CORRUPTION AND PHARMACEUTICALS: A SPECIAL RELATIONSHIP*

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In this article author will try to present an overview of the problem of corruption in the pharmaceutical sector, to identify vulnerabilities, and to prioritize strategies to tackle this problem. Access to safe, good quality and affordable pharmaceuticals continues to be one of the main problems affecting global health and corruption is one of the key driving factors. Author will try to point put the main reasons for vulnerability of pharmaceutical system to corruption and presents a framework through which vulnerabilities along the pharmaceutical value chain can be identified. Key decision points are defined as manufacturing, registration, selection, procurement, distribution, prescribing and dispensing.

Key words: *corruption, pharmaceutical, government, strategies.*

INTRODUCTION

The main importance of essential medicine, according to the World Health Organization (WHO), the one that saves lives and improve health is when "they are available, affordable, of assured quality and properly used" (World Health Organization, "Equitable access to essential medicines: a framework for collective action", 2004). At first glance, we can think that many people do not have medicines they need, or they have access only to poor drug, or they cannot afford drugs then need. Nearly 2 billion people have no access to basic medicines, causing a cascade of preventable misery and suffering.[1] WHO estimates that up to 90% of the population in low- and middle-income countries purchases medicines through out-of-pocket payments. If a household is forced to sell an asset this payment is unacceptable.[2]

People in developing countries make up about 80 percent of the global population but only represent about 20 percent of global pharmaceutical market by value although this number may be somewhat higher by volume.[3] Inadequate access to essential drugs is

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[1] https://www.who.int/publications/10-year-review/chapter-medicines.pdf [1/07/2020].

[2] *Ibid*, 2.

[3] https://www.efpia.eu/media/412931/the-pharmaceutical-industry-in-figures-2019.pdf [1/07/2020].

not only a concern in less developed countries. In the United States, for example, many senior citizens and uninsured people are not able to afford the drugs they need.[4] WHO estimates that by improving access to existing essential medicines (and vaccines) about 0 million lives per year could be saved.[5]

The reasons for inadequate use of drugs and inequalities in access to pharmaceuticals poverty are high drug prices, poor health infrastructure, and corruption. Because of limitation of time and page space, I will try to explain just the problem of corruption in pharmaceutical sector.

The presence of corruption in any one of the critical decision points in the pharmaceutical system from manufacture to retail sales can be detrimental to a country's ability to improve the health of its population by limiting population access to quality medicines and thereby reducing the health gains associated with the proper use of pharmaceuticals (Fighting Corruption in the Health Sector Methods, Tools and Good Practices, UNDP: 2011).

1. INTERNATIONAL ORGANIZATIONS AND FIGHT AGAINST CORRUPTION IN FARMACEUTICALS

Corruption in this field directly affects the development of disease and mortality, so the only way to tackle corruption in this field is globally. Actors here are big and important, influential, and the money that turns is huge. In this case, most adequate the fighters against it are international organizations.

First, we have The World Bank that has been involved in lending to strengthen pharmaceutical systems (including infrastructure, purchase of drugs, equipment, technical assistance, training and policy advice) since the early 1980s. It is increasing its activities in the area of governance and corruption. Important work it has undertaken in the area of pharmaceuticals and corruption includes its guidance on procurement with further action anticipated in this area.

The World Health Organization (the WHO) has long been concerned about counterfeit drugs and has led the effort in developing countries to combat counterfeit medicines and promote ethical practices in pharmaceutical marketing and retailing. It has published numerous documents on combating corruption and ensuring the integrity of the drugs supply, which are available on its website (www.who.int). The WHO is also undertaking research to better understand corruption issues and is developing tools to assess the vulnerability to corruption.

The European Union (EU) created a European Healthcare Fraud and Corruption Network (EHFCN) in 2004 to help member countries with enforcement activities in all areas of the health care and pharmaceutical systems. The Office is responsible for a range of activities including stopping patient, professional, staff/manager and supplier corruption.[6]

[4] https://www.health.harvard.edu/blog/millions-skip-medications-due-to-their-high-cost-201501307673 [1/07/2020].

[5] https://www.who.int/publications/10-year-review/chapter-medicines.pdf [1/07/2020].

[6] www.ehfcn.org [1/07/2020].

The International Federation of Pharmaceutical Manufacturers (IFPMA), the association of the research-based pharmaceutical industry, through its affiliate the Pharmaceutical Security Institute (PSI), monitors the sale of counterfeit and sub-standard drugs including incident reporting, analytical assessments and dissemination of reports on counterfeiting activities (see www.psi-inc.org).

2. WHY IS THE PHARMACEUTICAL SYSTEM VULNERABLE TO CORRUPTION

The pharmaceutical system is susceptible to fraud and corruption for a variety of reasons. First, most of the consumers of very expensive drugs are desperate and afraid, so they do not think about price and corruption, but life. Second, the sale of pharmaceutical products is lucrative, the more so because the final customers (patients and their families) are more vulnerable to opportunism than in many other product markets. Pharmaceutical suppliers (drug manufacturers, importers, wholesalers, prescribers, pharmacists) are profit maximizers and will choose to behave in ways that maximize their interests. In this area this is ethically bad, but legal offenses can often be seen here (See Picture 1.)

In the transition economies of Eastern Europe, the rapid deregulation and privatization of the pharmaceutical sector, combined with an often unstable economic and political environment created opportunities to engage in corruption. In Albania, instances of corruption in pharmaceutical procurement included private financial interests determining what drugs to procure for the public health system, kickbacks or bribes that enabled bidders to gain access to confidential information and use of direct procurement instead of competitive bidding without sound justification.[7]

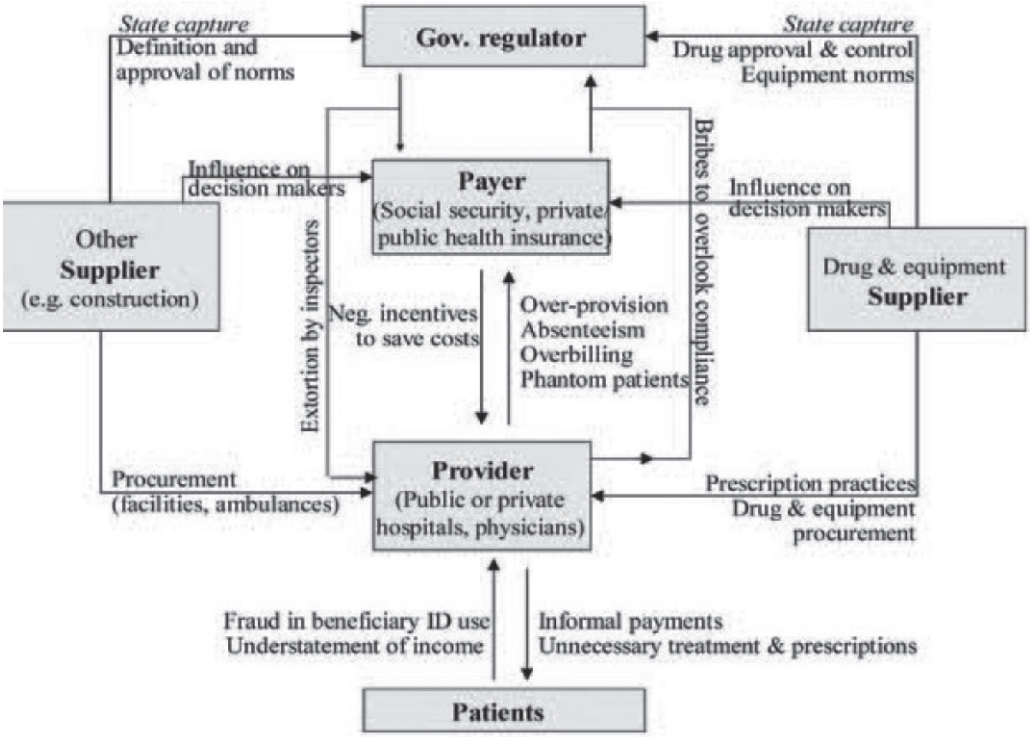
The second reason why the pharmaceutical sector is susceptible to fraud and corruption is that it is subject to a significant degree of government regulation. Government intervention is correctly justified in the pharmaceutical sector given the imperfect nature of the market and the need to improve the efficiency of resource allocation. Also, regulation is rationalized on the grounds of protecting human life and public health by ensuring that only safe and efficacious medicines are made available in the market (Marshall: 2001). Without proper Governmental directions and supervision, things would be even worse.

In many countries, a government will determine what drugs are included on a national essential drugs list or reimbursement list of a public health care payer.[8] That means that patients are not paying for drugs (that is, they pay through social security), and in that way patients will usually take the cheap, even worse drug. The inclusion of a drug on such a list, particularly a reimbursement list, can mean significant financial income for a drug manufacturer as it guarantees the product a relatively predictable market share. Weak legislative frameworks result in poor outcomes (high prices, problems in drug quality, availability of supply) and create opportunities for unethical and corrupt behavior.

[7] Vian, T "Corruption in the Health Sector in Albania," Report prepared for the USAID/Albanian Civil Society Corruption Reduction Project, Management Systems International (Boston, MA: Boston University School of Public Health. Available at URL: http://www.bu.edu/actforhealth [01/05/2020].

[8] In Serbia the official name is "list of positive drugs" *("lista pozitivnih lekova").

The third reason why the pharmaceutical sector is vulnerable to fraud and corruption is that the supply chain is extremely complex, often involving up to thirty different parties before the product reaches the end user, thus creating the opportunity for the introduction of counterfeit and substandard drugs.



Picture 1. Problems of corruption[9]

3. STRUCTURE OF THE PHARMACEUTICAL SECTOR: SIX CORE DECISION POINTS AND ANATOMY OF CORRUPTION

Three main pharmaceutical system decision points and related processes may be vulnerable to corruption. On these points we need to take extra care and those are: manufacturing, registration, selection, procurement, distribution, prescribing and dispensing. Again, because of page limitation I will try to be extra short (Hussmann: 2010).[10]

[9] www.dfid.gov.uk/Documents/publications1/How-to-Note-corruption-health.pdf [1/07/2020].

[10] Corruption in the Pharmaceutical Sector, available on stable internet address: https://www.transparency.org.uk/sites/default/files/pdf/publications/29-06-2016-Corruption_In_The_Pharmaceutical_Sector_Web-2.pdf [1/07/2020].

3.1. Manufacturing

Manufacturing of pharmaceutical products requires adherence to standards of Good Manufacturing Practice (GMP) to ensure "that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization" (World Health Organization, Expert Committee on Specifications for Pharmaceutical Preparations: 2003). GMP is a term used to describe a set of principles and procedures of quality assurance as defined in law to be followed by drug manufacturers in order to help ensure that the products produced meet the required quality.

The processes that needs to be done if we want a clean drugs we must follow these:

- Adherence to Good Manufacturing Practices (GMPs)
- Quality management
- Packaging and labeling Active Pharmaceutical Ingredients
- Master, batch and laboratory control records
- Production and in-process controls
- Certificates of analysis
- Validation
- Track complaints and recalls

3.2. Registration

The process of market authorization is generally undertaken by a national drug agency, responsible for the evaluation of a drug's safety, its efficacy against a specific disease, its possible side effects and its bioequivalency/bioavailability in the case of a generic. Drug regulatory agencies are also often responsible for the setting and enforcement of standards (as they relate to the manufacture, storage and distribution of pharmaceutical products), licensing (pharmacists, pharmacies, wholesalers), defining the requirements for labelling, marketing, usage, warning and prescription requirements, and post-market surveillance and pharmacovigilance.

Drug registration needs to have a strong legal basis that ensures transparency, and uniform and effective application of the defined standards. Transparency if vital to enforcing limits placed on individual discretion and minimizing risks of regulatory capture. In poorer countries where there capacity and effectiveness of the regulatory agency is depended on its financing from the fees it receives for the drugs it is meant to regulate, independence can be challenging, and it is particularly in such circumstances that independence of the regulatory staff, separation of functions and contact with manufacturers and transparency becomes even more important.

Processes that we must follow if we want to do everything according to moral and ethical norms are:

- Full registration or abbreviated drug applications
- Safety and efficacy

– Labeling
– Marketing
– Indications
– Pharmacovigilance and warnings
– Batch testing
– Reevaluation of older drugs

3.3. Selection

For publicly funded drugs, the primary government task in drug selection is to ensure that the most cost-effective and appropriate drugs for a population's health needs are chosen and that this is done fairly and transparently through the use of impartial expert committees. The use of essential drugs lists has helped to increase objectivity and transparency of selection process by listing cost-effective drugs according to their international non-proprietary names (generic names) and further stimulates generic competition. The WHO's Essential Drug List (EDL) is a helpful framework for most developing countries because it establishes priority areas of treatment and covers the most common diseases with effective and affordable drugs.[11]

The most important processes in this part are to:

– Determine budget
– Assess morbidity profile
– Determine drug needs to fit morbidity profile
– Cost/benefit analysis of drugs
– Consistency with WHO (and other evidence-based) criteria
– Pricing and reimbursement decisions

3.4. Procurement

Procurement is the principal interface between the public system and drug suppliers, and its goal is to acquire the right quantity of drugs in the most cost-effective manner. Government functions in this decision point includes: inventory management, aggregate purchasing, public bidding contests, technical analysis of offers, the proper allocation of resources, payments, receipts of drugs purchased and quality control checks. Procurement is often poorly documented and processed, which makes it an easy target for corruption. The best protection against corruption is generally international competitive procurement because it maximizes competition and minimizes opportunities for personal discretion in the selection of suppliers. Competitive procurement requires an open bidding process and clear criteria for the selection and process of winning bids. The procurement process must include continuous monitoring, including reviews from the inspector general's office (or similar internal and external audit institutions for the public sector).

[11] The WHO Model List of Essential Medicines, Available at: URL: http://www.who.int/medicines/publications/essentialmedicines/en/ [1/07/2020].

This is very demanding stage, so we should take special care of:

- Determine model of supply/distribution
- Reconcile needs and resources
- Develop criteria for tender
- Issue tender
- Evaluate bids
- Award supplier
- Determine contract terms
- Monitor order
- Make payment
- Quality assurance

3.5. Distribution

The system needs to ensure the timely and safe delivery of appropriate quantities of drugs to health facilities and pharmacies where supplies are needed. Distribution and storage costs can comprise a significant amount of the retail price of a drug, especially when drugs are distributed to remote locations. Poor storage conditions can lead to losses due to both the diversion (corruption) and expiration of drugs (inefficiency). A well-designed and well-managed distribution and storage system aims to: maintain a constant supply of drugs; keep drugs in good condition throughout the distribution process; minimize drug losses due to spoilage and expiry; rationalize drug storage points; and use available transportation resources as efficiently as possible.

There are a number of models for supplying drugs. First, the central medical store (CMS), in which drugs are financed, procured, and distributed by the government is most common in public-sector supply chains. In this model, the government is generally the owner, financer and manager of the entire supply system. This model is good because there are direct check and balance system, but it cost a lot so if the State is not stable then corruption is on the mission.

A second model is the autonomous supply agency. An autonomous or semi-autonomous agency has more flexibility than the first model, but fragmentation of purchasing volume can increase prices in comparison with a centralized purchasing system.

A third model is the direct delivery system, whereby a government procurement office tenders for drugs and other supplies but the drugs purchased are delivered directly from the drug supplier to the health facility. This model helps reduce costs related to centralized storage and transport from the government by shifting them to private suppliers. But, also in this model there may be a delay of supply that can trigger corruption.

A fourth model is the prime vendor system. In this system, a government procurement office tenders for two contracts, the first one is for drug sources and prices and the second one for supplying the drugs to stores and/or health facilities. The party contracted for supplying drugs (prime vendor) is responsible for maintaining sufficient stocks to fill orders from regional and district stores, and/or health facilities. Finally, drug

supplies can be purchased and distributed through a fully private supply system. If there is no proper administration and supervision, again we have a problem.

I cannot say which model is the best, because the key actor is state and if the State administration is, corrupt, then all these models are fail. There are few things we have to take in mind in this stage. Those are:

- Import approvals
- Receive and check drugs with order
- Ensure appropriate transportation and delivery to health facilities
- Appropriate storage
- Good distribution practices and inventory control of drugs
- Demand monitoring

3.6. Prescribing and Dispensing

Drug prescribing and dispensing involves the participation of doctors like physicians, pharmacists, and other health-care providers who diagnose patients and identify what drugs a patient should consume (if any) to treat a particular disease. This is the decision point at which patients should experience the benefits of the entire system, if it is functioning well. Patients should receive the right drug at the right time and with the appropriate information. In free market times, especially in development countries, doctors choose drugs for some other reasons then the best care, like because of better marketing, earning bonuses or some other self-interested profit motivation.

The best way to conquer corruption in these field id to follow:

- Adherence to Good Manufacturing Practices (GMPs)
- Quality management
- Packaging and labeling Active Pharmaceutical Ingredients
- Master, batch and laboratory control records
- Production and in-process controls
- Certificates of analysis
- Validation
- Track complaints and recalls

4. CORRUPTION IN PHARMACEUTICALS – CASE OF BALKAN COUNTRIES

The market for pharmaceuticals in these countries is dominated by off-patent, multi-sourced, branded generic drugs. The pharmaceutical sectors in all these countries underwent a significant transformation after the end of communism, followed by wide liberalization and privatization of the market. A period of re-regulation has followed during the last decades, albeit at a much slower pace, as the countries attempt to address challenges in developing a modern, safe, quality and affordable pharmaceutical system. The governments lack experience in regulating in this new market context and most

professional associations and codes of ethical practice are new, absent or weakly enforced. Also, simple rewriting of rules has led to over-regulation and legal solutions that are not appropriate for these countries.

The legislative frameworks however have tended to be weak resulting in poor outcomes (high prices, problems in drug quality, availability of supply) and creating the opportunity for unethical and corrupt behavior. This has been complicated by the establishment of insurance funds and purchasing groups which have been required to rapidly evolve systems to select, price, procure, reimburse and manage drug expenditures. These countries have largely branded generics markets and generic substitution is uncommon. Local or ex-Yugoslavian suppliers were dominant in many markets with favored arrangements, but after the collapse or bad privatization of them there was also a shortage of affordable medicines. All countries use a form of reference pricing and/or tender mechanism for out-patient and hospital drugs which should lead to competitive prices.

To assess drug selection and pricing/procurement a series of indicators were adapted from World Bank Study (Cohen *et al.*: 2002) to focus on this part of the pharmaceutical chain and asses its vulnerability to corruption. The countries showed more vulnerability to corruption in pricing and procurement than drug selection.

However, it must be acknowledged that in the last decade there have been significant changes and a large reduction in corruption in this field. Due to international and public pressure, there has been a reform of health care and better regulation in the field of pharmacy, and especially in the field of supply chain.

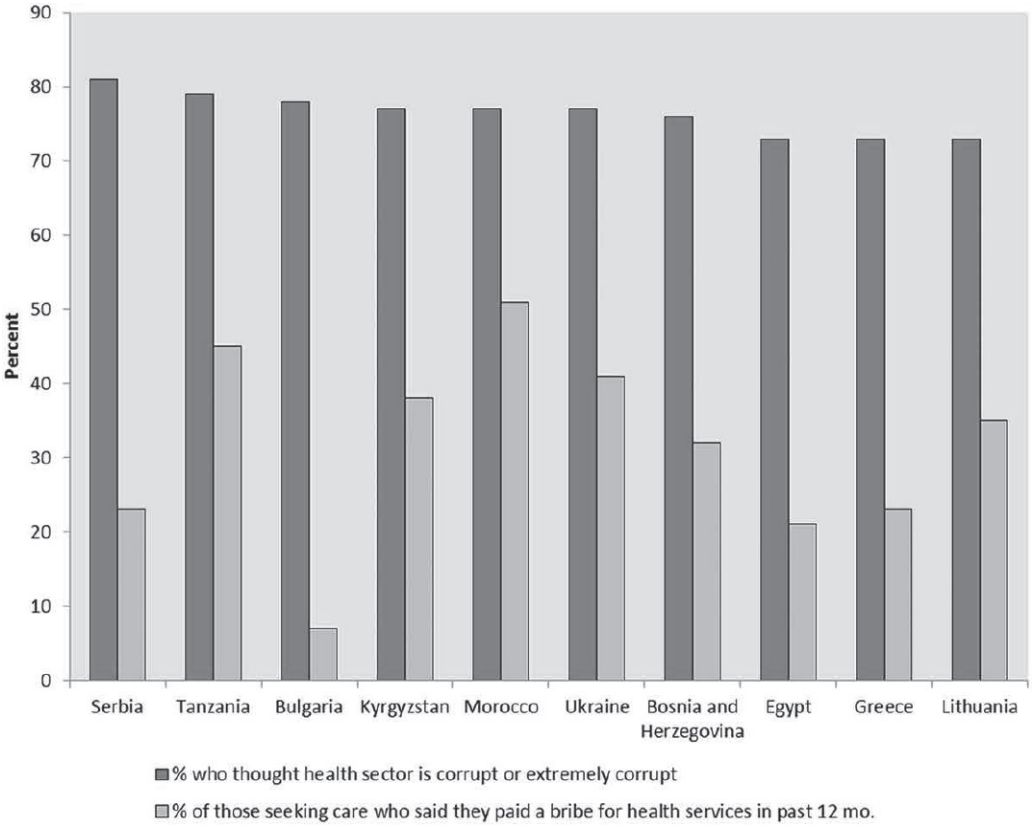


Figure 1. Countries with highest percentages of respondents reporting perceptions that the health sector is corrupt or extremely corrupt and reporting payment of a bribe in the past 12 months.[12]

CONCLUSION

It is very difficult to give a summary conclusion for a topic that is so broad and important. While corruption in the pharmaceutical system can affect the entire population, it is typically the poor that are most susceptible to its detrimental effects. In most poor countries drugs are purchased out-of-pocket by consumers and represent a significant share of household consumption on health care. Governments in these countries still have a responsibility to ensure that even the poorest can access quality essential drugs. Governments have a responsibility to create sound institutional structures, processes and policies, and reinforce outcomes that promote public welfare. As part of this effort, anticorruption measures, if implemented successfully, have the potential to benefit population access to medicines, save public money and improve the credibility to governments and other organizations like the World Bank that are involved in country

[12] Transparency International, 2013. Study included 107 countries. Albania and Russia, which had high-perceived health sector corruption, did not have bribe data, and therefore are not shown.

level drug delivery programs. Governments have two different core responsibilities in the pharmaceutical system. First, governments are responsible for regulating the manufacture, distribution, sale and use of pharmaceutical products, which includes regulating all actors involved in the pharmaceutical sector. Second, where coverage is provided, public purchasers are responsible for selecting, purchasing and logistical management of drugs for use through the public health care system.

If we focus on manufacturing we can follow some steps like we can ensure legal basis for GMP requirement including appropriate and credible fines for non-compliance; improve GMP compliance by regular and random inspections; hire a sufficient number of trained and well paid inspectors; develop a rotating schedule for inspectors of manufacturing sites; publicly post a list of compliant manufacturers; publicly 'Name and Shame' noncompliant manufacturers.

As we already stated before if we want to make a clean system in Registration part we have to develop transparent, effective and uniform law and standards for drug registration. We have to ensure adequate drug quality control capacity and educate public and professionals to identify unregistered drugs. To inform other health workers and the public we heed to publish drug registration information on the internet and implement market surveillance and random batch testing.

If we single out Selection then we can conclude that a special attention should be paid to define and publish clear criteria for selection and pricing, to have a drug selection committee membership that should be publicly available. Drug selection criteria should be based on international standards as set out by WHO. WE have to have regular reporting by the media of drug selection meetings and we have to have public posting of all the decisions and results that are important in this area.

Procurement procedures must be transparent, following formal published written procedures throughout the process and using explicit criteria to award contracts. Supplier selection should be justified and monitored and strict adherence to announced closing dates. Another neglected thing is that written records should be kept of all bids received not just in electronic but in hard copy to.

If we focus only on Distribution we can single out, as a conclusion, the following: where possible develop information systems to ensure drugs are allocated, transported and stored appropriately; regular communication between every level of the system to control inventory movements and deliveries: appropriately secured storage facilities and transport and use Electronic monitoring of stock in distribution and careful checking of delivery orders against inventories of products delivered to identify theft.

In Serbia, we have problems especially with pharmaceutical prescribing and dispensing. If we want to reduce corruption, we have to develop and engage professional associations to improve adherence to professional codes of conduct and use information systems to monitor physician prescription patterns. On the other side, we have to impose serious penalties, 'name, and shame' for breaches of legal and ethical standards and regulate industry interaction with prescribers through explicit criteria that limits industry gifts and payments. One other way to resolve this is to have strict policy for License and inspect pharmacies.

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KORUPCIJA I FARMACEUTSKI PROIZVODI: POSEBAN ODNOS

U ovom radu autorka ukazuje na problem korupcije u farmaceutskom sektoru i posebno ističe značaj strateškog pristupa prilikom rešavanja navedenog problema. Dostupnost bezbednih, kvalitetnih i prema cenama pristupačnih lekova predstavlja pitanje od izuzetnog značaja za zdravlje ljudi na globalnom nivou. Međutim, ono može biti poljuljano prisustvom korupcije u farmaceutskom sektoru. Autorka ukazuje na podložnost farmaceutskog sistema korupciji, a koju je moguće identifikovati kako tokom procesa proizvodnje, tako i prilikom registracije, nabavke, distribucije, proizvodnje i izdavanja farmaceutskih proizvoda.

Ključne reči: *korupcija, farmaceutski proizvodi, vlast, strategije*