

# Independent Joint Anti-Corruption Monitoring and Evaluation Committee

# VCA Report on Pharmaceuticals importation process

(Translated from Dari)

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# **SUMMARY**

This Vulnerability to Corruption Assessment (VCA) examines a range of issues pertaining to the importation of pharmaceuticals in Afghanistan. Analyses of regulatory, institutional, and procedural gaps/weaknesses are conducted in order to identify major corruption vulnerabilities and develop recommendations to address them. The VCA Team found that corruption in the pharmaceutical importation process is facilitated and perpetuated by a combination of high import volume and low surveillance and monitoring capacity.

#### I. INTRODUCTION

The widespread availability of quality pharmaceutical products is critical to promoting and maintaining public health. This is particularly important in impoverished, insecure, countries, such as Afghanistan, where there is heightened vulnerability to disease and other sources of morbidity/mortality. Unfortunately, increased demand for pharmaceutical products and significant financial incentives for engaging in illicit importation have led to a dramatic increase in the importation of poor quality medicine. According to the Ministry of Public Health's Pharmaceutical Affairs Directorate and Importers Union, at least 50% of Afghanistan's pharmaceutical import market is comprised of illegally imported products. It is estimated that the combined value of both illegal and legal pharmaceuticals in Afghanistan is USD 700-880 million.

While the rules and regulations that govern pharmaceutical imports in Afghanistan need to be significantly revised, there are procedures that, if followed, could mitigate the importation of poor quality pharmaceuticals. However, as with many rules and regulations in Afghanistan, they are easily circumvented through corruption.

In fact the entire importation process is highly vulnerable to corruption, from registration of foreign pharmaceutical companies, to pro forma registration, to laboratory-based quality control. Enormous financial incentives to engage in illicit importation of pharmaceuticals has led to an increase in smuggling, as well as the creation of an entire industry dedicated to producing and importing low quality pharmaceuticals into Afghanistan.

For example, it is estimated that up to 60% of pharmaceuticals imported into Afghanistan are produced in Pakistan specifically for the Afghanistan market. It is widely believed that the dramatic increase in the number of pharmaceutical companies in Pakistan is due to the ease with which low quality medicines can be produced and imported with relatively little oversight or quality control. Enormous profits can be made as a result, particularly since the producing companies do not even need to meet Pakistani quality control standards as long as the pharmaceuticals are produced for export to Afghanistan only.

The Independent Joint Anti-Corruption Monitoring and Evaluation Committee (MEC) have tasked the Vulnerability to Corruption Assessment (VCA) Team to examine the pharmaceutical import process and identify corruption vulnerabilities. This information will be shared with key stakeholders in an effort to identity corruption mitigation strategies and ultimately improve the quality of pharmaceuticals that are imported into Afghanistan. The VCA focuses on vulnerabilities in the following three areas:

Legal Framework

- Organizational Structure and Human Resources
- Importation Process

It should be noted that while the VCA Team also examined the process of distribution of pharmaceutical after importation, it was very clear from the outset that the more significant vulnerabilities from a policy standpoint are in the import process. As a result,, most of the VCA recommendations address institutional, human resource and procedural issues in the import process.

# VCA Data Collection/Methodology

VCAs are primarily designed to acquire a range of qualitative data relevant to identifying vulnerabilities in laws, regulations, procedures, processes, etc. The VCA Team used the following information sources in the process of data collection:

- General study of media reports about the import process
- Open interviews and discussion with officials and other key stakeholders
- Study and analysis of legal and administrative procedures
- Group meetings, interviews and focus groups
- Observations of procedures/processes associated with the pharmaceutical process at the national and provincial level.

#### II. LEGAL FRAMEWORK VULNERABILITIES

The legal and regulatory framework for pharmaceutical importation is comprised of a range of public health, procurement, and pharmaceutical specific laws and procedures. Many of the laws and regulations have significant gaps that facilitate corruption opportunities. The most relevant deficiencies and vulnerabilities are outlined below:

# Afghanistan Public Procurement Law (2008)

The VCA Team found that the law provides no specificity on selection criteria in relation to procurement of pharmaceuticals. The common practice is to select pharmaceuticals based on low cost as opposed to striking a proper balance between cost and quality. A common complaint is that procurement officers who choose higher cost/higher quality pharmaceuticals are often targeted for legal action by regulators for failing to choose lower cost/lower quality products. Procurement officers often have to pay bribes to avoid legal action for choosing better quality products.

# Pharmaceutical Law (2007)

The Pharmaceutical Law deals with selection, production, importation, distribution and consumption of pharmaceutical products in the country. It was enacted at a time when there was significant need for pharmaceutical products in Afghanistan, which the law addressed by over-simplifying much of the importation process. Given the dramatic increase in the volume of low quality pharmaceutical imports, this law is need of substantial revision.

Aside from the highly permissive environment the Pharmaceutical Law provides importers, it is deficient in addressing conflict of interest issues that are easily exploited by government staff. Information

provided to the VCA Team suggests that many MoPH staff members have direct or indirect business relationships with pharmaceutical companies.

During the interview process, the VCA Team learned that amendments/revisions to the Pharmaceutical Law are currently being drafted to address several deficiencies. It is hoped that recommendations from this VCA will be used to facilitate the revision process.

# **Licensed National Pharmaceutical Products List (2008)**

The Licensed National Pharmaceutical List determines which products can be imported, produced, and distributed. The list is supposed to be updated every 3 years, but it has not been updated for at least 7 years. Nevertheless, the National Pharmaceutical Board continues to approve importation/production of additional 50-60 items per year. Interviewees stated that this is a significant corruption opportunity as MoPH staff can simply ask for bribes for anything that is not on the list.

Vulnerabilities/recommendations of legal framework in this process have been summarized in table below:

Vulnerable Points	Vulnerabilities	Negative impact of vulnerabilities	Benchmarks
Afghanistan Public Procurement Law	The law is too broad in relation to the procurement of pharmaceuticals.  Procurement standards of pharmaceuticals are not well defined.	Limited procurement standards have led to processes that overvalue cost vs. quality, This benefits import companies and producers who are most likely to engage in corruption  Regulators can extort bribes from procurement officers who choose higher quality/higher cost products	Establishment of separate pharmaceutical procurement procedures that have better delineated criteria for selection and promote higher quality.
Pharmaceutical Law	Law creates highly permissive import environment conducive to exploitation  Law fails to address conflict of issues that are exploited by government staff	Relatively liberal import standards are easily exploited by producers of low quality pharmaceutical products  Law creates opportunity for government staff to have direct or indirect involvement with private pharmaceutical companies	Law must be reformed to adequately regulate the increased volume and diversity of pharmaceuticals entering the country.  Law must be reformed to prohibit government staff from having business interests in pharmaceutical companies.
Licensed National Pharmaceutical Products list	Products list has not been updated for 7 years.	Provides corruption incentives to bribe officials for allowing products off the list.	List must be updated annually and linked to the pro forma registration and licensing process.

#### III. INSTITUTIONAL AND HUMAN RESOURCE VULNERABILITIES

The Pharmaceutical Affairs Directorate (PAD) and the Health Laws and Regulation Directorate (HLRD), both under The Ministry of Public Health (MoPH), are the primary pharmaceutical oversight bodies in Afghanistan. Other departments within the Ministry play varying roles as well. For example, The Food and Drugs Quality Control (FDQC) department plays a role in conducting laboratory tests for quality control. Outside the MoPH, the Afghanistan Investment Support Agency (AISA) and the Customs Department (Under the Ministry of Foreign Affairs) play the most significant roles in the pharmaceutical importation process.

The VCA Team found that institutional and human resource deficiencies within PAD and MoPH in general were significant contributors to corruption vulnerabilities in the pharmaceutical import process. Many of these deficiencies have been previously been identified by WHO<sup>1</sup>, and center around two broad themes, weak organizational structure and highly under-qualified staff.

# **Organizational Structure Vulnerabilities**

The current organizational structure within the PAD was originally designed to manage much smaller import quotas and is not conducive to being able to manage and monitor the large and rapidly growing pharmaceutical import sector. This essentially means that that the PAD lacks the capacity to adequately manage and monitor the current level of pharmaceutical imports. This lack of monitoring capacity is a corruption vulnerability and one that is easily exploited by importers as well as MoPH staff.

Corruption vulnerabilities due to lack of monitoring or surveillance capacity are further enhanced by poorly defined and overlapping staffing roles/responsibilities, as well as lack of inter-departmental coordination. This allows MoPH staff to solicit bribes for activities outside their departmental mandates with little chance of being detected by supervisors, auditors, or M&E systems.

It should be pointed out that organizational structural weaknesses also have potentially harmful effects on reform efforts. For example, based on recommendations from previous pharmaceutical sector evaluations, the MoPH developed two strategic documents under the National Framework for Pharmaceutical Human Resources (for 1396-1392) and Competency Framework for Pharmaceutical Services. The strategic plans formulated in these documents do not adequately account for organizational deficiencies, including absorptive capacity, which will likely make their implementation very difficult

#### **Human Resource Vulnerabilities**

Deficiencies in organizational structure significantly compromise surveillance and monitoring capacity, a major corruption vulnerability. Even if coordination were improved, and roles/responsibilities clarified/streamlined, the PAD would still be limited by lack of adequately trained staff members. The

<sup>&</sup>lt;sup>1</sup> Wahidullah Karwar, M. Zafar Omari, Zakeria Fatehzada, Aisha Noorzaee, Inua Yusuf, D. Lee, M. Morris, and T. Layloff. April 2011. Afghanistan Medicines Quality Assurance Assessment – A Qualitative Survey. Submitted to the USAID by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

consequences for this deficiency for the import process are discussed in further detail below, however it is safe to say the entire import and distribution process is vulnerable to corruption because staff have very little, if any, training in monitoring and evaluation, surveillance, quality control, etc.

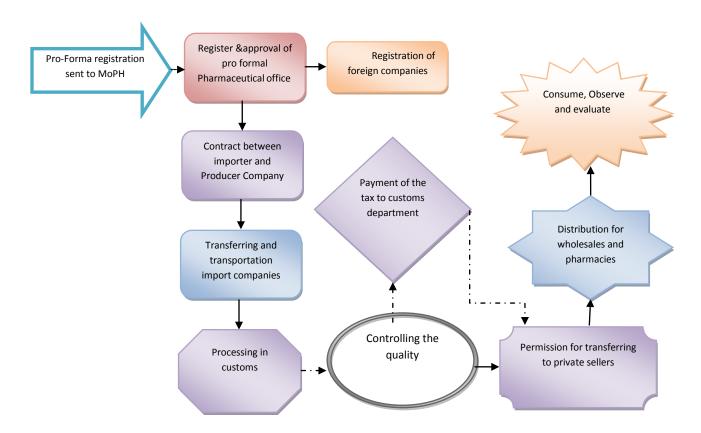
It is very difficult for MoPH to recruit staff with pharmaceutical backgrounds due to the lack of training capacity in Afghanistan, as well as the low salaries offered. While pharmaceutical training is highly technical, it is not considered a professional qualification for salary purposes and is not a highly promotable position.

# **Vulnerabilities/Recommendations Related to Organizational Structure and Human Resources**

Vulnerable Points	Vulnerabilities	Negative Impact of Vulnerabilities	Benchmarks
Organizational structure of Pharmacy Affairs Directorate	Organizational structure not conducive to addressing challenges and scope of pharmaceutical import issues	Poor performance/oversight Inability to formulate and implement plans/strategies conducive to improving quality control and anti-corruption measures Inability to control volume/quality of import market	Restructuring PAD organizational structure to ensure the human resources are allocated to improve surveillance/oversight capacity
Inter- Departmental Coordination	Lines of effort/responsibility not clearly defined.  Poor inter-departmental coordination	Intra-departmental oversight compromised by blurred lines of responsibility and is easily exploited by corrupt actors.	Clarifying roles and responsibilities to ensure that chains of command, and M&E systems within departments are better positioned to identify corruption.  Establishing formal coordination mechanism among department to enhance surveillance/monitoring capacity.
Human Resources	Lack of qualified staff, particularly those with pharmaceutical backgrounds.	Lack of technical capacity significantly compromises surveillance, monitoring, and quality control efforts.	Pharmaceutical training capacity must be enhanced.  Pharmaceutical training must be revalued as professional-level for salary determination and promotion purposes.

# IV. PHARMACEUTICAL IMPORTATION PROCESS VULNERABILITIES

Flow Chart of Pharmaceutical Import Process



Pharmaceutical import companies are required to obtain a business license from the Afghanistan Investment Support Agency (AISA) to apply for an import license from the Pharmacy Affairs Directorate (PAD) of the Ministry of Public Health (MoPH).

Once an import company has obtained the AISA license, it may then apply for an import license from the Pharmaceutical Affairs section of MoPH. Obtaining a license consists of around 44 steps, which exposes the process to significant corruption vulnerabilities.

The VCA team found that import companies have little incentive to follow the licensing process given that it is long, very complicated and can be easily overridden through bribery or leveraging relationships with high level officials both inside and outside the MoPH. Most companies are illegally importing medicine or obtaining licenses without following proper procedures.

Many interviewees suggested that the imports of certain high demand pharmaceuticals are controlled by powerful factions comprised of senior officials, including parliamentarians and ministers, and producing/import companies

**Registration of Foreign Pharmaceutical Companies** 

In addition to the AISA and MoPH licenses, pharmaceutical importers may only be purchased from companies that have been registered with the Pharmaceutical Affairs section of the MoPH. While this registration process is in theory a useful mechanism for quality control, the VCA Team felt that the registration process, as with the licensing processes, lacked integrity. There was little to no evidence that Pharmaceutical Affairs Directorate staff members possess the qualifications or have procedures in place to properly assess the quality of medicines produced by foreign companies.

In addition, no discernible or substantive mechanism for quality check or regulatory framework appears to exist for registering companies. The lack of regulation or quality control is apparent in the significant number of companies that have been registered in the recent past.

Even basic regulations requiring that imported drugs have Dari Labeling are frequently ignored. Iranian drugs are the only ones in compliance with the regulation, which has implications not only for quality control but for informed consumer consumption as well.

Currently, there are at least 450 foreign pharmaceutical suppliers registered with the MoPH. It is estimated that 250-300 of these companies are producing exclusively for the Afghanistan market, most of which are located in Pakistan. Many of these Pakistan based companies are not allowed to sell their products in Pakistan, but are allowed to export their products to Afghanistan. This raises serious concerns over Afghanistan's importation standards, even relative to the region. As a comparison, India, with a population of 1.3 billion has only 93 registered foreign companies.

#### **Pro Forma Registration**

Pro forma registration (obtaining early permission to import goods) is a critical step in the pharmaceutical importation process and is highly susceptible to corruption. The approval process consists of several steps, but official approval of the pro-forma registration resides with the Experts Board under the PAD. Import companies frequently claimed that the lengthy bureaucratic process of pro forma registration and illegal interference by senior officials in Board decisions are major drivers of pharmaceutical smuggling.

As a result, it is estimated that at least 50% of the medicines in the domestic market have been imported illegally from neighboring countries, raising serious concerns over quality control. Lack of official oversight, including lack of government staff with pharmaceutical backgrounds further exacerbates the problem.

One of the underlying themes of corruption in the context of pro forma registration is the lack of long-term planning on the part of PAD, including establishing import priorities and quotas. This essentially creates a situation in which there are few limitations on imports and provides little disincentive for corrupt actors to limit pro forma registration approvals. Corrupt actors within the MoPH frequently override the Expert Board by citing "shortages" of specific medicines produced by companies with whom they have established corrupt relations.

Interviewees stated that computerized tracking systems would significantly enhance the effectiveness of the pro forma process and allow regulators to incorporate pharmaceutical market data, pro forma registration data, etc. into long-term plans. The tracking system might also serve to minimize corruption.

# Pharmaceutical Company Contracts/Purchasing

Corruption vulnerabilities in contracts with Pharmaceutical companies could be minimized significantly if licensing and registration procedures, as well as pro-forma regulations were strictly observed. All of these procedures, if followed, contain numerous opportunities for quality control. When they are ignored, however, the ability to scrutinize and adequately monitor, the quality of drugs being purchased and imported decreases substantially. Consequently, the contract and purchasing process is highly vulnerable to corruption.

Forgery and falsification of purchasing bills is very common, allowing companies to artificially lower the value of their imports to avoid paying higher taxes.

# Transportation/Importation of Pharmaceuticals:

By the time pharmaceuticals are loaded on to trucks and shipped to Afghanistan, corruption has already played a significant role in obtaining licenses and registrations, effectively undermining a number of quality control checkpoints. Among other things, these results in the transportation of pharmaceuticals that will exceed demand/necessity, flooding Afghanistan with medicines that will likely expire, but continue to be sold. It also ensures that many of companies that have produced the drugs will not have been evaluated for the quality of their products or followed proper storage and cold chain maintenance procedures before and during transport. During the summer, pharmaceutical are often transported through areas that reach 40 centigrade, ensuring the many medications will be spoiled, but sold to consumers anyway.

In the end, pharmaceutical transport to and through Afghanistan is exposed to many of the same vulnerabilities found in Afghanistan's notoriously corrupt border management system. Bribes can be used to override almost every step of the importation process, including quality control checkpoints at the border, importing pharmaceuticals beyond those listed on the pro forma sheet or even without the required pro-forma registration.

# Laboratory Sampling / Customs

When pharmaceuticals arrive at the Afghanistan border, the importer notifies the Pharmaceutical Affairs Directorate that pharmaceuticals are at the Customs House. A representative from the Pharmacy Affairs Directorate tasked to the Customs House send samples of the imported product to a laboratory for testing. When the quality of the pharmaceuticals has been confirmed, the importer receives an exit license and is allowed to remove the products from the Customs House for distribution. The VCA Team identified numerous corruption vulnerabilities in this process, including forgery or falsification of lab results.

Import companies asserted that sometimes that PAD staff at the Customs House arrange for quality medicines to receive poor lab results as a mean of extorting bribes. These corruption strategies are particularly egregious, as they almost constitute a disincentive for companies to import quality

medications. Corruption in the laboratory approval process is also facilitated by lack of clearly stated standards and procedures.

#### **Price Determination**

Prices of imported pharmaceuticals are determined through a two-step process, once they are cleared by customs. The importer sends a letter to the PAD formally requesting a sales price. The PAD issues an order that the importer takes to the Procurement Department, which attaches all supporting documents relevant for price determination (including the pro forma document, transportation bills, purchasing bills, administrative costs, and a 10% margin for the importer). This packet is then sent to the Accounting Department for price determination.

According to MoPH staff members, falsification of purchasing bills is a corruption possibility due to the absence of a valid mechanism for confirming bills, as well as overall deficiencies in monitoring capacity.

#### **Distribution**

Many of the monitoring/surveillance capacity issues that have been discussed earlier are tested even further during the distribution process. It stands to reason that if the MoPH lacks capacity to monitor the process from production facilities to the border, it will have no realistic chance to monitor imported pharmaceuticals once they are distributed throughout the country. This problem is further exacerbated by insecurity and the proliferation of illegal pharmacies throughout the country.

For this reason, the VCA Team believes that efforts to address corruption in the importation of pharmaceuticals should focus on the beginning and middle stage of the process. End state corruption issues are best addressed through broader public health policy reforms. For example, Afghanistan is the world's largest importer of antibiotics and it is well established that this type of medication is highly over used. Public health interventions designed to educate the public on overuse of medication would likely do more harm to illegal importers or producers of low quality medicine than random inspections of pharmacies.

#### **Vulnerabilities/Recommendations for the Pharmaceutical Import Process**

Import Stage	Vulnerabilities	Negative effect of vulnerabilities	Recommendations
Licensing of Pharmaceutical Companies	Lengthy and convoluted licensing procedures provided strong incentive to bribe officials out of mere expediency.  No clear policy upon which to base licensing protocols, volume of licenses issued, priority needs, etc.  Culture of impunity among senior MoPH staff members	Huge number of companies producing low quality pharmaceuticals, the significantly exceed surveillance and monitoring capacity of health officials.  Monopolies of high value pharmaceuticals created by collusion among MoPH staff members and	Creation of data collection system to accurately balance supply with broader public health goals, inform planning processes, etc.  License issuance/renewal based on regular monitoring and evaluation of importing companies.  Leverage anti-corruption resources to investigate prosecute senior MoPH officials for illicit enrichment.

	allows procedures to be constantly undermined to the point of meaninglessness  Close relationships/substantial involvement of MoPH staff members with pharmaceutical import companies	pharmaceutical importers.  Oversupply leads sale of expired pharmaceuticals	In addition to reforms to Pharmaceutical on conflict of interest issues, MoPH must implement clear internal mechanism to prevent staff relations with pharmaceutical companies.
Registration of foreign pharmaceutical companies.	Lack of clearly defined criteria for registering foreign companies.  Lack of technical and monitoring capacity to properly inspect/assess foreign companies producing medicines in accordance with the WHO criteria	Registration and licensing for more than 450 foreign manufacturing companies, many of which do not meet WHO quality standards in their own countries.  Number of companies exceeds monitoring capacity of MoPH	Regular annual planning in distribution and renewal of licenses for a limited number production companies.  Annual quality assurance assessment/audit products manufactured by foreign companies. Licensing renewal should be contingent upon meeting clearly defined standards.  Criteria needed for establishing monitoring priorities, including volume of imports. Foreign companies that don't meet quality standards in home countries should be prioritized for monitoring /surveillance.  Increase pharmaceutical technical capacity within the Ministry to ensure that foreign production companies are properly vetted.
Laboratory Sampling/ Customs House	Lack of transparent evaluation criteria of laboratory procedures and oversight. Sampling and testing are sent to PAD from Customs House.  Quality control procedures easily overridden by importers due to flawed border management	Laboratory results easily manipulated due to lack of criteria and transparency.  Customs House and laboratory staff members are in advantageous corruption position due to lack of oversight.	Implement procedures for laboratory sampling, including secondary and tertiary sampling to minimize fraudulent results.  Additional samples should be collected for auditing purposes.

	systems.  Low technical capacity of laboratory staff and lack of equipment		
Pharmaceutical Pricing	No mechanism to monitor and verify pricing structure based on prof forma or purchasing bill.	Leads to possible customs fraud, including duty and/or overpricing of low pharmaceuticals.	General capacity improvements to ensure MoPH have up to date and accurate market price information.  Prices should be printed on pharmaceutical packaging by producing companies or "binding" price list must be provided to Pharmaceutical Affairs Directorate.

#### IV. CONCLUSION

In the Afghanistan pharmaceutical sector, corrupt actors are facilitated, if not encouraged, by inadequate rules and regulations that are easily exploited, as well as institutional and human resource deficiencies that significantly compromise surveillance, monitoring, and quality control capacity. While investigation and prosecution of corrupt actors would serve a legitimate purpose, particularly those involved in high volume/low quality imports, anti-corruption and public health goals would be better served through substantive institutional reforms that enhance surveillance and monitoring capacities and minimize incentives to engage in illegal behavior.

The VCA Team's recommendations, based on the corruption vulnerabilities identified, are consistent with this approach and are designed to achieve two primary objectives. The first objective is to limit the volume of low quality pharmaceutical products entering Afghanistan through a range of reforms to the registration and licensing process, as well as broader regulatory reforms.

The second objective is to promote technical surveillance and monitoring capacity to ensure that production and import companies are adequately vetted, and that pharmaceuticals entering the country are subjected to rigorous quality control.

It is important to note that our recommendations for broader institutional reform should not be equated with a lack of urgency. As signatory to numerous human rights treaties, the Government of Afghanistan has a fundamental duty to respect, protect and fulfill the human rights of its citizens. This includes a right to enjoy the "highest attainable standards of physical and mental health" as outlined in Article 12 of the United Nations Convention on Economic and Social Rights (UNCESR). The duty of Afghanistan to minimize the effect of low quality pharmaceuticals on its citizens is further clarified by General Comment 14 of the UNESCR, which highlights the right to quality health related goods and services. Given the population's heightened vulnerability to sources of mortality and morbidity, upholding these rights by minimizing the effect of corruption on the import of pharmaceuticals must be a priority for Afghanistan.

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