Analysis of public procurement in the health sector

THIS PUBLICATION IS SUPPORTED BY THE MINISTRY OF THE INTERIOR OF THE CZECH REPUBLIC THROUGH THE PROMOTION OF TRANSITION PROGRAM. TRANSPARENCY INTERNATIONAL IN BIH AND TRANSPARENCY INTERNATIONAL IN THE CZECH REPUBLIC ARE RESPONSIBLE FOR THE CONTENT OF THE PUBLICATION WHICH DOES NOT REFLECT THE OPINION OF THE MINISTRY OF THE INTERIOR OF THE CZECH REPUBLIC IN ANY WAY.

December 2016

Introduction

This document has been produced as part of the project *Public Procurement in the Health-Care Sector: Education of Contracting Authorities,* which is jointly implemented by Transparency International in Bosnia and Herzegovina and Transparency International Czech Republic. The project is funded by the Ministry of Foreign Affairs of the Czech Republic through the Transition programme and implemented during 2016.

The aim of the project was to compare the rules and practice of public procurement in the health-care sector of the Czech Republic, as an EU member country, and Bosnia and Herzegovina, and to come to knowledge that would improve the public procurement process in the health-care sector in BiH, with special emphasis on procedures and processes for procurement of medical equipment as a distinct type of procurement. How to expedite procurement, as well as how to better define the conditions for participation in bids in order to provide quality medical devices, is a problem faced by both countries.

As part of the project a study visit to Prague was organised for representatives of the Agency for Medicinal Products and Medical Devices, the Health Insurance and Reinsurance Fund of the Federation of BiH and the Health Insurance Fund of the Republika Srpska. During the visit they had the opportunity to meet and share experiences with representatives of the Ministry of Finance of the Czech Republic, as well as representatives of several contracting authorities and bidders. Comparative analysis and a summary of the main conclusions and recommendations inspired by the study visit are given below.

Why the public health-care sector?

Corruption in the health-care sector can mean the difference between life and death. According to **Transparency International**, poor people are worst affected. Medical personnel can charge unofficial fees to attend to patients. Or they may demand bribes for medication which should be free. Or they may let patients who bribe them queue-jump. Corruption also costs lives when counterfeit medicines or equipment are sold to health-care facilities.

Without proper checks from regulators, public health funds can easily disappear.

World Bank surveys show that in some countries, up to 80 per cent of non-salary health funds never reach where they are intended. Ministers and hospital administrators can siphon millions from health budgets. This distorts health policies and denies people treatment, medicines and qualified staff. Stolen funds seriously hamper efforts to beat major health challenges, such as malaria and HIV/AIDS.

It is not only developing countries which suffer. Wealthy countries, too, lose millions each year to fraud and corruption.

Ensuring transparency seems to be the only possible way to overcome the problem.

Transparency International recommends that governments publish detailed health budgets and financial information that is easy to understand. Then we can track funds and prevent them from being stolen.

Also, health workers need adequate pay and guarantees that salaries will reach them. This makes them less susceptible to bribes or likely to demand them.

Governments need to tackle counterfeit drugs at source. This means cooperation between countries, involving customs, suppliers, medical institutions and the police.

At the local level, we all have an important role to play. We must demand accountability from health professionals and administrators. We can scrutinise clinic or hospital budgets. Or make sure that the general public is aware of official charges for services – so that nobody pays more. We must also demand public consultations over health services. These allow us to participate actively in planning and implementation.

Open public contracting systems, clear procurement processes and open tender procedures are also needed. By monitoring these, we can help ensure that health facilities give us the best possible care.[1]

[1] https://www.transparency.org/topic/detail/health

According to the Organisation for Economic Co-operation and Development (OECD), health represents 14% of total government spending on average in OECD countries. Health-care spending per capita has risen by over 70% in real terms in OECD countries since the early 1990s.[2]

A significant share of health care spending is done through procurement. Improved procurement strategies and processes provide the opportunity for better health services at lower cost.

Competitive tender procedures can bring down the prices of *generic medicines*, which in Europe can vary by as much as 300%.[3]

When it comes to *health-care services*, ensuring quality results when outsourcing healthcare services is a challenge for governments. Result-based criteria and performance-based payment are increasingly being explored by countries as a method to ensure high-quality delivery. The OECD supports countries in public procurement of health-care services and provides practical recommendations on strengthening market knowledge and structuring procurement processes.

Building, maintaining and operating good *health-care infrastructure*, whether hospital, medical centres or other health care-units, is crucial to the provision of good health-care services for citizens. Analyses have found that infrastructure can take up a large part of the budget of health-care providers. For that reason, public contracts for health-care infrastructure should be tendered and awarded competitively. The OECD Recommendation for Enhancing Integrity in Public Procurement provides guidance on procurement processes and safeguards.[4]

The Open Government Partnership (OGP)[5] formally launched on 20 September 2011 as a platform for the 21st-century democracy. It is a multi-stakeholder initiative that aims to secure concrete commitments from governments to promote transparency, empower citizens, fight corruption and increase access to new technologies to improve governance. From the initial eight founding countries, OGP community has now expanded to include a total of 75 participating countries that have made over 2,500 commitments in their action plans to make their governments more open and accountable. Bosnia and Herzegovina, as an OGP member, is currently developing its first action plan. The four Partnership Pillars that are assessed for a country to be eligible to join the Partnership are:

[2] http://www.oecd.org/gov/ethics/procurement-healthcare.htm

[3] According to the Mexican Institute for Competitiveness, the Mexican Institute for Social Security saved 20 million euros in procurement spending on medicines in 2011 as a result of the OECD recommendations to improve its procurement procedures.

[4] http://www.oecd.org/gov/ethics/Recommendation-on-Public-Procurement.pdf

[5] Open Government Partnership, http://www.opengovpartnership.org and http://ogp.ba/

1. Fiscal Transparency (eligibility criteria are based on scores awarded for publication of two essential documents, namely Executive's Budget Proposal and Audit Report, and use of indicators from the Open Budget Index, conducted by the International Budget Partnership);

2. Access to Information (an access to information law in place serving as an essential means for achieving the spirit and practice of open government);

3. Public Officials Asset Disclosure (accessibility of data on income and assets of senior public officials as a vital prerequisite for anti-corruption and open, accountable government); and

4. Citizen Engagement (openness to citizen participation and engagement in decision-making, in particular with regard to the protection of basic civil liberties).

Budget openness and the application of the open contracting principle (which, in addition to public procurement, applies to other contracts concluded by the public sector with the private sector – privatisation, concessions, etc.), according to which information is available for the entire public procurement cycle, certainly constitutes a good platform for the health-care sector too.

Adding to all this are the increasing demands by voices around the world to bring the issues of poverty, inequality and climate change to the foreground. To turn these demands into actions, world leaders gathered on 25 September 2015 at the United Nations in New York to adopt the 2030 Agenda for Sustainable Development. The 2030 Agenda comprises 17 new Sustainable Development Goals (SDGs), as follows:

1. No poverty
2. Zero hunger
3. **Good health and well-being**
4. Quality education
5. Gender equality
6. Clean water and sanitation
7. Affordable and clean energy
8. Decent work and economic growth
9. Industry, innovation and infrastructure
10. Reduced inequalities
11. Sustainable cities and communities
12. Responsible consumption and production
13. **Climate action**
14. Life below water
15. Life on land
16. Peace, justice and strong institutions
17. Partnerships for the goals

Therefore, the concept of ***Green Public Procurement (GPP)*** is gaining increasing traction in the field of health. Green Public Procurement is a process whereby public contracting authorities seek to procure environmentally friendly goods, services and works, thus making an important contribution to sustainable consumption and production.

While green procurement is still a voluntary instrument, it has a key role to play in the EU's efforts to become a more resource-efficient economy. It can help stimulate a critical mass of demand for more sustainable goods and services. Also, it has an added value in that it provides a strong stimulus for eco-innovation.

To be effective, GPP requires the inclusion of clear and verifiable environmental criteria for products and services in the public procurement process. The European Commission and a number of European countries have developed guidance in this area, in the form of national GPP criteria. The challenge of furthering take-up by more public sector bodies so that GPP becomes common practice still remains.

"The idea of transparency will only become more important. Suppliers and hospitals around the world will be held accountable for impacts throughout the lifecycle of a product – from where it is produced and how it is used in the delivery of care, to how it is treated at end of use."[6]

Public procurement in Bosnia and Herzegovina – general overview

The first single state-level Public Procurement Law (PPL) in Bosnia and Herzegovina, enacted in 2004 as part of the harmonisation process with EU regulations, put the system in place and introduced the basic rules, obligations and responsibilities. However, over the following ten years reports by relevant international and national institutions and organisations pointed out failings, irregularities and corruption in all phases of the procurement process that undermined the basic principles of fair and active competition, transparency, equal treatment of bidders, and efficient and responsible public spending in BiH, as well as the need for incorporating the 2004 EU Directive on Public Procurement into BiH regulations.[7]

[6] Gary Cohen, President and Founder, Health Care Without Harm, an international coalition of sustainable health care advocates

[7] See the reports by Transparency International BiH: National Integrity System Study of 2013 and 2007, Monitoring the Implementation of the Public Procurement Law of 2012; reports by the Public Procurement Agency of BiH, the Agency for Prevention of Corruption and Coordination of the Fight against Corruption, the Audit Office of the Institutions of BiH, Federation of BiH and RS, etc.

This harmonisation did not happen until a decade later, with the adoption of the new Public Procurement Law in May 2014, and its entry into force on 28 November the same year.[8] This was followed by adoption of new and modification of some of the existing implementing regulations, which further elaborated specific issues. These implementing regulations stem from the Law and, in conjunction with it, constitute the foundation of the country's public procurement regulation system. According to the Public Procurement Agency, the Law has also resulted from the desire to eliminate bottlenecks that occurred in earlier practice and it makes the procedures more streamlined.

New EU rules on public procurement of 2014 (Directives 2014/24/EC and 2014/25/EC) have yet to be further incorporated into the BiH regulations, which is also the position of the European Commission[9] and the system's strategic objective as one of the most important areas for improvement.[10]

Overall, in some areas, the new PPL certainly represents an improvement over the previous one. However, some of its provisions have significantly undermined the public procurement system, primarily in the area of legal protection. In addition, the Law suffers from a number of other deficiencies, which have been pointed out by CSOs from the outset, as shown by the first official data on its implementation (2015 annual reports by the Public Procurement Agency and the Procurement Review Body).

Unlike the previous PPL, now the new one recognises and distinguishes between so-called classical contracting authorities and sectoral contracting authorities,[11] introduces modern instruments and techniques, defines exemptions in somewhat stricter terms, and includes a number of other novelties.[12]

The Law also expanded the mandate of the Public Procurement Agency – in cases where review procedure has not been initiated, the Agency shall submit an infringement report to the competent misdemeanour court, once it detects violations of this Law that come within its purview.

As regards the Law's strong points, first of all, it is important that it now covers segments of the entire procurement cycle – from the procurement plan to the execution of the contract, while the scope of the previous law ceased with the signing of a contract.

In its 2016 Report, the EC notes that BiH has achieved some level of preparation in this area, with the adoption of additional implementing regulations under the new Public Procurement

[8] Public Procurement Law, Official Gazette of Bosnia and Herzegovina No. 39/14
[9] EC Reports for BiH for 2015 and 2016
[10] Public Procurement Strategy of Bosnia and Herzegovina 2016 - 2020
[11] Namely, those performing activities in such areas as water supply, energy, transport or postal services.
[12] See Transparency International BiH, Analysis of the New Public Procurement Law and Its Implementing Regulations, May 2015

Law[13] (with the exception of the rules on the training of public procurement officers, which is still pending approval), as well as adoption of a new strategy and action plan for development of the public procurement system in Bosnia and Herzegovina in 2016-2020.

According to the European Commission, in the coming year, **Bosnia and Herzegovina should in particular**: further align the public procurement legislation with the 2014 EU acquis; further strengthen the monitoring role of the Public Procurement Agency by implementing the new rules on monitoring public procurement procedures, and make the procurement process more transparent by improving the use of the e-procurement system; establish a specialised procurement function within contracting authorities (and provide it with public procurement officials who have the relevant skills and capabilities).

Further, the European Commission also pinpoints some of the problems that TI BiH has already warned about, relating to procurement planning, conflict of interest and legal protection. The report notes that regarding the contracting authorities' capacity to implement and enforce public procurement processes, the **provisions of the new PPL on more detailed planning, preparation and publication of public procurement activities remain to be applied.** It further points out **that there has been no improvement in implementation of the provisions on integrity and conflict of interest in public procurement procedures. Also, the new remedies system model is not satisfactory.**

Transparency

The new PPL further provides for the establishment of a central online Public Procurement Portal, which consolidates the previous electronic systems and allows searches of contracting authorities and bidders, registration of contracting authorities and bidders, search and view of notices, daily publication of notices, new types of notices in accordance with the new law, and automatic creation of reports from contract award notices. The portal also enables electronic downloading of tender documents (only for registered bidders, while examples of good practice indicate the need to enable review of tender documents for other stakeholders too, which is essential in terms of control, especially of those segments which are typically susceptible to abuse – discriminatory technical specifications, inappropriate scoring criteria, etc.), electronic auction, and notification of bidders of published notices.

Establishment of the central portal can be considered the most notable achievement of the new Law. Following types of information can be found on the portal:

- Prior information notice (a new kind of notice that announces procurement for the coming period, while also shortening regular deadlines for the receipt of tenders)
- Notice of the establishment of a qualification system
- Procurement notice

[13] Rules on Conditions and Usage of e-auctions (Official Gazette of BiH, No. 66/16) and Rules on Monitoring Public Procurement Procedures (Official Gazette of BiH, No. 72/16)

- Public procurement cancellation notice
- Contract award notice
- Voluntary *ex ante* transparency notice
- Annual contract award notice
- Notice correction
- Annual contract award notice for a framework agreement
- Voluntary *ex ante* transparency notice for non-priority services

As Transparency International in BiH has already pointed out, the portal's main disadvantage is that it does not consolidate the procurement plans of contracting authorities and contract implementation reports, which can only be found on the websites of the contracting authorities, if at all. What is encouraging, however, is that these proposals are recognised in the strategic plans and official reports on the state of public procurement in BiH. The PP Strategy 2016-2020 thus provides for future publication of procurement plans and contract implementation plans on the Public Procurement Portal. This would improve the public procurement monitoring system, adding this information to the sources of monitoring conducted by the Public Procurement Agency. Furthermore, harmonisation with Directives 2014/24/EC and 2014/25/EC in this area would require the portal to be upgraded in terms of introducing new functionalities in order to simplify the search of critical points or red flags in notices, created on the basis of monitoring criteria and targeting procurement procedures where irregularities can be considered to have a greater impact (estimated contract value, qualification criteria, contract award criteria, reasons for applying negotiated procedure without publication of notice, etc.). This would help avoid reviewing all notices or low-risk notices and thus save time.[14]

The new PPL also provides that the decisions of the PRB and the Court of BiH relating to legal remedy procedures must be published on the public procurement portal. This segment of publication has remained most controversial in practice, which will be discussed in more detail further below.

Procurement planning

A procurement plan is prescribed as one of the conditions for starting the public procurement procedure. The Law makes it mandatory for the contracting authority to publish the procurement plan on its website (if it has one) within 60 days from the day of the adoption of the budget, and imposes fines on contracting authorities and persons responsible in contracting authorities if they fail to adopt or publish the procurement plan.[15] The plan includes procurement above a certain threshold value (these are defined in Article 14 of the

[14] Public Procurement Strategy of Bosnia and Herzegovina 2016 - 2020

[15] Public Procurement Law, Article 17 (Conditions for the Start of the Public Procurement Procedure) and Article 116 (Infringement Provisions)

Law, according to which, the procurement values below KM 50,000 in case of goods and services, or KM 80,000 in case of works are considered small and allow for application of the procedure of competitive request for quotations, and below KM 6,000 also for direct agreement, where procurement can be carried out based on a special decision to initiate the procedure without prior inclusion in the procurement plan).[16] TI BiH reiterates its recommendation that the value thresholds for the application of competitive request are not actually a "small value" for Bosnia and Herzegovina and its market and that this procedure should be incorporated as binding in the procurement plan.

Unfortunately, the regulations do not include the obligation to publish the procurement plan on the Public Procurement Portal too. This greatly hinders access to information by all interested parties and makes it possible for contracting authorities that do not have their own website to remain outside the reach of these very important provisions of the Law. Also, the regulations do not specify what the procurement plan should look like and what categories it should contain, with the exception of a template contained in the model procurement plan, which was initially published by the Public Procurement Agency and is used mainly by the contracting authorities. It contains the following categories:

- Serial number
- Scope of procurement
- Common Procurement Vocabulary (CPV) code
- Estimated value
- Type of procedure
- Indicative start date for the procedure
- Indicative date of the conclusion of the contract
- Source of funding
- Remarks

The regulations do not provide for the obligation of compiling and publishing reports on the execution of the plan as a mechanism of control by all stakeholders and a prerequisite for realistic procurement planning by contracting authorities in the next fiscal cycle.

The *Procurement Plan Corrections Allowed under the Law* documents show which procurement procedures were dropped by the contracting authorities during the year and which new procedures were planned, but there are no necessarily links with the procurement plans and consolidated data on total executed value vs total estimated value and on savings or additional costs generated in the meantime. That being said, the course of individual procurement procedures can be tracked through various types of information published on the Portal, but this requires far more time and other resources.

[16] Analysis of the New Public Procurement Law and Its Implementing Regulations, Transparency International BiH, May 2015

Also, the contract/framework agreement execution forms contain basic elements of the contract (value, execution duration/deadline, payment period, warranty period) as well as any changes made during execution, but this instrument could have a greater effect in terms of preventing the earlier practice if contract values were increased multiply, by means of contract annexes, compared to the initial values.

The OECD's document Methodology for Assessment of National Procurement Systems places emphasis on ensuring that procurement planning is better linked with budget planning, both with annual and with multi-annual financial plans (budget projections).[17] This has also been previously pointed out by TI BiH.

Application of the new Public Procurement Law

According to the *Annual Report on Contracts Concluded in Public Procurement Procedures in 2015*[18], of the total number of contracting authorities in Bosnia and Herzegovina that are required to apply the Public Procurement Law as at 31 December 2015, 2,053 contracting authorities were registered for submitting reports on public procurement procedures into the "E-procurement" information system. This is a 33.40% increase compared to 2014, when the number of registered contracting authorities was 1,539. Of these, 104 contracting authorities are registered at the state level, 1,099 in the Federation of BiH, 841 in the Republika Srpska and 9 in Brčko District.

What remains a problem is that **a large number of contracting authorities are not registered in the "E-procurement" system**[19], as a result of which they do not publish all the required information, which affects the accuracy of statistics on public procurement procedures in BiH.

Tabular and graphical overview of the number of registered contracting authorities by type:

Type of contracting authority	**Number of contracting authorities**	**%**
Government institutions	532	25.91
Legal entity	1,354	65.95
Sectoral contracting authority	167	8.13
Association	0	0.00
In total	**2,053**	**100.00**

Tabular and graphical overview of the number of legal entities as contracting authorities by industry:

Legal entity	**Number**	**%**
Education	673	49.70
Defence	0	0.00
Other	271	20.01

[17] http://www.oecd.org/gov/ethics/37390076.pdf

[18] Public Procurement Agency of BiH, *Annual Report on Contracts Concluded in Public Procurement Procedures in 2015*

[19] According to some estimates, there are more than 3,000 contracting authorities in Bosnia and Herzegovina.

Economy and finance	19	1.40
Leisure, culture and religion	52	3.84
Public order and safety	3	0.22
Social protection	65	4.80
Management and maintenance of residential buildings and other public utility services	65	4.80
Environmental protection	17	1.26
Health care	189	13.96
In total	**1,354.00**	**100.00**

In 2015 there were a total of 95,465 public procurement procedures, of which 3,822 open procedures, 5 restricted procedures, 12 negotiated procedures with publication of a procurement notice, 881 negotiated procedures without publication of a procurement notice, no competitive dialogue, 8,691 competitive requests for quotations and 82,054 direct agreements.

The **share of individual types of public procurement procedures in the total value of executed contracts** looks as follows: open procedure – 51.67% (a decrease of 40.46% compared to 2014), restricted procedure – 0.16% (a decrease of 94.27%), negotiated procedure with publication – 0.11% (a decrease of 18.02%), negotiated procedure without publication – 21.38% (a decrease of 66.15%), competitive request for quotations – 9.75% (a decrease of 60.32%) and direct agreement – 6.19% (an **increase** of 17.21%).

This shows that the number of opaque procedures remains very high, but their share in the total value of executed contracts, however, is lower than it was under the old Law.

The total number of contracts awarded in 2015 was 105,412, of which 103,553 were awarded to domestic bidders (98.24%) and 1,759 to foreign bidders (1.76%).

As regards the provisions of the Law that have not been properly implemented, some shortcomings of the previous law have been corrected, while others have remained.

The Public Procurement Agency has compiled a report on the monitoring of public procurement procedures for year 2015, which identified the following most common irregularities: 22.47% of all irregularities relate to Article 21 (Conditions for Application of Negotiated Procedure without Publication of Notice), followed by Article 40 (Regular Time Limits for Submission of Requests for Participation and Bids – 20.22%), Article 88 (Competitive Request for Quotations – 17,98%), Article 41 (Shortened Time Limits for Submission of Bids – 17.98%), etc.

Deficiencies identified by the supreme audit offices relating to procurement planning, which are also mentioned in the Agency's monitoring report, continue to persist. The auditors have found that public procurement plans only broadly and minimally touch upon the planned activities as a starting point for planning the public procurement of goods and services in

accordance with the planned budget. In fact, this is the first document to directly recommend that institutions should seek to make efficient use of public funds with regard to the purpose and scope of the procurement and ensure timely implementation of all necessary measures to prevent or at least mitigate any difficulties in the implementation of individual procurement procedures.

Deficiencies identified by audits also relate to the inefficiency of the public procurement process, resulting in frequent repetition of procedures, high number of complaints and appeals, failure to sign contracts in a timely fashion, and procurement of unnecessary supplies. The auditors also recommend that before launching a public procurement procedure, contracting authorities should do market research for the supplies to be procured.

Directorate for Economic Planning of BiH estimated the nominal GDP for 2015 at KM 29,277,000,000.00 and the real GDP at KM 28,198,000,000.00. The share of public procurement in the total nominal GDP in 2015 was 4.48% – a progressive decrease from 8.14% in 2014; 9.68% in 2013; 12.95% in 2012; and 12.38% in 2011.[20]

In 2015 the Procurement Review Body (PRB) received 2,011 appeals that were lodged in the public procurement process, an increase of 77.65% (879 appeals) compared to 2014.

The number of appeals resolved in 2015 was 1,820, of which 125 were received in 2014 and 1,695 in 2014. The number of appeals received in 2015 that have remained unresolved is 316.

Of the total number of appeals received in 2015, the Sarajevo-based PRB headquarters received 1,595 and resolved 1,522. Since 19 October 2015, when members of PRB branches were appointed, the PRB branch offices have received 416 appeals and resolved 173. Specifically, the branch office in Banja Luka has received 148 appeals and resolved 67 and the branch office in Mostar has received 268 appeals and resolved 106. The fact that the Mostar branch received more appeals does not necessarily mean that the contracting authorities in FBiH are less efficient in implementing the Law, but reflects the fact that, due to its complex administrative arrangements, FBiH has a greater number of contracting authorities, which further suggests that there is a disproportionate division of labour among the PRB branches, with each having the same number of members – five.

Also, the PRB received 184 lawsuits relating to 2015 and previous years.

As at 30 November 2016 a total of 557 decisions of the PRB and the Court of BiH were published on the portal, and even these few decisions were not accessible all the time. Recently, some PRB members openly acknowledged that the lack of transparency in the remedies system occurred mainly because different decisions were being made in similar cases, which, in other words, means a lack of legal certainty, discrimination against some bidders, and points to a high likelihood of serious corruption offences existing in the system.

[20] Public Procurement Agency of BiH, Proposed *Annual Report on Contracts Concluded in Public Procurement Procedures in 2015*, Sarajevo, July 2016

Establishment of the PRB branch offices in Mostar and Banja Luka and the appointment as PRB members of persons who did not have the most extensive experience in the subject area compared to other applicants, has led to the remedies system currently being considered the weakest link of the entire public procurement system.

The 2016 European Commission report for BiH, the Reform Agenda for BiH for 2015-2018, the Public Procurement Strategy 2016-2020 and other relevant documents, including those prepared by TI BiH, stress that the publication of decisions on appeals is central to ensuring transparency in procurement procedures. Reports also note that the PRB's capacity to handle the complexity and high number of procurement-related appeals remains limited, which only goes to confirm, as mentioned earlier, that the new remedies model (including appointments to the PRB branches) has not led to the much needed progress as expected.

Public Procurement in the health-care sector in BiH – a comparison with the Czech Republic

In addition to general problems in the functioning of the public procurement system in BiH, which also exist in the health-care sector, another chronic problem besetting the health-care sector is an ongoing lack of funding.

The public health-care sector is heavily indebted – governments owe the health insurance funds significant financial resources, health insurance contributions remain largely unpaid, and reform delays and lack of other relevant regulations result in bids with payment period of almost a year. This means that suppliers are effectively giving loans to contracting authorities and that the conditions, in particular payment terms, have a major impact on the selection of bids. As a result, the prices of medicinal products, medical devices and equipment are significantly higher in BiH than in other countries in the region.

The Reform Agenda in the area of **Public Finance, Taxation and Fiscal Sustainability** provides that the governments of the Entities, Cantons and Brčko District will seek financial and technical assistance of the World Bank to implement the reform of the health-care sector. The reform is to include a solution for outstanding debts in the health-care sector, introduction of the treasury system and the definition of new models and sources of funding, with a more precise regulation of the network of health-care facilities. This is particularly important as the Agenda envisages reduction of the burden on labour by reducing contributions for health insurance, which will not be possible without at the same time ensuring additional revenues for extra-budgetary funds to cover the losses generated as a result of the reduced contribution rate.

As in other areas, public procurement in the health-care sector is financed from a range of different sources, and some procurement contracts are exempted from the application of the

Public Procurement Law, specifically, the following: a contract awarded in accordance with an international agreement according to which special procedure applies in terms of international, loan, or donor arrangements, or a public procurement contract concluded on the basis of special rules defined by an international agreement between Bosnia and Herzegovina and one or several other countries for projects that will be jointly executed or used by contracting parties, or based on international agreements on troop stationing concluded by Bosnia and Herzegovina.

Reconstruction of some major health-care facilities and procurement of medical equipment of greater value were financed in this way.

On the other hand, this area too has been rocked by a series of major corruption scandals, the biggest of which involved the two largest health-care facilities in the country, namely the Sarajevo University Clinical Centre and the University Clinical Centre of the Republika Srpska.[21] According to these media sources, both senior domestic politicians as well as some foreign bidders were involved in serious and fatal irregularities. Also, due to the cases of alleged conflict of interest that were not detected and sanctioned by the authorities due to the lack of relevant regulations and lack of political will, a significant portion of irregularities concerned redirection of patients, medicinal products and medical equipment to private clinics owned by or linked through nepotism to particular doctors, medical staff and senior officials in the health-care sector.

The procurement plans for the two largest clinical centres for year 2016 require significant amounts of money from public budgets.

The total value envisaged in the 2016 procurement plan of the Sarajevo University Clinical Centre amounts to KM 80,540,500.00, of which KM 65,461,000.00 for supplies, KM 13,416,500.00 for services, and KM 1,663,000.00 for works. A subsequent amendment to the 2016 procurement plan relating to the clinical pharmacy increased the value to KM 18,766,300.00.

Of the total number of procurement procedures planned (206), the plan envisaged 112 open procedures, 68 competitive requests (along with an unspecified number of procedures relating to the procurement of equipment, small-value supplies and spare parts that will be conducted as per the "actual urgent needs of the SUCC").

Further, the plan envisages 13 negotiated procedures, whereby item no. 68 (Supply of spare parts for medical equipment – multiple manufacturers for the needs of all clinics) is envisaged to consist of multiple negotiated procedures on account of the bidders being sole distributors and repairers of medical equipment.

[21] More information is available from http://slobodanvaskovic.blogspot.ba and http://www.zurnal.info/

The plan also envisages 5 procurement procedures under Chapter IV of the Public Procurement Law relating to sectoral contracting authorities (for the procurement of gas, water, electricity, telecommunications and utilities).

The total value envisaged in the 2016 procurement plan of the University Clinical Centre of the Republika Srpska, exclusive of VAT, amounted to KM 39,653,015.00 (KM 46,394,027.55 inclusive of VAT), of which amount KM 3,693,250.00 for the purchase of medical equipment and spare parts. The plan envisages a total of 32 procurement procedures for medical equipment and spare parts, of which 15 competitive requests for quotations and 17 open procedures.

According to the Centre's procurement plan for 2015,[22] the estimated value of procurement of medical equipment and spare parts exclusive of VAT was KM 1,000,000.00, whereas, based on the amended public procurement plan for 2015[23], KM 774,775.00 worth of procurement procedures were executed, exclusive of VAT, of which 23 competitive request for quotations and one open procedure.

As an Annex to the Annual Report on Contracts Concluded in Public Procurement Procedures in 2015, the Public Procurement Agency of BiH published a review of 20 highest-value contracts awarded to foreign bidders and a review of 20 highest-value exemptions from the application of the Law. These also include some health-care facilities.

Annex 2 – Review of 20 highest-value contracts awarded to foreign bidders

18	SARAJEVO UNIVERSITY CLINICAL CENTRE – SUCC	SAP West Balkans d.o.o.	448,930.94	Services	Negotiated procedure without publication of a procurement notice	Procurement services and renewal of SAP licenses for the purposes of SUCC

Annex 3 – Review of 20 highest-value exemptions from the application of the Law

Serial No.	Contracting authority	Type of the contracting authority	Contract value (KM)	Type of procurement	Grounds for exemption	Scope of procurement
1	MINISTRY OF HEALTH AND SOCIAL WELFARE OF THE REPUBLIKA SRPSKA	Government institution	4,885,663.34	Services	Article 10, Paragraph (1), Sub-paragraph c)	Consultant's services for contract management and supervision

[22] Adopted by the Management Board on 5 February 2015.
[23] Adopted by the Management Board on 18 February 2016.

						of construction works - reconstruction of the RS University Clinical Centre, Banja Luka
11	AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES	Government institution	591,300.00	Services	Article 10, Paragraph (1), Sub-paragraph e)	Renting office space in Banja Luka
14	MINISTRY OF HEALTH AND SOCIAL WELFARE OF THE REPUBLIKA SRPSKA	Government institution	398,552.00	Supplies	Article 10, Paragraph (1), Sub-paragraph c)	Provision of IT equipment for the social protection information system

As has been mentioned earlier, as at 30 November 2016 there were a total of 558 decisions of the PRB and the Court of BiH published on the PP Portal. A significant number of these relate to the health-care sector.

Three of the decisions that are available on the portal concern the Health Insurance and Reinsurance Fund of the Federation of Bosnia and Herzegovina. The first decision dismissed the appeal as unfounded. The second decision upheld the appeal and relates to the compensation of costs of the previous lawsuit that was partially upheld by the Court of BiH. The third decision upheld the bidder's appeal because of errors in the tender documents relating to the prescribed ways of controlling medicines that are registered with the Agency for Medicinal Products and Medical Devices and those that are not, the trade in which is approved by the entity ministries of finance.

Two PRB decisions relate to the Health Insurance Fund of the Republika Srpska. One decision upheld the bidder's appeal[24] due to the selection of bidders for individual lots whose bids did not meet the specified scoring criteria (lowest price). The other decision rejected the appeal in which the appellant claimed that the contracting authority failed to establish the facts properly, but the PRB found that this was not the case.

Sixteen PRB decisions published on the portal relate to the Sarajevo University Clinical Centre – SUCC, with bidders mostly complaining about the tender documents and irregular selection of the best bidder.

As regards the University Clinical Centre of the Republika Srpska, there are three PRB decisions published on the portal, two of which upheld the appeals and one rejected the

[24] Decision No. JN2-01-07-1-173-6 /16

bidder's appeal. Appellants' allegations also concern the tender documents and decisions on the selection of the best bidder.

The portal also contains decisions related to the Health-care Centre Brčko in the Brčko District of BiH (10 decisions), cantonal health insurance funds and other public health-care facilities, mainly with allegations similar to those described above.

As can partly be seen from this brief overview, apart from the institutions of the public procurement system (the Public Procurement Agency and the Procurement Review Body of BiH) and suppliers, other key actors in the field of public procurement in the health-care sector in BiH also include:

- Agency for Medicinal Products and Medical Devices of BiH
- Health Insurance and Reinsurance Fund of the Federation of BiH
- 10 cantonal health insurance funds
- Health Insurance Fund of the Republika Srpska
- health facilities and
- other actors

The Agency for Medicinal Products and Medical Devices of BiH was established by the Law on Medicinal Products and Medical Devices[25] to be an authority responsible in the area of medicinal products and medical devices which are manufactured and used in medical practices in BiH. It became operational on 1 May 2009. Its mission is protecting public health of people in BiH through regulation of medicinal products and medical devices and related business operators.

In addition to the Law on Medicinal Products and Medical Devices, the Agency's operation is further governed by other important regulations such as the Rules on Medical Devices[26] and the Rules on Monitoring Adverse Events Related to Medical Devices (materiovigilance of medical devices).[27]

The role of the Agency in the area of medical devices includes:

- keeping a register of medical devices for the territory of BiH;
- keeping a register of manufacturers of medical devices for the territory of BiH;
- keeping a register of legal entities engaged in wholesale of medical devices for the territory of BiH;
- issuing of certificates of registering manufacturers of medical devices;
- issuing of certificates of registering legal entities engaged in wholesale of medical devices;
- *issuing of certificates of registering medical devices in the Register of medical devices;*

[25] Official Gazette of BiH, No. 58/08 "
[26] Official Gazette of BiH, No. 4/10
[27] Official Gazette of BiH, No. 58/12

- *collecting information, analysing and responding to adverse events in the application of medical devices, or materiovigilance of medical devices;*
- *participating in activities related to assessing conformity and labelling of medical devices in BiH with harmonised European standards and technical regulations in accordance with the Law on Technical Requirements and Conformity Assessment of Products;*
- *carrying out inspection of production and wholesale of medical devices;*
- *organising an information system on medical devices;*
- performing other tasks in the area of medical devices.

The table below shows the number of reports of adverse effects of medical devices in BiH received by the Agency, by year

year	number of reports of adverse effects of MDs in BiH
2010	5
2011	9
2012	17
2013	40
2014	48
2015	68

This number is alarmingly low and is not nearly as close to the number of reports that occur in countries with more developed markets, higher confidence in the institutions, and far better health care than is the case in BiH. The concealment of errors, failures and other anomalies by medical personnel is yet another in a series of "public secrets" that characterises the health-care sector.

Pursuant to the provisions of the Law on Health Care[28], Law on Health Insurance[29], Decision Establishing the Basic Health Care Package[30], Decision Establishing Priority Vertical Programmes[31] and Decision on the List of Medicaments of the Solidarity Fund of the Federation of BiH,[32] the Health Insurance and Reinsurance Fund of the Federation of BiH

[28] Official Gazette of the Federation of BiH, Nos. 46/10 and 75/13 – Article 52
[29] Official Gazette of the Federation of BiH, Nos. 30/97, 07/02, 70/08 and 48/11 – Article 104, paragraph 1, indent 13
[30] Official Gazette of the Federation of BiH, No. 21/09 – Section XIII
[31] Official Gazette of the Federation of BiH, Nos. 08/05, 11/07, 44/07, 97a/07, 33/08 and 52/08
[32] Official Gazette of BiH, Nos. 89 /13, 74/14, 91/14 and 24/16

carries out, as a contracting authority, public procurement procedures for medicinal products, medical devices and health-care services that are funded by the FBiH Solidarity Fund.

These public procurement procedures are also subject to provisions of other regulations such as, *inter alia*, the Law on Medicinal Products and Medical Devices, the Rules on Medical Devices, and the Rules on Requirements in Terms of Space, Staff and Medical Technical Equipment for the Establishment and Operation of Health-care Facilities Engaged in Provision of Dialysis Services[33], etc.

According to the public procurement plans for the current year and to the extent possible within approved funding, these procedures are conducted in accordance with the provisions of the Public Procurement Law and the accompanying implementing regulations.

The FBiH Fund carries out centralised procurement of medicinal products, medical devices and health-care services that are funded by the FBiH Solidarity Fund, in accordance with the mandate and authority conferred on it under the above regulations. Procurement conducted by the FBiH Fund includes overall implementation of public procurement by this authority.

As regards medical devices, the FBiH Fund conducts centralised procurement of dialysis consumables, which are defined in the Rules on Requirements in Terms of Space, Staff and Medical Technical Equipment for the Establishment and Operation of Health-care Facilities Engaged in Provision of Dialysis Services (a standard set of dialysis consumables). Medical devices and medicinal products are delivered to the health-care facilities in the territory of FBiH which provide medical haemodialysis services. This helps to ensure that the health-care facilities that provide medical haemodialysis services in the territory of FBiH have the same medical devices and consumables for dialysis (a standard set of dialysis consumables) procured at the same price, or, in other words, all persons covered by state health insurance in FBiH have equal rights and access to this health-care service.

Public procurement of the medicinal products, medical devices and health-care services that are not funded by the FBiH Solidarity Fund is carried out by the cantonal health insurance funds and health-care facilities in FBiH.

In the Republika Srpska centralised public procurement for the needs of health-care facilities was introduced in 2006. This procurement is carried out by the RS Health Insurance Fund of the Republika Srpska (HIFRS), which is the central procurement authority that implements the entire activity: drawing up a public procurement plan, preparing tender documents, publishing a procurement notice, conducting the procurement procedure, concluding a contract with suppliers, monitoring contract execution and making the payment. Contracts

[33] Official Gazette of BiH, Nos. 89 /11 and 101/14

on health care provision and financing specify the types of items that the HIFRS procures for health-care facilities. Health-care facilities procure whatever items are not specified in the contracts on their own, in mandatory compliance with the Public Procurement Law. This helps to ensure that health-care facilities have the same medicinal products, medical devices, medical equipment and at the same price. In other words, all persons covered by state health insurance are thus provided with equal rights and access to this health-care service.

Below is a comparative analysis of regulations and practices in the Czech Republic and Bosnia and Herzegovina, based on findings of the study visit to the Czech Republic.

The **study visit** was organised by Transparency International Czech Republic. This included visits to the following institutions:

- manufacturer of medical beds and anti-decubitus mattresses (Linet);
- Ministry of Finance of the Czech Republic;
- two major hospitals in Prague; and
- wholesale supplier of medical devices (CzechMed).

Topics discussed during the study visit included public procurement, centralised public procurement, preparation of technical specifications in the procurement process, ensuring the quality of medical devices, how much weight is given to the price of medical devices in the scoring criteria, financing of public procurement, introduction of the most cost-effective bid as the main criteria in public procurement, registration of medical devices, manufacturers and wholesale suppliers, etc.

➢ Centralised/decentralised public procurement

Czech Republic

In the Czech Republic, the procurement of medical equipment, as well as all other necessary medicinal products and medical devices, is decentralised and carried out by hospitals. The law provides that centralised procurement is used for standardised items and, in accordance with this, the Ministry of Finance carries out procurement for the following items:

- energy
- cars
- office supplies
- IT services
- asset protection services

All other items are procured by hospitals themselves. There have been attempts at centralised procurement by the Ministry of Finance, but these procurement procedures were annulled due to numerous complaints.

The use of this procurement method is understandable since the Czech Republic has state, regional and city hospitals, which are all financed differently (from EU funds, donations, projects, etc.). The health insurance fund has been privatised and does not have the same role as it does in BiH. The result of such decentralised procurement is that two different hospitals, located in the same city, procure the same medical devices at different prices. This does not help ensure equal rights and access to health care for all, which is one of the drawbacks of decentralised procurement.

Bosnia and Herzegovina

As already explained above, public procurement in the health-care sector in BiH is centralised in part and carried out by health insurance funds of the entities and cantons, while a portion of public procurement is conducted independently by health-care facilities.

Centralised public procurement in the health-care sector brings many benefits. One of the ultimate aims of the Public Procurement Strategy 2016 - 2020 is the establishment of central procurement authorities (CPAs), through a pilot project - the establishment of CPAs at the cantonal level as well as in certain areas, with a view to ensuring more efficient use of public money (e.g. the area of medicinal products, to meet the needs of primary schools, etc.). The strategy provides for the implementation, in cooperation with the World Bank, of a pilot project to support the preparation of draft guidelines for the central authority for the procurement of medicines, which should be adopted by hospitals that show interest in the project.

➢ Technical specifications

Czech Republic

The positive effect of decentralised procurement carried out in the Czech Republic is the ability to precisely define the technical specifications, since the hospital procures the necessary equipment for its own needs, and specifications are prepared by experts, i.e. doctors who will use this equipment. When procuring medical equipment, the aim is to get the best value for money or the state-of-the-art modern equipment. Appeals are mainly made by suppliers who want to sell obsolete equipment they have in stock, alleging in their appeals that the specifications are discriminatory. The hospital solves this problem by having the specialists who prepare specifications provide reasons for insisting on equipment with specific functions or innovative equipment. This is an example of why it is important to ensure that the profession is involved and participates in the preparation of tender documents.

Federation of BiH

Technical specifications for the medical devices procured by the FBiH Fund, i.e. technical specifications and framework technical specifications for dialysis consumables (a standard set

of dialysis consumables), are specified in the Rules on Requirements in Terms of Space, Staff and Medical Technical Equipment for the Establishment and Operation of Health-care Facilities Engaged in Provision of Dialysis Services.

Also, before the FBiH Fund launches a procurement procedure for these items, all registered wholesale suppliers of medical devices are asked to deliver the technical specifications of the registered medical devices so as to ensure that the technical specifications of the devices being procured fit those specified in the tender documents, i.e. to prevent infringement of fair competition and to allow all bidders to submit bids on an equal basis. These data are updated with those on newly registered medical devices and, if necessary, the specified frames are expanded.

Appointments to the public procurement commissions are made from amongst dialysis specialists (doctors) from the health-care facilities in the territory of FBiH which provide medical haemodialysis services.

As regards public procurement that is conducted by the FBiH Fund, *the most common appeals in the Federation of BiH are those brought by suppliers who already have concluded contracts and who seek deadline extensions for the procurement procedures or to be allowed to make additional deliveries under existing contracts.*

In both the Czech Republic and Bosnia and Herzegovina specialists who are members of the procurement commissions tend to be somewhat sceptical and mistrustful of “newly registered”' medical devices, as well as sceptical of medical devices from particular countries even though they have been registered for some time.

Republika Srpska

Since the items being procured in the health-care sector are unique, special technical expertise is needed to describe the scope of procurement accurately, clearly, without reference to specific brands and without expressing preference for any manufacturer. The central procurement authority does not have a sufficient number of experts in all areas in which centralised procurement is implemented. *The largest number of appeals in the Republika Srpska relate precisely to technical specifications, where they are described as discriminatory, restrictive and containing references to specific brands.*

In 2013 SIGMA/OECD made a recommendation, which was recognised in the documents of the official institutions in the public procurement system, that the Public Procurement Agency and the relevant line ministries should develop and implement sector-specialised – e.g. IT services and supplies, health supplies, road construction, and office supplies – operational tools, including model tender documents, standard technical specifications, and

methodologies for tender evaluation based on the most economically advantageous tender criteria.[34]

➢ Scoring criteria (contract award criteria)

Czech Republic

In the Czech Republic the most commonly used contract award criterion is "best price", because it is the only criterion prescribed under the old Law. The new Law has also introduced the "the most economically advantageous tender" criterion. All other criteria (warranty, service) are laid down in the tender documents. Quality is ensured through precisely defined specifications. In procurement of hospital beds, for example, specifications must be written such to suit the purpose of the procurement. Requirements laid down in the specifications mainly relate to the basic functions that the bed must have, while all additional special requirements must be accompanied with an explanation of reasons and properly documented in order not to reflect a preference towards one bidder (e.g. the specifications may require a bed that is narrower than standard beds, which can be produced only by a limited number of manufacturers, if the doors in the hospital are narrow). Terms of payment are not a scoring sub-criterion, as the deadline for payment is 30 days from the date of maturity, while in practice this period is from 60 to 90 days, or maximum 180 days.

Federation of BiH

In public procurement of medical devices conducted by the FBiH Fund, the "best price" criterion is used for contract awards. Quality is ensured through precisely defined specifications and the delivery of quality assurance documents, as follows:

- For registered medical devices (a certified photocopy of the valid decision/approval issued by the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina granting registration of the medical device offered in the bid in the register of medical devices kept by the Agency and a statement by the bidder that at least 2/3 of the time will remain counting from the date of delivery to the end of the prescribed shelf life of the medical device);
- For unregistered medical devices (a certificate of quality of the medical device being imported, issued by the properly authorised authority – "EC certificate or Declaration of conformity", a statement of compliance of the medical device with the corresponding European Directive issued by the manufacturer of the medical device, and a statement by the bidder that at least 2/3 of the time will remain counting from the date of delivery to the end of the prescribed shelf life of the medical device).

Republika Srpska

[34] OECD (2013), "Bosnia and Herzegovina Priorities Report 2013", SIGMA Assessment Country Reports, 2013/11, OECD Publishing. http://dx.doi.org/10.1787/5jz2rqk0rpbt-en

In the Republika Srpska, the criterion used for this type of procurement is “the most economically advantageous tender”, where the price carries most weight in terms of scoring, while one of the sub-criteria used is the “payment period”, which defeats the purpose of this criterion. Specifically, the purpose of the “most economically advantageous tender” criterion is to enable contracting authorities to obtain the best value for public money, as the cheapest does not mean the best. This criterion allows for awarding extra points for quality and thus procuring better-quality equipment. The payment period is irrelevant and does not ensure fulfilment of the criterion’s purpose.

➢ References and exclusion of bidders

Czech Republic

In the Czech Republic it is not possible to exclude a bidder on the grounds of poor track record, but there is a system of so-called “demerit points”. If a bidder accumulates three “demerit points”, he may be excluded from procurement. “Demerit points” are awarded in the case of negative references by a contracting authority (for example, if the bidder offered a hospital bed that does not meet the procurement requirements).

Republika Srpska

In the Republika Srpska references cannot be a scoring sub-criterion, but only one of the conditions for participation. The Law provides that the request for participation or the bid shall be rejected if the candidate/bidder has been guilty of grave professional misconduct committed during the period of three years prior to the onset of procedure which the contracting authority may prove by any means, in particular, significant and/or repeated faults in performing essential requirements under the contract which led to its premature termination, damage or other similar consequences due to wrongful intent or negligence of a certain gravity of an economic operator. It is important to note that this applies only to the bad experience that the contracting authority has had directly with that bidder. If another contracting authority has been forced to terminate a contract with that bidder for the above reasons, this cannot be used as grounds for eliminating the bidder from the procurement procedure.

➢ Qualification requirements – ability to pursue professional activity (registration of wholesale suppliers and medical devices)

Czech Republic

In the Czech Republic all wholesale suppliers must be registered with the competent agency and entered in a special register in order to be allowed to trade in medical devices. This is also

one of the conditions laid down in the tender documents when conducting public procurement.
All medical devices must also be registered and must meet quality standards. In the event of adverse effects, these must be immediately reported to the Agency using special forms.

Federation of BiH

In the Federation of BiH, as regards public procurement of medical devices carried out by the FBiH Fund, in order to demonstrate the ability to pursue professional activity, bidders – wholesale suppliers need to submit the following supporting documents:

- A certified photocopy of the decision on entry in the court register of the activities of import of and wholesale trade in medical devices, with attachments, issued by the competent court;
- A certified copy of the Agency's decision approving the entry in the register of wholesale suppliers of medical devices kept by the Agency

If unregistered medical devices need to be procured, they should comply with the applicable requirements.

Republika Srpska

In the Republika Srpska too all wholesale suppliers must be registered with the competent agency and entered in a special register in order to be allowed to trade in medical devices. This is also one of the conditions laid down in the tender documents when conducting public procurement.
All medical devices must also be registered and must meet quality standards. In the event of adverse effects, these must be immediately reported to the Agency using special forms.

➢ Samples

Czech Republic

In the Czech Republic samples are delivered immediately along with the bid in three packages (two are used for testing, and one is left as proof of quality). Since hospitals themselves procure medical devices for their needs, samples are tested by those who will use them. This is done to avoid subsequent complaints regarding quality and functionality. When procuring medical equipment, before a contract with the most successful bidder is concluded, the bidder is required to install and commission the equipment so that parties can respond promptly if the equipment fails to meet the specified conditions.

Federation of BiH

In the Federation of BiH, as regards public procurement of medical devices carried out by the FBiH Fund, samples are delivered for certain medical devices – LOTS which must comply with the conditions laid down in the tender documents (must conform to the procurement subject

matter specified in the tender documents, must be authentic/identical to the medical device offered in the bid and must be accompanied by the relevant documents attesting to their quality). Ensuring the authenticity of samples is the responsibility of the bidder. If necessary, samples (i.e. their compatibility with the devices in use) are tested in dialysis centres in the Federation of BiH by members of the Public Procurement Commission who directly use these devices in their work.

Republika Srpska

In the Republika Srpska samples are not delivered immediately along with the bid, but the contracting authority subsequently requires the submission of samples from qualified bidders. Samples are tested by a special commission appointed by the central procurement authority. The inherent problem, however, is that those who will be working directly with these medical devices cannot test them, which results in a high number of complaints being raised in the course of the contract execution regarding the quality and functionality of procured items.

➢ Contracts

Czech Republic

In the Czech Republic all contracts are published on the website. All contracts for the procurement of medical devices and equipment must include the following clause: "if the same defect occurs three times, the contract shall be terminated". Draft contract is included in the tender documents and all bidders are aware of this clause. Terms of payment – statutory deadline for payment is 30 days from the date of maturity, while in practice this period is from 60 to 90 days, maximum 180 days.

Federation of BiH

In the Federation of BiH, as regards public procurement of medical devices carried out by the FBiH Fund, "Draft Contracts" or "Basic Elements of the Contract" are an integral part of the tender documents. The latter are published on the website of the Contracting Authority.

The basic elements of the contract include: the scope of procurement, price, place of delivery, delivery lead time, manner and terms of payment, period for which the contract is concluded, guarantee of the functionality of the delivered medical devices, provision of supplies for the medical devices, guarantee for the proper execution of the contract, mandatory condition under Article 72, paragraph (6) of the Public Procurement Law (the bidder to whom public procurement contract was awarded shall have no right to employ, for the purpose of execution of public procurement contract, physical or legal persons that had participated in preparation of tender documents or had stood in the capacity of members or expert persons engaged by Procurement Commission, for at least six months after contract conclusion, i.e. from the beginning of contract execution), etc.

Also, in contracts concluded by the FBiH Fund, a contractual provision is included requiring that the bidder should deliver to the person authorised for receipt of delivery, in respect of each medical device, a confirmation which guarantees:

- that the medical devices are delivered in compliance with the type, unit of measure and the amount specified in the contracting authority's order;
- that the medical devices delivered have the properties/characteristics described in the specifications of the procurement subject-matter;
- that at least 2/3 of the time will remain counting from the date of delivery to the end of the prescribed shelf life of the medical device)
- that the medical device will work properly in accordance with its purpose;
- that he will act in accordance with the regulations/rules on the seller's liability for defects of delivered medical devices (visible and hidden defects); and
- that the medical devices are labelled in accordance with the provisions of Article 38 of the Rules on Medical Devices.[35]

Terms of payment in the Federation of BiH are regulated by the Law on Financial Operations (Official Gazette of the Federation of BiH, No. 48/16), as follows: "payment period can be set at up to 60 days", "exceptionally, a longer payment period can be set, but no longer than 90 days" and "if the contract did not specify a payment period, the debtor shall, without having to be called by the creditor to execute, discharge his financial liabilities within 30 days".

Republika Srpska

Draft contract is an integral part of tender documents and all bidders are aware of this clause.

➢ Subsidies, grants and EU funds

Czech Republic

In the Czech Republic, all procurement, whether financed from one's own funds or from grants, is carried out in accordance with the Public Procurement Law. This means that the contracting authorities carry out procurement procedures in the manner provided for under the Law and, additionally, report to the donors.

Bosnia and Herzegovina

The Public Procurement Law of BiH provides that the following contracts shall be exempted from the application of the Law: a contract awarded in accordance with an international agreement according to which special procedure applies in terms of international, loan, or donor arrangements, or a public procurement contract concluded on the basis of special rules defined by an international agreement between Bosnia and Herzegovina and one or several

[35] Official Gazette of BiH, No. 04/10

other countries for projects that will be jointly executed or used by contracting parties, or based on international agreements on troop stationing concluded by Bosnia and Herzegovina. **Medical equipment is mostly procured through the use of loans and as such is exempt from the application of PPL.**

CONCLUSIONS AND RECOMMENDATIONS

- Centralised procurement in the health-care sector is more efficient and ensures equal access to health care for all persons covered by state health insurance. **It is necessary to strive towards greater centralisation of public procurement** (i.e. increase the volume of centralised procurement), but with the prior provision of the legal basis and human and material resources as a precondition for implementation of this type of public procurement.
- **In order to avoid abuse and preferential treatment of certain manufacturers, it is necessary to introduce standard specifications for the equipment to be procured.** These specifications are to lay down the minimum requirements that the equipment must meet in order to achieve the purpose of the procurement.
- The absence of a Law on Internal Payment System has resulted in bids with payment periods of almost a year, which means that the supplier is effectively giving a loan to the contracting authority. For this reason, the prices of medicinal products, medical devices and equipment are significantly higher in BiH than in other countries in the region.
- **Introduction of quality standards** would enable the procurement of better quality equipment and make it easier for the contracting authorities to implement the procurement process. Further, it would facilitate termination of contracts with suppliers whose medical devices do not meet the required quality, as established upon inspection or testing of medical devices, or upon receiving complaints about their poor quality. Further recommendation calls for introduction of the warranty period as a bid evaluation sub-criterion.
- **Use open procedure as the most transparent one as much as possible and ensure that transparent types of procedures are given precedence over those that are more opaque (such as negotiated procedure).**
- **Enhance procurement transparency by ensuring that tender documents are made publicly available** (currently, tender documents can be downloaded from the public procurement portal only if you are registered as a supplier). This would enable public oversight of procurement processes.
- **Procurement procedures need to allow for participation of those who work directly with the equipment to be procured with a view to avoiding subsequent complaints regarding quality and functionality**.
- **Technical consultation should be used in practice as much as possible and more attention should be devoted to market research** prior to publication of procurement.
- **More attention needs to be devoted to contract drafting**. Contracts should contain as many clauses as possible to serve as insurance against flippant bidders.
- **Employees should receive additional training regarding the "most economically advantageous bid" criterion**; interactive workshops should be organised to discuss

such sub-criteria as product life cycle, the cost of consumables, records of clinical studies, prices of spare parts, serviceability, etc.; also, in using this criterion, one needs to be particularly vigilant with regard to registered medical devices because, once registered, they can be put on the market, and sub-criteria must not be stricter than the criteria already established for registration.