUSION

Despite the reform process that was carried out in recent years in order to improve health care system, increase the quality of health services, prevent informal payments and other possible corruption activities in the health care system of Montenegro, achieved results, especially in the field of fighting against corruption, are still unsatisfactory. Majority of anti-corruption measures set and implemented in the healthcare system, are addressing healthcare practitioner-patient relationship. In this area, the Law on Patients' Rights was adopted, with modified and improved regulation, in order to prevent abuse of additional work (contemporaneous work in the public and the private sector), new institutions were established such as Protector of Patients' Rights and Commission for Quality Control of healthcare, which are also responsible for suppression of the corruption activities in the field of health services, etc.

However, the implementation of these anti-corruption measures has not promoted public trust in the integrity of the health system. In fact, according to the results of public opinion research (CATI method), 43.1% of examinees still believe that corruption is present, or is present in high level in Montenegrin health care system. This confirms the results of previous studies, which testified increase of the perception of corruption in the healthcare sector.

Low public trust is probably caused by the fact that, in the past three years, was an insignificant number of criminal charges and indictments for corruption in healthcare, as well as the fact that that between 1st January 2010 – 5th March 2013, only one final conviction for corruption in the health sector was adopted.

In addition, the Medical Chamber hasn't revoked, either temporarily or permanently, license to any physician. There are no documented cases of suspension of the health practitioner, not even of those workers who were indicted.

For successfully fighting against corruption in the health care sector, as well as in the process of providing health care services, it is necessary to more effectively identify and punish cases of informal payments, bribery and corruption, and to improve and properly implement established anti-corruption mechanisms, especially in the field of quality control of health care, implementation and monitoring of the system of defining of waiting lists, system of financial motivations of health workers, strengthening of human resource capacity in areas where health workers are primarily burdened with too many requests and overtime working hours, promotion of disciplinary sanction of violations of codes of ethics, strengthening the independence of Ombuds-

man for patient's rights and raise public awareness of the rights of patients, as well as providing greater participation of users of health services and the civil society in decision-making process in health care system.

In relations between healthcare and pharmaceutical sector, and in process of supplying with medicines and medical devices, it is necessary to: adopt lacking bylaws, provide public accessibility of all relevant information, prescribe clear and transparent criteria on the basis of which would be based placement of medicines on essential/positive list, strengthen department of pharmaceutical inspection, restrict and regulate interactions among medical staff and pharmaceutical companies, as well as to conduct effective monitoring and control in order to diminish possibility of abuses and various kinds of informal influences on decision making process in healthcare and pharmaceutical sector.

Also, in the area of public procurement in healthcare sector, this policy study proposes series of measures, implementation of which would significantly decrease risks of corruption. In this sense it is recommended to: clearly define services and goods, which are mandatory subject to the Law on Public Procurement; to additionally clarify the procedure of integration of private service providers into the Network of healthcare Institutions; to create publicly accessible databases of providers of medicines and medical devices, with price ranges; to strengthen function of the internal audit and to make accessible results of the audit to all interested parties

Finally, we consider that the main precondition for suppression of corruption at all levels of healthcare sector is the strong political will, as well as systematic and more serious approach of healthcare officials to identification of problems and creation and implementation of anti-corruption measures in this area.

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REPORT ON THE IMPLEMENTATION OF THE NATIONAL ACTION PLAN AND SECTOR ACTION PLAN FOR FIGHT AGAINST CORRUPTION IN THE AREA OF HEALTH CARE SECTOR

Introduction

Within the project “Fight against corruption in the health care sector of Montenegro”, supported by the Embassy of the Federal Republic of Germany, the Centre for Monitoring and Research has created the report on implementation of the strategic framework for fight against corruption in the health care sector.

Strategic Framework for the Fight against Corruption and Organized Crime consists of the Strategy for the Fight against Corruption and Organized Crime 2010 - 2014, the Action Plan for the Implementation of the Strategy for the period 2010 – 2012 as well as the innovated Action Plan for the Implementation of the Strategy for the period 2013-2014. The Action Plan for Fight against Corruption in the Health Care Sector was adopted in 2009.

This report is the result of the six months long monitoring of implementation of the Action Plan for Fight against Corruption and Organized Crime in the area of health care, as well as the Sector Action Plan for Fight against Corruption in the health care sector. In the period December 2012 – May 2013, CeMI has conducted the monitoring and evaluation of both action plans, through sending requests for free access to information to institutions responsible for its implementation and through the interviews with decision makers and medical staff in those institutions. In the mentioned period published are 24 interviews and 31 requests for access to information were sent. The implementation of each measure was assessed quantitatively - using indicators listed in the action plans, and qualitatively - from the viewpoint of the quality of the implemented measure and its impact on the implementation of the required goals.

The institutional framework for monitoring of the strategic documents includes the National Commission for monitoring of the implementation of the Action Plan for the Implementation of the Strategy for Fight against Corruption and Organized Crime, and the same is consisted of representatives from the judiciary, authority and the Parliament of Montenegro, as well as representatives of NGOs: CeMI and MANS.

Implementation of the Sector Action Plan is controlled by the Ministry of Health, which in this three-year period adopted six semiannual reports. The aim of this report is not to repeat the findings of these bodies, but to objectively assess the implementation of strategic documents and their effectiveness.

2. The National Action Plan for Fight against Corruption and Organized Crime – Health Care Sector

It should be noted that the objectives and measures recognized through the National Action Plan as the key for fight against corruption in the health care sector, are quite generally defined, which creates a barrier to clearly locate problems and define precise and effective indicators based on which the possible progress in the fight against corruption in the health care sector could be adequately measured. The part of the National Action Plan focusing on health care sector remained limited to the area of protection of patients' rights, while other areas of the health care sector which are vulnerable to corruption - such as public procurement of medical equipment and supplies, registration and distribution of medicines, management of funds – remained unaddressed by this document.

2.1. The required goals

The objectives set in the National Action Plan, in the part that treats health care sector, are following:

- 1. Implementation and control of the implementation of code of ethics;**
- 2. Improving administrative and institutional capacities in the area of public health, as well as quality of health care services, patients' safety and equal access to health care;**
- 3. Limited engagement of health care workers, in both, public and private sector and curbing of illegal payments for health care services;**
- 4. Transparency of public procurement in the area of health care sector and achieving an adequate degree of control;**

5. Monitoring of the Sector Action Plan and its alignment with the National Action Plan.

2.2. Foreseen measures and degree of implementation

Within the **first goal** foreseen are measures of **providing training on application of the Code of Ethics**, as well as **monitoring of compliance of the Code of Ethics**. All of these measures were not implemented on time by the end of the fourth quarter of 2012 year.

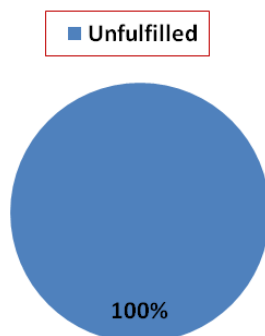
In the report of the Ministry of Health submitted to the National Commission for the Implementation of the Strategy for Fight against Corruption and Organized Crime is stated that the Code of Ethics of health care workers constitutes acceptance and adherence of the Hippocratic Oath as part of their professional competence, which they gain after the completion of the Faculty of Medicine and represents mandatory ethical principles on which the work medical profession is functioning. The Ministry of Health states that for these reasons it is not necessary to conduct training on the implementation of the provisions of the Code of Ethics. However, the “Code of ethics and deontology of health care workers”, foreseen by the Action Plan, was adopted, and not related to the Hippocratic Oath. Accordingly, the measures from the Action Plan have not been implemented and trainings on application of the provisions of the “Code of ethics and deontology of healthcare workers” were not organized, any disciplinary action was not fully implemented, neither the monitoring was performed to determine the number of possible medical workers who violated aforementioned Code of Ethics. It is also important to note that the “Code of ethics and deontology of health care workers” is not available on the website of the Medical Association and the Ministry of Health, or the site of any other public health care institution²³⁴. Therefore, we conclude that citizens, users of health care services are not allowed to access the content of the Code of Ethics of health care workers. All this indicates deficiency that prevents users of health care services to clearly identify the responsibilities of health care workers who would have to comply with it, and to recognize when their rights as patients are compromised.

²³⁴ Application of the Code of Ethics of health care workers is under the responsibility of the Medical Association of Montenegro, and therefore we send to it the request for access to information (February 15, 2013) where we were asking for the submission of the Code of Ethics of health care workers. Requested Code of Ethics, even after urgings (March 11, 2013) for submission of the same, we have not received.

None of the defined indicators within the proposed measures from the first goal (the number of trainings/number of participants, number of procedures and number of medical professionals who have violated the Code of Ethics) is fulfilled.

Degree of implementation:

Goal1: Implementation and control of the implementation of the Code of Ethics



Within the **second goal** foreseen are **measures of introduction of IT systems in the health care institutions in order to improve and control data and determination of procedures for placement on waiting lists for medical intervention.**

The first measure is not fully implemented on time by the end of the fourth quarter of 2012. IT (ICT) support was introduced in 18 health care centers, 7 general hospitals, Healthcare Insurance Fund, Institute for Public Health and Pharmacy of Montenegro "Montefarm".²³⁵ Since the beginning of 2009 in the health care system of Montenegro, at the primary level, is being applied an electronic prescription, electronic referral, electronic remittances of sick leave and fully electronic invoicing at the level of primary health care protection. This means that all processes of work in the health care center are IT supported. It is noted from the above that the IT system was not introduced in three special hospitals, or in the Clinical Center of Montenegro, the largest health care institution. Considering that special hospitals and Clinical Center of Montenegro are not yet part of this system, it is a considerable gap in the analysis and assessment of the functioning of all the subjects of the health care

²³⁵ Information on the number of health care institutions where was introduced IT (ICT) in the period since 2009, we have received upon the Request for access to information addressed to the Ministry of Health (February 15, 2013)

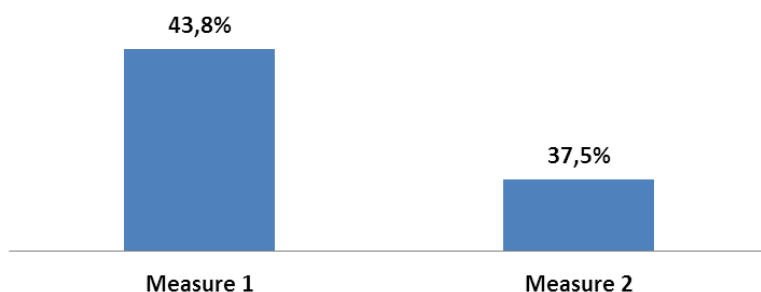
system and in improving the quality of health care protection and monitoring of quality of work in mentioned health care institutions that yet have not been integrated into the IT system.

Second measure also is not fully implemented. Identified are waiting lists for cardiac surgeries, for interventional cardiology, radiotherapy, neurology (EMG), as well as for hip surgery and eye surgery.²³⁶ Namely, the waiting lists are introduced to some procedures which cover only a part of provided medical services. Besides that the waiting list system was not fully implemented, also there is no clear procedure that would determine the waiting lists, and the system which determines the urgency and ranking on the relevant waiting lists is not transparent.

Based on the above mentioned degree of implementation of foreseen measures that are related to the second goal, it can be concluded that from the six indicators (number of institutions which has introduced IT; report on the effects of the work of IT systems; established and published procedures; the number of established waiting lists according to established procedures; regularly updated and available lists on the website of the MH; the number of interventions in line with the waiting list), none was implemented fully. In other words, the implementation of these measures is not completed, which indicates to the necessity of intensive work in order to implement them, especially when it comes to transparency and daily updating of relevant waiting lists.

Degree of implementation:

Goal 2: Improving administrative and institutional capacities in the area of public health, as well as the quality of health care services, patients; safety and equal access to health careprotection



²³⁶ Information about the updated waiting lists in the period since 2009, we have received upon the Request for access to information addressed to the Ministry of Health (February 15, 2013)

Within the **third goal** foreseen are **measures of adoption of the bylaws for implementation of the Law on Health Care Protection and the Law on Protection of Patients' Rights, measures of implementation of activities in order to raise awareness on the patients' rights and analysis of results of the national survey on corruption in the health care sector.**

The first measure was not implemented in the foreseen timeline until the end of the fourth quarter of 2012. The Regulation on supplementary work of the health care workers within the network of health care institutions ("Official Gazette of Montenegro", no 9/11, February 8, 2011) and Regulation on criteria for signing the contract on providing health care services ("Official Gazette of Montenegro", no 9/11, February 8, 2012) are adopted. By-law Act related to the Law on the Protection of Patients' Rights from 2010, has not been passed, which is an obstacle for the effective implementation of the Law on the Protection of Patients' Rights.

Second measure is to a significant degree implemented. Within the campaign on patients' rights implemented are media appearances on Radio of Montenegro in the show "Radio Practice" and on Radio Antena M, in which the representatives of the Ministry of Health spoke about the quality of health care and patients' rights, as well as the fight against corruption in the health sector. Nine national clinical practice guidelines are developed for the most common diseases in Montenegro. The Ministry of Health has supported the campaign "Not a penny for a bribe." Directorate for Anticorruption Initiative has produced 1000 leaflets, which were distributed to all public health institutions in Montenegro. Also published are two articles on the Law on Patients' Rights (journal "Medical" no January 2011, daily "Pobjeda"), numerous articles in the electronic and print media about the activities, methods and measures for fighting corruption. The hotline at the Ministry of Health 0800 81 444 for reporting suspicion of corruption was promoted. Boxes for complaints of patients (including the report of corruption) are set in all public health care institutions, appointed are protectors of patients' rights in all public health care institutions starting to work on January 01, 2011. Namely, certain improvement is achieved when it comes to promotion of patients' rights and problem of the topic of corruption in the health care system.

Third measure related to analysis of the results of the national research on corruption in the health care sector is partially implemented. Recommendations from the mentioned research are integrated in the "Strategy for optimization of the secondary and tertiary level of health protection", and are related to the following recommendations:²³⁷

²³⁷ Information on number and type of recommendations which are developed based

Change of the system of paying of medical staff;

Introducing the control and ensuring the quality of health care services;

Participation of medical and local community in the estimation of the achieved performance;

Launching a campaign aimed at changing the existing culture/tradition on the need that to than for the medical care is expressed by giving gifts;

Launching information campaigns about the positive changes that occur as a result of the reform at the hospital level, in order to contribute to raise awareness of patients about their rights and build trust in the health care system.

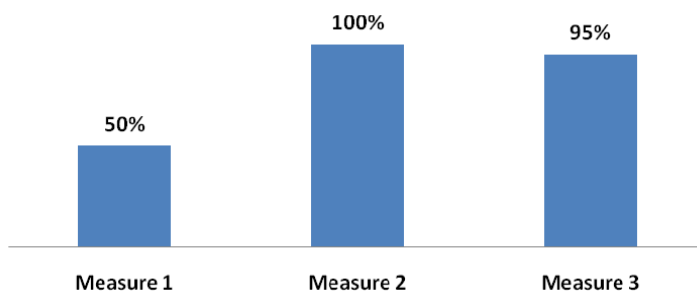
From the above mentioned five recommendations, it is necessary to work especially on the third, it is necessary to include medical staff, local communities and civil society in the whole process of monitoring the reforms of the health care system, as well as the evaluation of achieved results. As for the rest, the above mentioned recommendations, they are being implemented, and in order to achieve a quality performance their implementation must be continuous.

Based on the analysis of the fulfillment of measures within the third goal, and having in mind the indicators which measure the success of implemented measures (number and name of needed by-laws; number of adopted by-laws; number of conducted info campaigns; number of TV shows/ developed brochures available to patients in health care institutions; analysis of results of the national research with recommendations; number of implemented measures) could be concluded that the most of indicators was implemented to a satisfactory extent. However, campaigns focused to the users of of health care services must be represented with the evident results in order to improve patients' awareness on their rights.

on results of the national research on corruption in health care sector we received upon the request for access to information addressed to the Ministry of Health (February 15, 2013)

Degree of implementation:

Goal 3: Limited work of health care workers in both public and private sector and curbing illegal payments for health services



Within the **fourth goal** foreseen is **measure of submitting of the report on public procurement**. This measure is implemented. All public health care institutions have submitted to the Ministry of Health the report for 2011. Namely, all public institutions as obligatory to enforce the Law on Public Procurement are obliged to submit to the relevant authority the report on public procurement no later than end of February concluded in the previous year. Public health care institutions also submit the mentioned reports to the Ministry of Health, and accordingly they submitted the reports for 2009, 2010 and 2011.

The reports that the PHI submit to the Directorate for Public Procurement include data related to the contracts concluded and implemented public procurement procedures. The data is related to: the number of public procurement procedures by types of procedures, the largest contraction authority and suppliers, the most common basis for the implementation of the negotiated procedure without prior publication of a tender, the number of submitted requests for approval for the implementation of the negotiated procedure without prior publication of a tender, the number of applicants who meet the requirements for the implementation of the negotiated procedure without prior publication of a tender, the number of rejected requests, the average number of bids per tender etc. However, information concerning the number of canceled tenders, the number and type of complaints to the relevant tender, number and type of recorded violations of anti-corruption policies, are not included in the above reports.

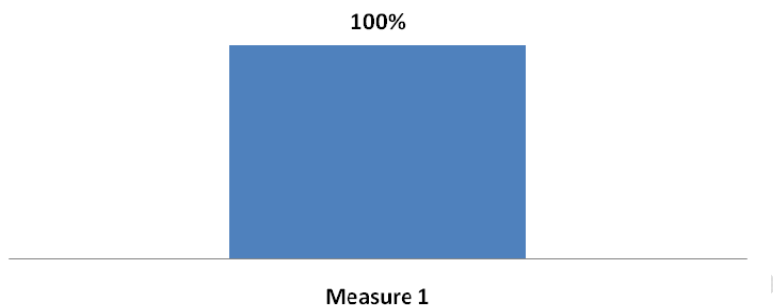
It is important to point out that according to the Law on Public Procurement every PHI is obliged to submit to the Directorate the report on implemented public procurement as well as the plan of public procurement for the current year. Based on a detailed analysis of both documents, it is possible to detect

irregularities and discrepancies in the management of the resources available to health care institutions. Directorate for Public Procurement has no competence to audit and for inspection of the implementation of the public procurement is responsible the Inspection for Public Procurement, which is now part of the Inspection. The mentioned inspection for public procurement, with a total of one inspector, does not have the capacity to perform their duties in an appropriate manner, and this indicates a minor number of detected irregularities and imposed sanctions. Problems that are not treated with the measures proposed in the Action Plan are related to the legislative of the emergency of procedure of public procurement of medical products (medical devices and medicines), the locked tender specifications, the monopolistic position of individual suppliers, and lack of competition.

From the above it can be concluded that the above-mentioned measure (although implemented because the indicator relating to the submission and publication of the annual report on public procurement in the health sector is fulfilled) is not sufficient to provide the necessary level of transparency of public procurement in the area of health care and attained an adequate degree of control.

Degree of implementation:

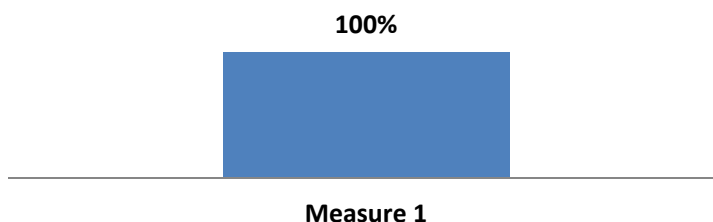
Goal 4: Transparency in the public procurement in the area of health care and achieving of adequate degree of control



Within the **fifth goal** foreseen is the measure of publishing the Report on implementation of the Sector Action Plan in the area of health for the period **III Q 2011 to IV Q 2012**. Mentioned measure is implemented. Semiannual report for the period January – June 2012 was prepared and submitted. The National Action Plan was innovated in May this year, and until the end of the year is expected an innovation of the Sector Action Plan, after what it could be considered its compliance with the main strategic document.

Degree of implementation:

Goal 5: Monitoring of the Sector Action Plan and its compliance with the National Action Plan



3. The Sector Action Plan for Fight Against Corruption in the Area of Health

The Sector Action Plan that addresses the issue of corruption in the health sector was adopted in 2009. Implementation of the measures from the mentioned plan is foreseen for the period 2009 - 2013. Some of the measures from the Sector Action Plan are taken from the National Action Plan, and as we analyzed above the degree of implementation of the measures from the National Action Plan, in this section will be displayed only measures from the Sector Action Plan that are not found in the National Action Plan.

3.1. The required goals

Goals that are defined in the Sector Action Plan are the following:

Improvement of the legal and institutional framework for effective and systematic fight against corruption;

Recognition and respect of patients' rights in the areas defined by the law;

Improvement of professional skills of health care workers and raising awareness on the importance of continuous quality improvement of health care protection and development of specific knowledge and skills in order to the balanced approach to quality treatment;

Creating conditions that promote a culture of continuous improvement of quality of health care protection and patients' safety in the health care institutions;

Providing safety, security and profitability of health technologies;

Providing financial incentives for continuous improvement of the quality of healthcare protection and patients' safety.

3.2. The foreseen measures and degree of implementation

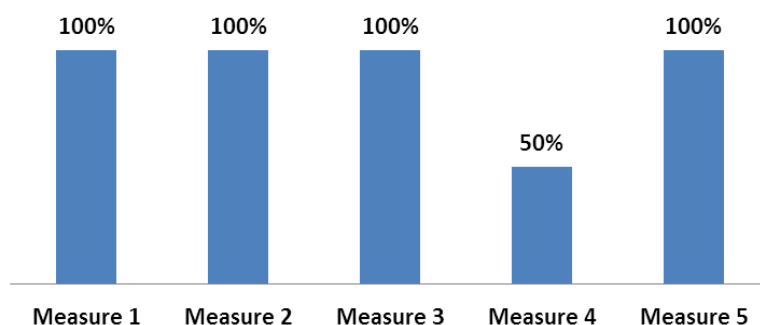
Within the **first goal** defined are the following measures: 1 Development and adoption of the Action Plan by the Government of Montenegro, 2 Amendments to the Law on Health Protection, 3 drafting of the Law on the Protection of Patients' Rights, 4 Adoption of by-laws for the implementation of the Law on Health Protection and the Law on the Protection of Patients' Rights, 5 establishment of a new sector for the quality control within the Ministry of Health.

Measures 3 and 5 are not provided by the National Action Plan, why we will analyze it here detail. The Law on Amendments to the Law on Health Protection and the Law on Protection of Patients' Rights is adopted; however, by-laws have not been passed, leaving many questions about the position of the Protector of patients' rights, terms of complaints, as well as their proceedings.

Within the Sector Action Plan is defined the establishment of the special body work of which would improve the quality of the health protection. Namely, the Law on Health Protection specifies the work of the Commission for control of the quality of health protection, and same is appointed in all public health care institutions. The law provides that the Commission shall perform the following: Monitoring and evaluation, proposing to the Director measures to improve the quality of the work in the health care institution, giving to the director opinions and proposals on the organization of work and conditions for development of health care activities, planning and implementing anti-corruption measures and other measures determined by the statute of health institution. Commission members are appointed by the Director of health institution. As already mentioned, the Commissions for control of the quality of health protection are available in all health institutions, but are not active in the planning and making decisions on anti-corruption measures. This is due to a misunderstanding of the fact that the fight against corruption increases the quality of health care services, and they are more committed in their work to other matters within its jurisdiction. For these reasons it is necessary to oblige commissions and protectors of the patients' rights to report on the implementation of anti-corruption measures.

Degree of implementation:

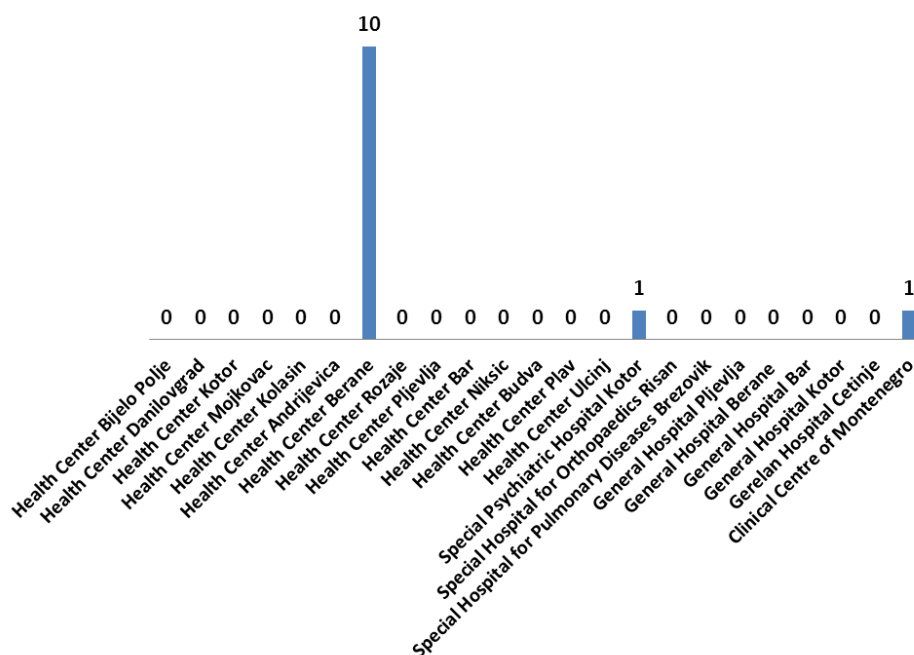
Goal 1: Improvement of the legal and institutional framework for the efficient and systematic fight against corruption



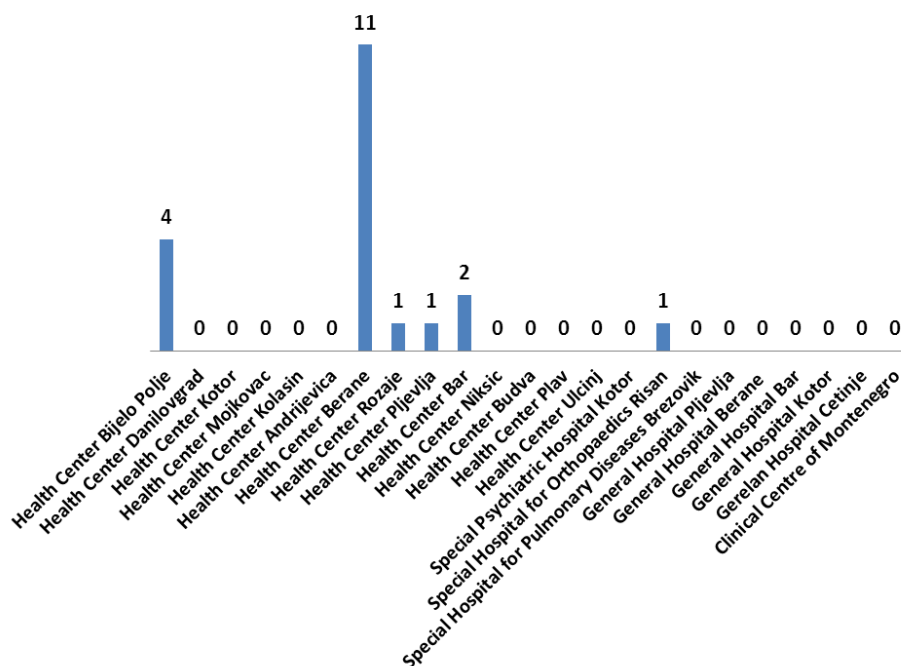
Within the **second goal** foreseen are 1. Activities focused on organization of campaigns aimed to raising awareness of the public on the patients' right and measures which could be implemented in order to combat corruption as well as conducting researches and 2. Analyzing the results on satisfaction of users provided with the health services. Considering that the second measure is included in the Action Plan, and that we have already talked about it, here will be analyzed only implementation of the first measure. Indicators (number of TV shows, brochures made available to patients in health care institutions, introduced systems for patients' complaints - complaints boxes in health care institutions, the number of disciplinary actions undertaken on the basis of complaints of citizens), based on which implementation is measured the degree of mentioned measure, are significantly harmonized with the indicators from the National Action Plan. Namely, implemented is only the certain number of campaigns which were aimed at raising awareness of citizens on patients' rights, in all public health institutions are set complaints boxes (including the reports on report on corruption cases) and appointed are protectors of the rights of patients. It is important to note that the number of disciplinary proceedings conducted on the basis of patients' complaints, the protector or the Director of Health Institution, is minor.²³⁸

²³⁸ Request for access to information addressed to health care centers, genral and special hospitals, and we got the information on the number of sunctions imposed upon the complaints of the patients, Protector or Director of the health care institution, for 2010, 2011 and 2012.

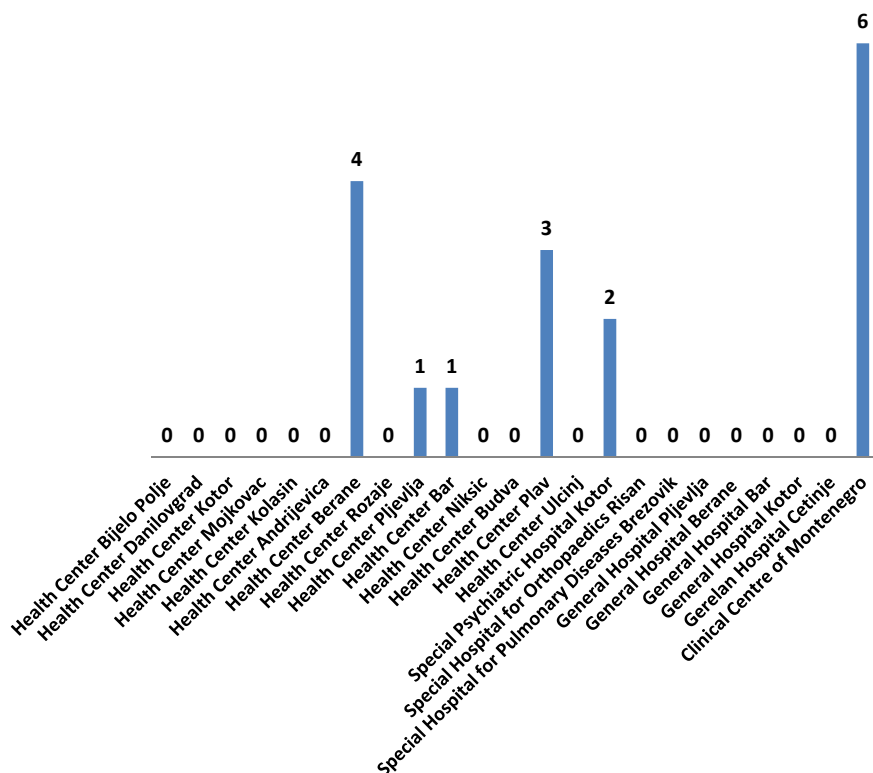
■ Number of of sanctions imposed on the patients' complaints in 2010



■ Number of sanctions imposed on the patients' complaints in 2011

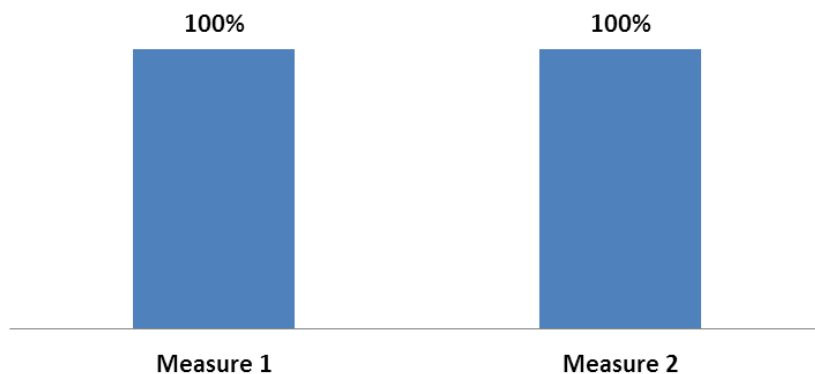


■ Number of sanctions imposed on patients' complaints in 2012



Degree of implementation:

Goal 2: Recognition and respect of patients' rights in the areas defined by the law



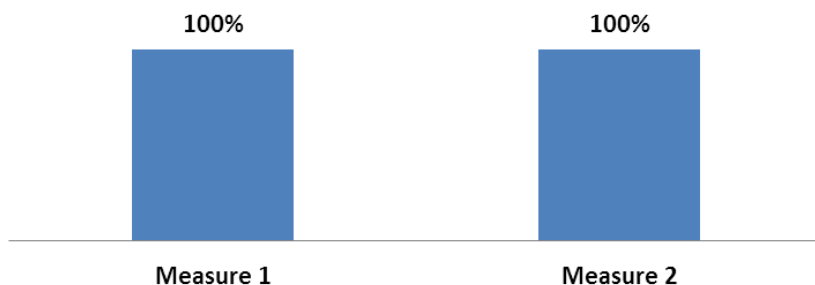
Within the **third goal** foreseen are the following two measures: 1. Development of professional norms and standards which improve the quality of the work and patients' safety; 2. Development of protocols, guides and clinical guidelines for improvement of the quality of health care protection.

When it comes to the second measure – development of professional norms and standards, it is referred to the Code of Ethics of health care workers, so the same measure is defined by the National Action Plan.

Second measure related to development of guide and clinical guidelines is implemented because national guidelines of a good clinical practice are developed: Acute ischemic stroke, hypertension, Hand hygiene, Medical treatment of chronic cancer pain, prevention of cardiovascular disease, rational use of antibiotics, sepsis and septic shock, Schizophrenia, laboratory diagnostics in clinical bacteriology, treatment of acute myocardial infarction with ST elevation (STEMI).²³⁹ Guidelines are published on the website of the Ministry of Health, and representatives of the Fund for Health Care Insurance have posted published guidelines on the personal PCs of selected doctors.

Degree of implementation:

Goal 3: Improvement of professional skills of health care workers and raising awareness on the importance of continuous quality improvement of health care protection and development of specific knowledge and skills in order to the balanced approach to qua



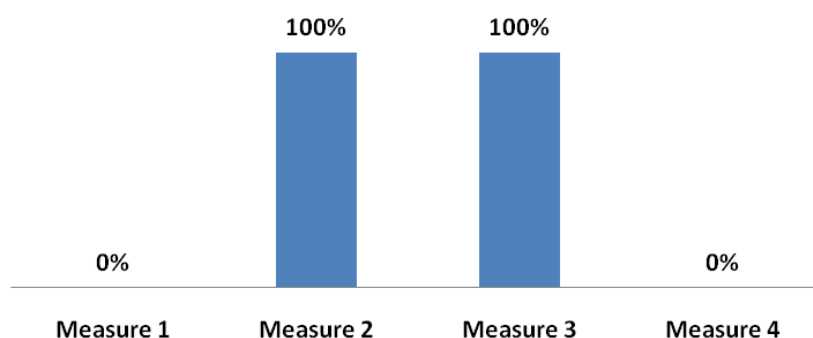
Within the **fourth goal** the following measures are defined: 1. monitoring and analysis of contrary events and implementation of corrective measures at the level of health care institution; 2. Introduction of information and communication technologies in health care institutions in order to improve and control

²³⁹ Information on the number and type of good clinical practice we got upon the Request for access to information addressed to the Ministry of Health (February 15, 2013)

the quality of data and indicators of the quality of work; 3. determination of procedures and interventions for placement on the waiting list; 4. daily update of waiting lists which are available on the website of the Ministry of Health. Only the first measure was not foreseen by the National Action Plan, and it is related to monitoring and analysis of undesirable events and implementation of corrective measures at the level of health care institution. Relevant ministry with the Public Health Care Institution is implementing the mentioned activity, however the Ministry of Health is not familiar with the number of analysis and reports created based on the results of monitoring of undesirable events at the level of all health care institutions. Also, the Ministry of Health does not have the information on the number and type of corrective measures implemented in order to reduce undesirable events in the health care system.²⁴⁰

Degree of implementation:

Goal 4: Creating conditions that promote a culture of continuous improvement of the quality of health care and patients' safety in health care institutions



Within the **fifth goal**, defined are measures that are not recognized by the National Action Plan, and include: 1. prioritization of medical equipment and investments in health care institutions; 2. development of a good practice guidelines; 3. review of public procurement systems in health care institutions in order to identify potential corruption risks: submission of annual reports on public procurement in the health sector to the Ministry of Health.

The first measure was not implemented. On the website of the Ministry of Health, as provided in the Sector Action Plans, there are no defined priorities for the purchase of medical equipment, which speaks about the problem of

²⁴⁰ Request for access to information addressed to the Ministry of Health on February 15, 2013.

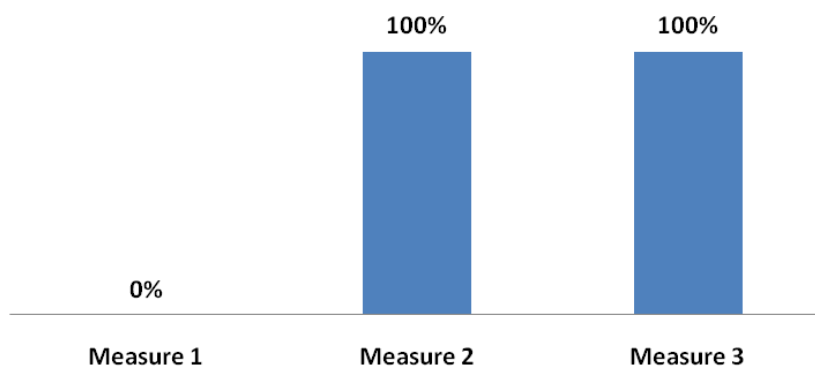
poor planning and management of available resources, as well as the problem of overestimated amount or quantity of public procurement of medical products. Timely initiation of planning is a precondition that there is no urgent requirement of public procurement which is particularly vulnerable to the risks of corruption. It is necessary to harmonize the principle of legality and the principle of efficiency in the planning phase and during the implementation of public procurement procedure.

The second measure, although defined by the National Action Plan includes a new indicator of success - the submission of a report on the quality of public procurement and its publication on the website of the Ministry of Health. This report would significantly contribute to the assessment of deficiencies in the system of public procurement and present basis for their improvement. However, this report is not prepared, what indicates the lack of analysis of the efficiency of public procurement in the health care sector and possibilities for its improvement.

The third measure, development of guides to good practice is implemented, since there are developed guidelines to good clinical practice and distributed to all public health institutions, and the same are published on the website of the Ministry of Health.

Degree of implementation:

Goal 5: Providing safety, security and cost-effectiveness of health technologies



Within the **sixth goal** defined are the following measures: 1. Pharmacoeconomic monitoring and research of therapeutic programs; 2. introduction of quality indicators as criteria for signing contracts between the Healthcare Insurance Fund and health care institutions; 3. financial incentives for health care workers and associates.

The first measure was not implemented.²⁴¹ The Agency for Medicines and Medical Devices does not have the report on the pharmacy-economic monitoring and research of therapeutic programs. Lack of the mentioned report the Agency has justified in a way that indicated their jurisdiction in accordance with the Law on Medicines, in the sense that it is responsible for collecting and processing data on trade and consumption of medicines, which is certainly not a reason for inaction within activities foreseen by the Action Plan.

Second measure within this goal is fulfilled to a larger extent. Namely, the Regulation on criteria for signing the contract on providing health care services and way of paying for health care services ("Official Gazette of Montenegro", no 09/11) issued by the Ministry of Health, defines the criteria under which the Fund signs a contract with service providers. The Healthcare Insurance Fund has signs the contract on providing health care services with the following health institutions: 18 health centers for providing health care services on a primary level of a health protection, 7 general hospitals, for providing specialist consulting and hospital health care, General hospital Meljine, 169 private dental clinics, to provide dental care in all municipalities in Montenegro, the Institute dr Simo Milosevic, for providing specialized medical rehabilitation, Pharmacies Ltd. Galenika Montenegro, in terms of providing drugs to insured persons on prescription, 13 private health care institutions for providing specialist consultation and diagnostic services in the following areas: ophthalmology, cardiology, echo and x-ray diagnostics, health protection in the treatment of assisted reproductive technologies (IVF fertilization), etc²⁴².

The third measure related to the financial incentives of health care workers and associates is not implemented in the way specified by the Sector Action Plan. Namely, the Ministry of Health and Healthcare Insurance Fund are designated for implementation of activities. However, the Ministry of Health, sector institution of health policy, does not have the information on the number of awarded health care workers and associates, and thus provide the report on the number of awarded²⁴³.

²⁴¹ The request for access to information we have sent to the Agency for Medicines and Medical Devices (February 15, 2013), in which we asked for the submission of the report on pharmaco-economic monitoring and research. By the Sectoral Action Plan, the Agency is anticipated as the implementator of activities – pharmaeconomic monitoring and research of therapeutic programs. The requested report was not submitted to us, because the Agency does not have in its possession.

²⁴² Information on the number of signed contracts between the Fund for Health Insurance and health care institutions in the past 4 years that we got upon the requests for access to information addressed to the Fund for Health Insurance (February 15, 2013)

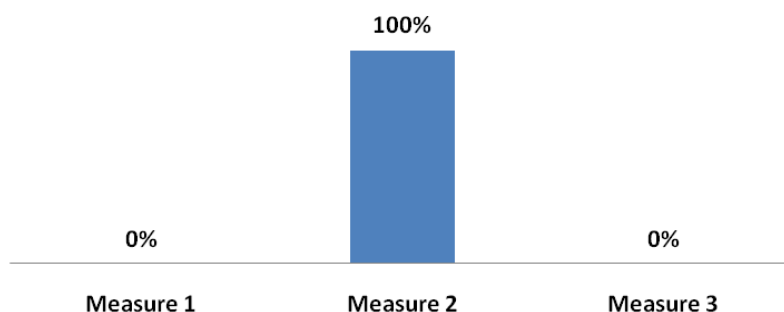
²⁴³ Requirement has been requested in order to provide information on the number of

The criteria that must be met in order to gain right to rewarding health care workers and associates is regulated by the Sector collective agreement for health care services (Official Gazette no. 11/12). This collective agreement provides that the salaries of employees in the health care facilities increase based on: science degrees, professional titles and mentoring, as well as to increase salaries based on a scientific or professional positions. The results of work are determined by the employer in accordance with the general act of the institution. Employees who during the month exercise results of work in the scope and quality of the above of average or planned, has the right to increased salary up to 15% in proportion to the achieved results, and financial means to exercise this right are 1.85% of the salary planned by the Budget for Public Health Care Institutions. The funds are allocated according to the criteria established jointly by the employer and representatives of the trade unions.²⁴⁴

The issue of financial incentives is regulated by the Sector Action Plan, but to make results evident, each of the measures must be implemented primarily procedure of rewarding health care workers must be transparent and based on objective indicators.

Degree of implementation:

Goal 6: Providing financial incentives for continuous improvement of the quality of healthcare protection and patient's safety



awarded health care workers and associates in order to their financial incentives in the period since 2009.

²⁴⁴ Information on the type of criteria that must be met in order to gain the right on rewarding a health care workers and associates we got upon the requests for access to information addressed to the Fund for Health Insurance, because based on the Sectoral Action Plans the Fund is set as the carrier of activities - introduction of quality indicators as criteria for signing the contract between the Fund for Health Insurance and health care institutions.

Conclusion

In summary, the Sector Action Plan discusses areas in which there is no basis for the occurrence of corrupt actions, such as the signing of a contract between the Healthcare Insurance Fund with health care institutions, methods and criteria of rewarding of health care workers, the profitability of the respective public procurement and similar.

However, the Sector Action Plan does not address adequately the areas of the health system that are most vulnerable to corrupt actions, such as the registration and distribution of medicines and public procurement. Although the issue of public procurement is included in this Action Plan, issues of urgent public procurement, locked specification, the relation between price and quality, the question of preferred suppliers are not even discussed, for which, based on the research that will be presented in the policy study on this topic, we conclude that are burning issues of the health care system of Montenegro.

The National Action Plan for the Fight against Corruption in the Health Care Sector should present a main document, while the Sector Action Plan should develop in details common goals and measures of this plan. However, the Sector Action Plan, to the greatest extent, is overtaken part of the National Action Plan, with minor additional measures.

We suggest when writing a new Sector Action Plan for Fight against Corruption in Health Care Sector, to consult experts in the field of pharmacy-economics, public procurement and anti-corruption policies, in order to define plan contains concrete measures, clearer indicators and organizational units of institutions directly responsible for their implementation.

About the Centre for Monitoring and Research – CeMI

The Centre for Monitoring and Research – CeMI is a, nonprofit organization, founded in March 2000, whose main goal is to provide infrastructural and expert support for continuous monitoring of the overall process of transition in Montenegro.

During its long and consistent work CeMI has contributed to changing social and political circumstances in which it was created, and consequently expanded the scope of its work towards legislative initiatives, public opinion polls, fight against corruption and respect of human rights and freedoms. The change of the constitutional status and progress in the European integration process have positively impact the development of civil society in Montenegro, giving it an entirely new framework of the work. In that context, CeMI deviates from the work of regular non-governmental organization and is getting closer to the concept of a research center for the creation and representation of policy proposals.

CeMI, with the support by the OSI Think Tank Fund, Budapest, CeMI has restructured an internal organization in order to achieve optimal capacity utilization. Also the mission and vision of CeMI have changed in line with the newly established objectives.

CeMI organizes its work in three programs: (1) **Democratization and Human Rights**, (2) **Fight against corruption**, (3) **Security and Defense**. In this way, CeMI will limit its work on the areas where has a significant experience and within which the actions of our organizations are recognized.

CeMI also has three departments: Public Policy Research Department, Public Opinion Research Department, Legal Department as well as Service for Public Relations. These organizational units maintain continuity of operations and provide operational support for the implementation of projects.

Among numerous achievements of CeMI, we would like to point out following:

- CeMI is the first organization in Montenegro (and the region), whose four draft laws were adopted by the national Parliament.
- CeMI is one of the first organizations in Montenegro that deals with fight against corruption.

- CeMI is one of two civil society organizations which have their representative in the National Commission for the Fight against Corruption and Organized Crime.
- CeMI has so far, through its programs, implemented more than 70 different projects, supported by numerous donors.
- CeMI is the first organization in Montenegro, founded with the aim of election monitoring, and it has monitored vast majority of election processes in Montenegro since 2000.
- CeMI is one of the founding members of ENEMO (European Network of Election Monitoring Organizations).
- CeMI is one of founders of biggest NGO coalition in Montenegro „Strategy as Aim“ with almost 100 members.

CeMI is one of 10 organizations which have signed Memorandum of Understanding with EU Integrations Secretariat in 2007.

Vision: Montenegro as a country of free citizens, social justice, rule of law and equal opportunities.

Mission: CEMI is a Think Tank organization whose mission is to continuously provide support to process of democratic consolidation and europeisation of Montenegro.

Goals:

Contribution to the effective implementation of public policies and international commitments in the areas of human rights and freedoms of European integration and fight against corruption;

Contribution to harmonization of national legislation and institutional framework with the requirements of the EU accession process;

To improve awareness and educate public about human rights protection and freedoms, European integration and fight against corruption;

Contribution to improving the efficiency of the work of institutions involved in the protection of human rights and freedoms, European integration and fight against corruption;

Increasing the transparency of the institutions of political system and civil society organizations.

Users of CeMI are: citizens, civil society organizations, media, local governments, public administration and enterprises.



