

# Sector Integrity Vulnerability Assessment

in Health Product  
Procurement

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## **UNDP DISCLAIMER:**

The views expressed in this report are the authors' and do not necessarily represent those of the United Nations, including UNDP, or its Member States.

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# Background

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In 2015, the Ministry of Health of Ukraine requested the assistance of UNDP, UNICEF, WHO and Crown Agents in procuring health products for the country on basis of national legislation.

On 19 March 2015, the Verkhovna Rada of Ukraine (legislature) adopted the Law of Ukraine “On Amending Certain Laws of Ukraine (Regarding Providing Patients with Timely Access to Necessary Pharmaceuticals and Medical Products for Budget Funds Involving Specialized Organizations Performing Purchases)” registered under bill No.2150. The rationale for international procurement of pharmaceuticals in Ukraine lies within one of the key factors for the Euromaidan revolution of early 2014 – the endemic level of corruption in the country. Since the independence of Ukraine in 1991, the country has been plagued with weak state structures unable to keep up the rule of law and the intrusion of private interests that trump the public interests in the governance system of the country. The distortions of the dual political and economic transitions over the last 25 years have created a system in which vested interests and oligarchs dominate both the political and economic landscape while a poorly paid civil servants engage in rent-seeking across the range of public service delivery.

This endemic level of corruption reaches deeply into the pharmaceutical sector in Ukraine with a system in place in which a few key players are able to dominate the market and impact on the regulatory system for their own advantage. This has lead to regulatory capture or even acute form – state capture, from the pharmaceutical industry over the state agencies responsible in the identification, procurement and distribution of pharmaceuticals.<sup>1</sup>

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1. <http://antac.org.ua/en/analytics/12-mlrd-koshitiv-na-liky-u-2014-vytracheni-neeefektyvno-eksperty/>

# General corruption vulnerabilities in the health sector

Corruption in the health sector, and in particular in the area of procurement, is far from being a typically Ukrainian problem. In fact, across Europe, the healthcare sector has been described as one of the areas that is particularly vulnerable to corruption.<sup>2</sup> This is mainly due to the following characteristics of the healthcare sector, as has been outlined by the European Healthcare Fraud & Corruption Network and other experts on corruption in healthcare:

- A high degree of information asymmetry between providers of care and consumers exercising demand for services to become healthy;
- Large number of actors which have complex inter-relations;
- The responsibility given to providers in choosing services for their patients;
- Healthcare services that are highly decentralised and individualised making it difficult to standardise and monitor service provision and procurement;
- Unlike consumer markets for more regular goods, where market supply and demand determine 'the right price', in the complex market of healthcare pricing is much more opaque.
- The ethical implications involved in healthcare decisions make it nearly impossible to define the 'right' amount to be spent on healthcare;
- The payer is often not the same as the direct recipient of healthcare services; there is no immediate check on the actual provision of goods and services. The payer has no direct way of verifying that the service was provided and the customer has no way of knowing that the insurance provider has billed for a service the consumer did not receive.

These systemic features of the health sector are equally prevalent in Ukraine, which is additionally characterized by a largely unreformed Soviet legacy in terms of health care systems, facilities, institutions and attitudes, and is additionally complicated by

the existence of a constitutional provision<sup>3</sup> that guarantees free basic health care for all citizens, a provision which is constitutionally entrenched and can therefore nor even be amended through a normal constitutional amendment procedure.

2. [http://ec.europa.eu/dgs/home-affairs/what-is-new/news/news/docs/20131219\\_study\\_on\\_corruption\\_in\\_the\\_healthcare\\_sector\\_en.pdf](http://ec.europa.eu/dgs/home-affairs/what-is-new/news/news/docs/20131219_study_on_corruption_in_the_healthcare_sector_en.pdf)

3. Article 49. "Everyone shall have the right to health protection, medical care and medical insurance. Health protection shall be ensured through state funding of the relevant socio-economic, medical and sanitary, health improvement and prevention programmes. The State shall create conditions for effective medical service accessible to all citizens. State and communal health protection institutions shall render medical care free of charge; the existing network of such institutions shall not be reduced. The State shall promote the development of medical institutions under all forms of ownership. [...]"

# Health products procurement

Health products can be defined, in analogy with the definition<sup>4</sup> used by the Global Fund, as (i) pharmaceutical products; (ii) durable and non-durable in vitro diagnostic products, microscopes and imaging equipment; (iii) consumable/single-use health products (including condoms, insecticides, therapeutic nutritional support, general laboratory items and injection syringes).

Procurement and supply management refers to all procurement, supply and distribution activities required to ensure the continuous and reliable availability of sufficient quantities of quality-assured, effective products to end-users, procured at the lowest possible prices in accordance with national and international laws.

In order to ensure access to effective and quality assured health products, the Global Fund has developed a set of policies and principles on procurement and supply management that aim to:

- support the timely procurement of quality-assured health products in adequate quantities;
- attain cost efficiencies in procurement and supply management activities;
- ensure the reliability and security of distribution systems;
- encourage appropriate use of health products; and
- enable the monitoring of all procurement and supply management activities.

These principles. Adjusted to the Ukrainian context, are also taken as a benchmark for the analysis of health products procurement in Ukraine in the course of the present SIVA.

4. Guide To Global Fund Policies On Procurement and Supply Management of Health Products, June 2012

# Pilot Sector Integrity Vulnerability Assessment in Health Product Procurement

**The purpose of this assessment is focused on identifying how the health product procurement process in Ukraine is vulnerable to corruption.**

Managing integrity and preventing corruption within the public sector business processes and the operations of individual institutions is a critical component of managing their efficiency and effectiveness as well as that of the entire public service. As such it is complementary to the work of specifically dedicated governmental anti-corruption bodies and mechanisms, such as the newly created National Anti-Corruption Bureau (NABU)

and the National Agency for the Prevention of Corruption (NAPC). Ensuring that the health sector institutions' personnel operate in the interest of the public and not their own private interests is crucial in establishing an effective system of internal control and management. Any individual can be prone to malfeasance or the misuse of delegated power, if the system they work in allows or even encourages it.

Hence, the problem of corruption lies more in the integrity management system and regulatory environment of operations rather than on the individual's moral compass, which can only usually be changed over a long-term.

## **INTEGRITY MANAGEMENT INVOLVES THE ESTABLISHMENT OF A SYSTEM THAT:**

- Identifies the opportunities for engaging in malfeasance;
- Develops and implements effective strategies to mitigate those opportunities;
- Strengthens internal control through the detection, enforcement and prevention of corrupt acts, which are defined as the abuse of public or private office for personal gain.

Sector Integrity Vulnerabilities Assessments (SIVAs) are a second-generation risk assessment methodology developed by UNDP and specifically adapted to the current context in Ukraine for identifying where opportunities for corruption and system weaknesses exist within sectors and public sector institutions. It moves on from the formal procedures of submitting questionnaire-based corruption risk assessments that rely on participation from the institutions that suffer vulnerabilities, to the use of individual discussions with key informants (experts). SIVAs examine the lapses in the system that allow corruption to occur without direct accusations on the interviewee by focusing on how the current system of operations could allow lapses in integrity rather than focusing on personal liability.<sup>5</sup>

National-level-based assessments like the National Integrity System pioneered by Transparency International are useful tools in comparing countries or covering the overall level of governance reform efforts in a country. However, they are insufficient as an instrument that can be used operationally to mitigate specific opportunities for corruption or to measure or rank levels of risk within Ministries or institutions. Also, many current institutional corruption risk assessments rely on those involved in corruption to self-assess what risks exist by using standard survey methodologies, which have been found not to be reliable indicators for the extent of and detailed diagnostic understanding of the nature of corruption in individual sectors and institutions.

Sector/Institutional specific methods allow a more focused approach on reforms efforts that are directly impacting on the public rather than a long shopping list of reforms that may or may not be impacting on the delivery of public services. Integrity vulnerability assessments allow agents of reform to understand where the actual opportunities for corruption are and allow targeted and measureable actions that mitigate them. The final matrix of vulnerabilities and its related mitigation plan offer the basis for a self-assessment checklist but are not generated by self-assessments themselves. This approach creates the means for more effective action in reducing corruption by narrowing the focus of reform efforts and delivers the mechanism to more effectively monitor and evaluate the progress of such efforts.

# Methodology of the Sector Integrity Vulnerability Assessment adapted to the Health Products Procurement

The SIVA is a participatory diagnosis methodology in the form of semi-structured key informant (expert) interviews (KIIs) that capture the informal practices that lead to vulnerabilities in operations. It is focused on understanding how vulnerable the integrity of operations is in a specific sector or an institution, and in what specific manner, by interviewing practitioners in the area of interest on how the system can be used for corruption or other lapses.

Previous similar exercises have shown that between 10 to 20 interviews with carefully selected, experienced practitioners should produce a fairly complete picture of the vulnerabilities in a given sector. Each interview consists of open-ended questions for qualitative information (e.g., existing issues and recommendations for improvement) and takes up to 90 minutes. In the case of this SIVA for health product procurement 28 individuals were interviewed.

The SIVA begins by first identifying how the sector business process operates and what steps are involved from start to finish. Once various steps and institutions are compiled into a list, a matrix can be made that also outlines:

- What vulnerabilities exist;
- Who can mitigate the vulnerabilities;
- What priority they should have;
- What is the timeframe and resources necessary to mitigate them.

**28**  
INDIVIDUALS  
WERE INTERVIEWED

## KEY INFORMANT INTERVIEWS

The SIVA methodology relies on conducting face-to-face semi-structured interviews with experienced practitioners/experts or Key Informant Interviews (KIs). By interviewing individual experts the methodology elicits responses that focus on how the integrity system in the sector contains opportunities for either corruption or perceptions of corruption based on inefficiencies and insufficiencies. Information from KIs will be reviewed and verified through comparison with secondary sources (desk review) and comparison to the other vulnerabilities identified by previous or follow on KIs.

## IN THE COURSE OF THIS SIVA 28 PRACTITIONERS HAVE BEEN INTERVIEWED INCLUDING:

- Former senior management of the Ministry of Health of Ukraine
- Pharmaceutical manufacturers (both national and international)
- Pharmaceutical distributors
- Civil society including international NGOs
- Independent experts
- International organisations
- Journalists

The interview process for the Health Products Procurement SIVA drew from specific day-to-day operational knowledge of the sector by mid-level to higher-level practitioners who know the sector best and who have long-term experience and first-hand knowledge of the area to be examined. It focuses not on the policy maker level as in many other formal risk assessment processes but relies on those who are directly involved in operations with long-term experience of the area to be examined. This notably also includes, at least potentially, individuals who may themselves have committed acts of corruption. Key is the identification of a number of practitioners who know the operations of area of interest, whether in specific department or the whole institution and are drawn from mid to upper level personnel who know 'how things really work'. They included current staff, outsiders who work with the institutions and ex-staff.

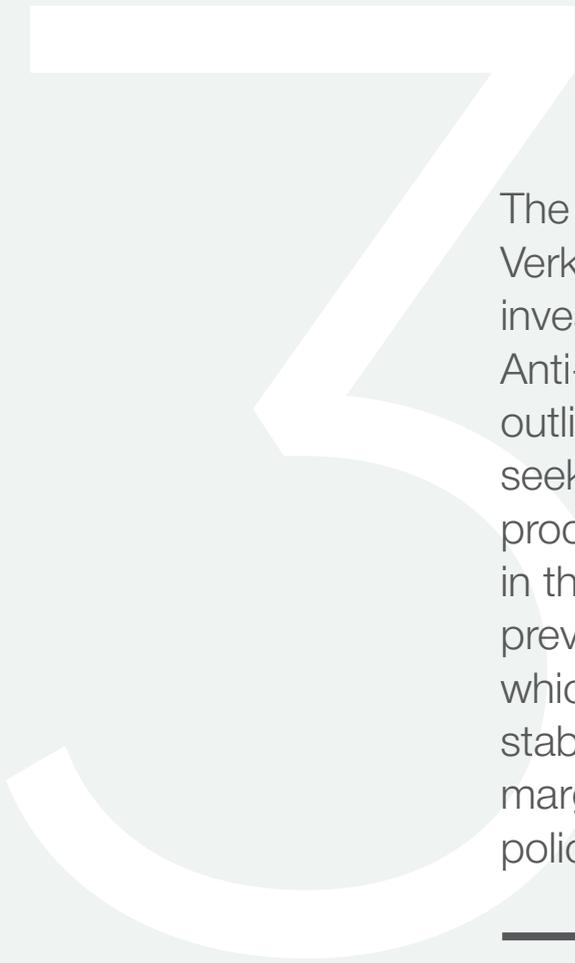
The second phase of the interview process consisted of holding semi-structured interviews beginning with the simple question "How is the health products procurement system vulnerable to corruption?" The responses varied from person to person but over a number of interviews (at this initial pilot stage 12 interviews were conducted) a reliable picture emerged as to the areas, extent and nature of vulnerabilities.

Verification and support to the conclusions were done by reviewing what 'gaps' have already been identified through existing reports (references are listed in Annex I), or other evidence that demonstrate the corruption vulnerabilities in the sector. This was through a desk review of previous reports as well as the regulatory, procedural and legislative framework. This technical desk benefitted from the deployment of a UNDP/UNICEF/WHO Exploratory Inter-Agency Mission on capacity building development for health procurement reform in Ukraine (4-8 April 2016). By cross-checking the gaps thus identified with the SIVA interviews, a more complete institutional assessment emerged.

The draft version of the SIVA was then verified through group discussions with individual experts and a verification exercise was held with the Technical Working Group of the Ministry of Health that was held on August 2, 2016. There were only a small number of changes that were necessary to be made in the matrix of integrity vulnerabilities presented and the matrix has been duly amended.

# Findings of the Sector Integrity Vulnerability Assessment

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The 2008 Konovaliuk Report of the Verkhovna Rada of Ukraine<sup>6</sup> as well as the investigative reports of the Ukrainian NGO Anti-corruption Action Center<sup>7</sup> have already outlined and documented how the rent-seeking schemes work within the health procurement system. The KIIs conducted in the course of the SIVA confirmed the prevalence of these systemic vulnerabilities, which appear to have maintained rather stable for the recent decade, and have only marginally been affected by legislative and policy changes in the past two years.

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After completing almost double the average number of key informant interviews conducted, the SIVA process has resulted in enough evidence to identify the prevailing vulnerabilities in the sector.

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6. <https://www.scribd.com/doc/130334957>  
7. <http://likycontrol.org.ua/>

The SIVA confirmed the existence in general of the following vulnerabilities within the health products procurement system:

1. Lack of technical knowledge of personnel of the operational system of the sector in exercising their duties. (Inefficiency)
2. Gaps in the legislation, regulatory and management environment that allow corruption to occur. (Inefficiency)
3. Lack of human and financial resources to fully implement the laws and regulations properly. (Insufficiency)
4. Lack of capacity in state agencies to perform their duties with integrity. (Insufficiency)
5. Undue influence by industry to create their own regulatory environment (regulatory/state capture)
6. Systemic corruption/ malfeasance that is either a) opportunistic or b) directed from above involving the following:
  - False companies under direction of political elites in order to simulate competitive procurement. (Fraud/Collusion)
  - Development of inappropriate regulations (e.g. specifications, norms, conditions, etc.) that benefit companies beneficial to public officials. (Fraud/ Collusion)
  - Misappropriation or misdirection of state budget or resources into private use of public officials. (Theft)
  - Extortion from or acceptance of bribes to public companies for favourable decisions by public officials. (Bribery/Extortion)

### 3.1. Malfeasance within the Previous Procurement Process

As outlined above, in both a Parliamentary inquiry that resulted in the Konvalyuk Report and the Anti-corruption Action Center (AntAC) reports issued before the transfer of procurement through international organizations note the undue influence of several key players in both the manufacturing and distribution side of health products procurement. Two sets of companies who were shown to be under the control of one beneficial owner won 96% of the tenders for each of their programs in the period covered by the NGO Anti-corruption Action Centre's report. It is usually considered that in any system where there are a number of competitors and one firm wins is an indication of regulatory or state capture.<sup>8</sup> The domination of selected firms resulted in the increased costs and delivery of inferior medication to Ukrainians that in turn resulted in the radical decision to remove the tendering component of the procurement of medical products from the Ministry of Health and entrust it to international organisations.

### 3.2. Continued Undue Influence and Issues

As outlined above and identified in the vulnerabilities matrix the influence of pharmaceutical companies on the health system are a continued concern, according to the SIVA interviews. While the current international procurement of medical products removes the ability for direct corruption of the tendering process with inflated costs and delivery of low-quality goods, there still remain many systemic vulnerabilities for collusion and regulatory capture in a largely unreformed public health sector dominated by roughly the same actors found to have mismanaged and abused the system prior to the entry of international procurement service providers. One of the concerns that continued to emerge in the interviews was that the previous system of domination of a small number of pharmaceutical firms would return once the international procurement was finished or halted.

8. See the new research conducted by the Corruption Research Center in Budapest. <http://corruptionresearchnetwork.org/acrn-news/blog/from-corruption-to-state-capture-a-new-analytical-framework>

## **INSUFFICIENCIES**

Low wages in the public health sector, both in terms of administrative and managerial staff as well as the medical professions, still serve as a prime driver of 'need based' corruption as does the result of several decades of low levels of capital investment in public health infrastructure. The insufficiencies in the system are continual barriers to reduction of integrity vulnerabilities within the health system that cannot be mitigated without large-scale public sector reforms and significant changes to the financial model for the health sector.

## **INEFFICIENCIES**

Over the course of the last 25 years, the Ukrainian public health system has suffered from both an inefficient centralized Soviet type system that is paradoxically under-regulated and affected by undue influence of the private sector. The strong influence exercised by private interests has created a tangled web of contradictory regulation that make the sector inefficient in execution of its mandate and open to abuse by the same private interests. This is exacerbated with a bureaucratic culture based on formal compliance and strict literal interpretation of regulatory provisions, often without any room for the exercise of judgement or discretion that would enable the emergence of a culture of accountability for outcomes. Partially in response to perceived corruption risks, the requirements and regulations surrounding compliance have grown overly complex, duplicative, and burdensome.

A substantial bureaucratic mechanism has been built and is maintained to ensure compliance. But all of these compliance activities say little about what is actually being accomplished. Outcome-based accountability would shift this focus from accountability for pure compliance to accountability for outcomes, such as the actual continuous and reliable availability of sufficient quantities of quality-assured, effective products to end-users. The lack of transparent laws and regulations combined with the absence of a strong system of oversight have created a byzantine system that facilitates corruption. In addition, it hampers the provision of internationally procured health products as a result of incompatible standards and specifications.

## **MALFEASANCE/ CORRUPTION**

A continual theme that emerged in the course of the SIVA interviews revolved around the manipulation of the system by and for private interests. The forms of corruption practiced involve both active (extortion) and passive (bribery) by public officials and lower level administrative corruption. The grand level corruption practices were seen as being a more complex system of abuse of power where the procurement process was orientated to serve private interests rather than public good.

The corruption practices utilized in the health products procurement process were seen as resulting from collusion exercised by specific firms. Even if in theory there are a number of firms competing in the tendering process collusion between firms and potentially in cooperation with public officials results in an unfair process. As noted by the EC these forms of collusive behaviour are common across the region and are intertwined with corruption:

“In the sphere of public procurement, corruption and collusion are often considered as distinct phenomena. Corruption is a vertical relationship between one or more bidders and the procurement official. Collusion is a horizontal relationship between bidders that restricts competition and harms the public purchaser. Collusion can take many forms such as bid-rigging, price fixing or market division”<sup>9</sup>.

These collusive practices have been identified by the majority of those interviewed to be central to the corruption schemes practiced in the Ukrainian health products sector and in particular with regard to pharmaceuticals procurement.

As number of interviewees, the system was seen as lacking any integrity and it had been ‘captured’ completely by private interests especially the so-called ‘pharma mafia’ that have been practicing unfair business practices by manipulating regulations and administrative decisions to their own advantage. This depth and extent of corruption was seen as to go so far to have a sole purpose to rent-seek. This system is detailed in the following section.

### 3.3. Regulatory and State Capture in Ukraine

One of the key concepts to emerge in the post-Soviet studies on corruption is that of state capture. State capture refers to “the actions of private interests to influence the formation of the rules of the game (e.g. government legislation, laws regulations and decrees) to their own advantage through illegal provision of private gains to public officials”<sup>10</sup> State capture is seen to be the most drastic form of regulatory capture in which not only is a single regulatory agency under the control of private interests but the entire state is subverted to serve as a promotion mechanisms for individual or firms interests.

In the health product procurement system in Ukraine the majority of interviewees saw the state procurement as a system manipulated by several individuals and that this had created the distortions in the market place as well as making the state an ineffective regulator. With a system in place to promote private interests the entire edifice of the state becomes a facade covering corrupt practices. The actual mechanisms and collusive relationships amounting to this state capture in Ukraine will be diagnosed in-depth in a follow-on study that assesses the mechanisms and characteristics of state capture in this sector. It is recommended that this State Capture Assessment be conducted in 2016.

10. Kaufmann & Helmann. Anticorruption in Transition: Confronting the Challenge of State Capture Summary Report prepared for ECA External Advisory Board on Governance. World Bank Washington, 2000.

# Mitigating the Integrity Vulnerabilities

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## 4.1 Recommendations

The Integrity Vulnerability Matrix in the following section is the result of the key informant interviews conducted so far. However, this process has not been concluded nor has UNDP yet conducted a presentation of the results to obtain suggested mitigation methods by the stakeholders.

Therefore the mitigation methods outlined below are building on the results of the Health Mission conducted by the UN in April of 2016. A lengthier mitigation document will be prepared once the process is concluded in the coming months.

The SIVA process has been completed with the following measures identified that could mitigate corruption vulnerability risks:

1. Establishing an independent health procurement agency that has an oversight body that involves both national and international members who are vetted as well as undergo regular conflict of interest checks.
2. Develop an independent and effective Regulatory (anti-monopoly) Agency that assumes some of the functions of the Anti-monopoly Committee of Ukraine (AMCU), as well as stronger investigative powers. In an interim measure a sub-structure of the business ombudsman could be established to focus on the pharmaceutical sector. Also to establish a user-friendly mechanism to report anti-competitive behavior.
3. Encourage new entries (firms) into the procurement system through outreach to international companies and a campaign to inform the private sector of the new 'rules of the game' in the international procurement process.
4. A comprehensive system for preventing corruption in the health product procurement be developed by the National Agency for the Prevention of Corruption that includes:
  - Submission and verification of asset declarations by all public officials including Deputies of the Verkhovna Rada involved in the regulatory and legislative processes.
  - Submission and verification of conflict of interest declarations by all public officials including Deputies of the Verkhovna Rada and the relevant politically exposed people (PEPs) around them, involved in the regulatory and legislative processes.
  - A civil oversight body that involves both civil society and international organisations.
5. A targeted campaign of corruption investigation based on analysis (including this SIVA) by the National Anti-corruption Bureau of Ukraine (NABU).

## 4.2 Developing the Integrity Vulnerabilities Mitigation Plan and Implementing the Recommendations

Since the start of this assessment there have been a number of changes in the senior administration of the Ministry of Health. With the recent change in the leadership of Ministry of Health there is a renewed opportunity to cooperate effectively with the Ministry to develop jointly a mitigation plan for the vulnerabilities that have been identified in this assessment. As well, the project will need to work with the Ministry to develop and action plan for implementing the recommendations outlined above.

It is anticipated that the project will work with the Ministry in the coming months to develop the next steps necessary for enhancing integrity in the Ministry.

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# Integrity Vulnerability Matrix



INTEGRITY VULNERABILITY	TYPE OF VULNERABILITY	PRIORITY	POSSIBLE MITIGATION MEASURES
1. Policy and Regulatory Environment (Ministry of Health and related Agencies)			
1.1	Insufficient salaries paid to Ministry and other Officials may oblige staff to seek other forms of compensation.	Insufficiency	<ol style="list-style-type: none"> <li>1. Move to pay-as-you-go system based on patient resources or</li> <li>2. Patient based resource allocation (follow the patient)</li> <li>3. Consult the previous functional reviews and other assessments done previously for the Ministry of Health in order to determine the most efficient and cost-effective personnel structure for the MoH.</li> </ol>
1.3	Inconsistencies due to the lack of comprehensive country and regional development strategies in health sector development hinders proper allocation of resources.	Inefficiency	<ol style="list-style-type: none"> <li>1. Development of evidence based strategies at both national and regional strategies that are focused on actual needs.</li> </ol>
1.4	Consult the previous functional reviews and other assessments done previously for the Ministry of Health in order to determine the most efficient and cost-effective person nel structure for the MoH.	Fraud, Collusion, Theft	<ol style="list-style-type: none"> <li>1. Improvement of the MoH's Internal Audit Unit in order to turn its activities from sporadic checking to more systemic control over health facilities' operations including performance audits.</li> <li>2. Capacity Building for the Chamber of Accounts (Supreme Audit) including performance audit training.</li> <li>3. Regular Audit of resource distribution.</li> <li>4. Change formation regulations of the expert working groups on the development of Procurement Selection List (nomenclature) to restrict the membership to those that have relevant professional qualifications and expertise to exercise discretion on the issue. Also introduce term limits of its members and allow for non-voting observers to increase transparency.</li> <li>5. Develop regulations for the necessity of obtaining expert opinion of the international organizations if there are disagreements among Technical Group members on an approved range of medicines of the Procurement Selection List/Essential Medicines List.</li> </ol>

INTEGRITY VULNERABILITY	TYPE OF VULNERABILITY	PRIORITY	POSSIBLE MITIGATION MEASURES
1.5	Lack of efficient oversight and accountability mechanisms over institutions allows lapses of integrity.	Fraud, Collusion, Theft	<ol style="list-style-type: none"> <li>1. Introduction of a transparent and realistic billing system for all medical services to reflect all treatments, drugs and medical services, accommodation, meal etc. provided for every patient; (follow the patient)</li> <li>1. Separate medical decision making from administration of medical facilities.</li> <li>1. Organization of independent appeal board over state supervision and control institutions.</li> <li>1. Introduce citizen monitoring or other oversight mechanisms</li> <li>1. Create and publish the electronic registry of drugs and medicines in the forecast with the placement of information on the official Internet resource of Ministry of Health.</li> </ol>
1.6	Lack of weak regulation and fragmentation of development and implementation of policy issues leads to contrary rules and regulations that allow corruption and industry to undue influence officials.	Inefficiency, Conflict of Interests	Strengthen the policy development and oversight capacity in the Ministry of Health
1.7	Lack of insufficient integrity mechanisms in any new medicine procurement agency may not introduce measures to stop undue influence and corruption.	Bribery, Inefficiency	Create a policy of having integrity management of the system as a primary focus of new procurement agency.
1.9	Health Committee of Parliament may be unduly influenced by the pharmaceutical industry.	State/Regulatory Capture	<ol style="list-style-type: none"> <li>1. Introduction of detailed and verified (by NAPC and CSOs) conflict of interest statements of each member of the Health Committee.</li> <li>2. Requirement for a transparent and well-maintained lobbying registry.</li> </ol>
1.10	Pharmaceuticals budget is influenced by the pharmaceutical industry.	Insufficiencies / Inefficiencies	<ol style="list-style-type: none"> <li>1. The establishment of the Essential Medicine List/EML (see 2.1 for details) and other open technical descriptions and budgeting mechanisms.</li> <li>2. Stronger oversight by CSOs and other neutral parties on the budgeting process.</li> </ol>

	INTEGRITY VULNERABILITY	TYPE OF VULNERABILITY	PRIORITY	POSSIBLE MITIGATION MEASURES
				<ol style="list-style-type: none"> <li>3. Give the expert Working Group of Reforms of Ministry of Health give a wider range of responsibilities, including the identification of monopolies, assisting in the development of the Procurement Selection List (nomenclature).</li> </ol>
1.11	Patient associations and other CSOs could be manipulated by pharmaceutical industry.	Fraud		Encourage the further development of coalitions made up of different CSOs and a peer review mechanism amongst civil society partners.
1.12	Lack of a public health focus leads to manipulation in regulation of pharmaceutical procurement .	Insufficiency		<ol style="list-style-type: none"> <li>1. Strengthen capacity of an independent Public Health Institute to provide independent expertise.</li> <li>2. Utilize effectively international technical assistance including foreign experts and consultants in the expert Working Groups on reforms and others related to reforms such as WG on procurement and EML.</li> <li>3. Create pool of potential foreign and national experts, in order to continually provide input to the formation and adoption of an effective Procurement Selection List.</li> </ol>
1.13	Limited competition due to monopolization of the policy process by distributors as well as specific firms.	Fraud, anti-competitive		<ol style="list-style-type: none"> <li>1. Strengthen the anti-monopoly regime of Ukraine with the either reform of the anti-monopoly committee or a new competition authority.</li> <li>2. Develop amendments to the Budget Code, involving the transfer of money for the procurement of local budgets in the area of responsibility of centralized health product procurement agency (subject to long-term contracts, best price and supply), to distribute medicines.</li> <li>3. Provide timely access to the information without delay and implementing and effective document handling and record keeping system in the Ministry of Health.</li> </ol>

INTEGRITY VULNERABILITY	TYPE OF VULNERABILITY	PRIORITY	POSSIBLE MITIGATION MEASURES
2. Pharmaceuticals Identification (Needs and Technical Description)			
2.1	Lobbying to decision makers by the international or local pharmaceutical industry for establishment of technical description that benefit their firms	Collusion, patronage,	<ol style="list-style-type: none"> <li>1. Develop an open and transparent process for the development of the EML.</li> <li>2. Create a lobbying registry at the MoH and other state bodies.</li> <li>3. Oversight over discretion exercised by public officials via a CSO and/or international body that can monitor decisions made.</li> <li>4. Prepare a plan for reforming the procedures of selection of the Procurement Selection List (nomenclature) to an Essential Medicines List The plan should include development of the process road map, change the selection of members of Expert Working Groups of procedures, including transparent selection process of members, verification of their asset and conflict of interest statements, officials minutes of Working Group meetings; including expert opinions on the EML of specialized international organization including other countries lists and publishing openly on the Ministry of Health website the decisions made by the Expert Working Groups on procurement and implementation of EML</li> </ol>
2.2	Benefits given to or demanded by political elites/decision makers to influence pharmaceutical policy decisions.	Bribery, extortion	<ol style="list-style-type: none"> <li>1. Strengthened conflict of interest regulation regime.</li> <li>2. Lifestyle checks on senior officials (NAPC &amp; NABU)</li> </ol>
2.3	Definition of Essential Medicines List is manipulated	Fraud, bribery	<ol style="list-style-type: none"> <li>1. Create an open and transparent development of a selection medicine list that is compliant with international/regional norms.</li> <li>2. To systematize the collection of data on the number of patients who require the use of treatment regimes.</li> </ol>

INTEGRITY VULNERABILITY	TYPE OF VULNERABILITY	PRIORITY	POSSIBLE MITIGATION MEASURES
2.4	Manipulation by collusion of EML by a number of companies in the pharmaceutical industry.	Collusion	<ol style="list-style-type: none"> <li>1. Oversee the transparent process in the development of an essential medicine list that is compliant with international/regional norms.</li> <li>2. Maintaining a lobbying registry at MoH</li> </ol>
2.5	Undue influence of specific pharmaceutical firms at regional level including dosage and other nomenclature issues.	Fraud, bribery	<ol style="list-style-type: none"> <li>1. Strengthened system of controls in the health system at regional level. (See above recommendations for the national level.)</li> </ol>
2.6	Manipulation of dosages and other technical terms so that only one firm can fulfill requirements.	Fraud, bribery	<ol style="list-style-type: none"> <li>1. Open and transparent development of a selection medicine list that is compliant with international/regional norms as well as review of proposed and final policies.</li> <li>1. To systematize the collection of data on the number of patients who require the use of treatment regimes.</li> </ol>
2.7	Manipulation of technical description of specific treatment regimes could be used to clear backlog of stocks of specific firms	Fraud, bribery	Open and transparent development of an selection medicine list that is compliant with international/regional norms.

INTEGRITY VULNERABILITY	TYPE OF VULNERABILITY	PRIORITY	POSSIBLE MITIGATION MEASURES
<b>3. Medicine Selection</b>			
3.1	State Expert Centre is able to be influenced by industry and others interests.	Collusion, Bribery	Strengthen capacity of a genuine independent expert centre staffed by international and national experts.
3.2	Use of courts to block of registration which involves bribery or fraudulent claims	Bribery, fraud	Creation and maintenance of a transparent process of pharmaceutical registration and development of a new standards authority/registry that is independent and has an oversight body.
3.3	Illicit purchase of national safety standard (GNSP) certificate	Bribery	Conduct assurance control of medicine from the Expert Center side, and cooperation with reference labs to ensure independent assessments.
<b>4. Pharmaceutical Procurement (Tenders)</b>			
4.1	Winning of procurement tenders by pharmaceutical firms linked and beneficiary to politically exposed persons (PEPs) including Ministry staff	Collusion, theft	<ol style="list-style-type: none"> <li>1. Strengthened integrity system including development of independent Health Products Procurement Agency;</li> <li>2. Development of new system of oversight involving internationals and CS organisations</li> <li>3. Development of new system of registry of products.</li> </ol>
4.2	Collusion between pharmaceutical industry and procurement staff to manipulate procurement system.	Bribery, theft	<ol style="list-style-type: none"> <li>1. Strengthened integrity system including development of independent Health Products Procurement Agency;</li> <li>2. Development of new system of oversight involving internationals and CS organisations</li> <li>3. Development of new system of registry of products.</li> </ol>

INTEGRITY VULNERABILITY	TYPE OF VULNERABILITY	PRIORITY	POSSIBLE MITIGATION MEASURES
4.3	Lack of open procedures and public control over procurement procedures that allow product selection based on public officials and politically exposed persons interests	Nepotism, bribery, collusion,	<ol style="list-style-type: none"> <li>1. Strengthened integrity system including development of independent Health Products Procurement Agency;</li> <li>2. Development of new system of oversight involving internationals and CS organisations</li> <li>3. Development of new system of registry of products.</li> <li>4. To systematize the collection of data on the number of patients who require the use of specific treatment regimes.</li> </ol>
4.4	Pharmaceutical industry unduly influences: Ministry of Health and related agencies; Parliament and its Health Committee and civil society to draft regulations for its own interests.	Regulatory capture;	<ol style="list-style-type: none"> <li>1. Enhanced oversight of MoH staff and other officials by National Agency for Prevention of Corruption (NAPC) and National Anti-corruption Bureau Ukraine (NABU)</li> <li>2. Development and enforcement of a lobbying registry.</li> <li>3. Enforcement of conflict of interests regulations and declarations.</li> </ol>
4.5	Discretion of treatment regime by doctors leads to extortion or bribery from patients.	Extortion, bribery	<ol style="list-style-type: none"> <li>1. Enhanced oversight by independent civil oversight bodies selected through a transparent process.</li> <li>2. Develop a methodology for consultations of patients for the treatment program and provide oversight of Chief Doctors discretion.</li> </ol>
4.6	Lack of controls over Global Funds and other projects under Ministry of Health led to more civil society implementation	Theft, fraud	Increase both internal control and external oversight over project expenditure.
4.7	Collusion between procurement officers and bidder unduly influence the tender.	Collusion, bribery	<ol style="list-style-type: none"> <li>1. Strengthened integrity system including development of independent Health Products Procurement Agency;</li> <li>2. Development of new system of oversight involving internationals and CS organisations.</li> </ol>
4.8	Specific treatment regimes are vulnerable to manipulation by pharmaceutical firms due to the limited nature of producers.	Collusion, fraud, bribery	Increase competition through encourage of new entries into tenders.

INTEGRITY VULNERABILITY	TYPE OF VULNERABILITY	PRIORITY	POSSIBLE MITIGATION MEASURES
5. Pharmaceutical Distribution			
5.1	Distribution of pharmaceuticals to local medical institutions not based on need but for rent-seeking purposes including re-sale.	Fraud, theft	<ol style="list-style-type: none"> <li>1. Introduce a centralized distribution system that allocates based on actual needs as identified by evidence base in local medical institutions.</li> <li>2. Development of patient based resource allocation (follow the patient)</li> <li>3. Develop and implement a methodology for the calculation of the need for each program separately.</li> <li>4. Publish transparently the availability of drugs in health facilities which is updated weekly.</li> </ol>
5.2	Physicians paid to promote and request specific pharmaceuticals products.	Bribery, conflict of interest	<ol style="list-style-type: none"> <li>1. Enforcement of conflict of interest regulations.</li> <li>2. Lifestyle checks on asset declarations of head doctors by NAPC and/or CSOs.</li> </ol>
5.3	Waivers for firms in acquisition and delivery of medicines become the norm rather than exception and allow falsification in price, quality and quantity.	Fraud,	Oversight over delivery of medication through a system of independent third party monitoring using CSOs to check quality and quantity.
5.4	Automated transfer with pharmaceutical bar codes at pharmacies that allow undue advantage for selected firms.	Fraud,	Oversight over delivery of medication through a system of independent third party monitoring using CSOs to check on unfair business practices.

# Annex I: Sources

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## 6.1 Primary Sources/Key Informant Interviews (where more than one interviewee was present it is listed as an one session)

- 6.1.1 Former Senior Ministry of Health Official 1
- 6.1.1 Former mid-level Ministry of Health Official
- 6.1.2 Parliamentary staff member
- 6.1.3 Member of Parliament 1
- 6.1.4 Member of Parliament 2
- 6.1.5 Senior International organisation staff 1
- 6.1.6 Senior International organisation staff 2
- 6.1.7 International expert
- 6.1.8 International project Head
- 6.1.9 International project staff 1-4 (4 total combined input)
- 6.1.10 Civil society representative 1
- 6.1.11 Civil society representative 2
- 6.1.12 Local trade association 1-5 (5 total combined input)
- 6.1.13 Local pharmaceutical manufacturer representative
- 6.1.14 Local pharmaceutical distributor representative
- 6.1.15 International pharmaceutical manufacturer representative 1
- 6.1.16 International pharmaceutical manufacturer representative 2
- 6.1.17 Civil society representative 3
- 6.1.18 Senior International organisation staff 3
- 6.1.19 Former Senior Ministry of Health Official
- 6.1.20 Civil society representatives 4
- 6.1.21 Civil society representatives 5
- 6.1.22 Medical staff member from regions 1
- 6.1.23 Senior staff member of expert agency under MoH
- 6.1.24 Health Sector Academic
- 6.1.25 Medical staff member from regions 2
- 6.1.26 Senior International organisation staff 4
- 6.1.27 Senior Specialist of MoH
- 6.1.28 Senior International organisation staff 5

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## 6.2 Secondary Sources/ Literature Review

6.2.1 The seminal report that led to the international procurement of health products was developed by the Ukrainian NGO Anti-corruption Action Center. See - <http://antac.org.ua/en/analytics/12-mlrd-koshtiv-naliky-u-2014-vytracheni-neefektyvno-eksperty/>

6.2.2 Konovaliuk Report based on a Parliamentary Investigative Committee headed by Member of Parliament (Party of Regions) Valeriy Konovaliuk <https://www.scribd.com/doc/130334957>

6.2.3 For views on other countries see the eastern European overview report of the European Commission: [http://ec.europa.eu/dgs/home-affairs/what-is-new/news/news/docs/20131219\\_study\\_on\\_corruption\\_in\\_the\\_healthcare\\_sector\\_en.pdf](http://ec.europa.eu/dgs/home-affairs/what-is-new/news/news/docs/20131219_study_on_corruption_in_the_healthcare_sector_en.pdf)

6.2.4 See the new research conducted by the Corruption Research Center in Budapest. <http://corruptionresearchnetwork.org/acrn-news/blog/from-corruption-to-state-capture-a-new-analytical-framework>



# **Sector Integrity Vulnerability Assessment**

in Health Product  
Procurement

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Donald Bowser -  
Senior Anti-corruption Advisor  
August 25th, 2016

