

**LEGAL AND REGULATORY
ENVIRONMENT FOR CONTRACEPTIVE
MARKETING IN THE COMMERCIAL
SECTOR: KAZAKSTAN**

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by

Betty Ravenholt

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Edited and Produced by

Population Technical Assistance Project
1611 North Kent Street, Suite 508
Arlington, VA 22209 USA
Phone: 703/247-8630
Fax: 703/247-8640
E-mail: poptech@bhm.com

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TABLE OF CONTENTS

LIST OF ABBREVIATIONS	iii
EXECUTIVE SUMMARY	v
1. INTRODUCTION	1
2. METHODOLOGY	3
3. LAWS AND REGULATIONS GOVERNING THE COMMERCIAL PHARMACEUTICAL SECTOR	5
4. CONSTRAINTS TO GROWTH OF CONTRACEPTIVE SALES IN THE COMMERCIAL SECTOR	7
4.1 Legal and Regulatory Constraints	7
4.2 Primary Legal and Regulatory Constraints in the Commercial Pharmaceutical Sector	8
4.2.1 Inconsistent Implementation of the Regulatory Systems, Particularly Customs	8
4.2.2 Value Added Tax Especially as Applied to Pharmaceutical and Contraceptive Products	10
4.2.3 Regulatory Layers in the Importation Process	11
4.2.4 Absence of a Health Policy for Segmentation of the Contraceptive Market Which can be Implemented	13
5. RECOMMENDATIONS FOR RESOLUTION OF EXISTING CONSTRAINTS ...	15
5.1 Recommended Changes in Current Laws and Regulations	15
5.2 Recommended Mechanisms for Achieving Change	16
5.2.1 Improved Liaison Between the United States Agency for International Development's Social and Market Transition Projects	16
5.2.2 Government-to-Government Advocacy	17
5.2.3 Strengthening of Selected Nongovernmental Organizations as Advocates for Change	17
5.2.4 Technical Assistance to the Ministry of Health	18

LIST OF ABBREVIATIONS

ABA	American Bar Association
AVSC	Association for Voluntary and Safe Contraception
CA	Cooperating Agency
CAR	Central Asian Republics
GOK	Government of Kazakstan
JHPIEGO	Johns Hopkins Program for International Education in Reproductive Health
JHU/PCS	Johns Hopkins University/Population Communications Services
MOH	Ministry of Health
MOIT	Ministry of Industry and Trade
NGO	nongovernmental organization
POLICY	Policy Analysis, Planning, and Action Project
POPTECH	Population Technical Assistance Project
RHSEP	Reproductive Health Services Expansion Program
SOMARC	Social Marketing for Change (project)
VAT	Value Added Tax
WTO	World Trade Organization

EXECUTIVE SUMMARY

Based on this assessment of the legal and regulatory environment for contraceptive marketing in Kazakhstan's commercial sector, it appears that marketing constraints rather than legal and regulatory constraints have had the most negative impact on Red Apple project sales performance and on the overall commercial contraceptive sales in the Republic of Kazakhstan. The primary constraints to growth of contraceptive sales seem to be (1) the impact of relatively low contraceptive demand—caused primarily by consumer and provider resistance to hormonal contraceptives—on retailers' and importers' use-of-cash-for-product-purchasing decisions; and (2) the absence of a pro-active promotional and sales infrastructure within the distribution chain.

There are, however, some legal and regulatory constraints involving commercial sector pharmaceuticals that prevent the commercial sector from operating optimally—with greatest ease and at lowest cost—to ensure a consistent supply of high quality contraceptives in the Kazakhstan marketplace. These constraints do not appear to be focused on contraceptives per se; they apply to all pharmaceutical products and operations.

The primary legal and regulatory constraints to optimal operation of the commercial pharmaceutical sector are the following:

- The inconsistent application—through lack of knowledge or corruption—of the existing regulatory framework, particularly in the customs area;
- The 20 percent Value Added Tax (VAT) that is applied to pharmaceutical products, including contraceptives, and the timing of its collection;
- The number of government agencies and ministries involved and the lack of transparency in the process of issuing the import licenses and certificates of compliance necessary for importation; and
- The absence of a segmentation policy within the Ministry of Health (MOH) that provides free or low-cost contraceptives to potential users through public-sector outlets.

Constraints such as the inconsistent implementation of regulations, especially in customs and importation, may not be easily changed through short-term interventions. However, other constraints might be changed through short-term interventions.

The consultant recommends that the following efforts be made to change the current laws, regulations, and policies that affect commercial, pharmaceutical-sector operations:

- Reduce (i.e., to 10 percent or to 0 percent) the VAT on pharmaceuticals or at least on contraceptives;

- Include contraceptives in any existing opportunities for delayed payment of the VAT that are open to other types of pharmaceuticals;
- Clarify the authority to certify drugs for importation (Medstandart or Standarty);
- Implement annual licensing of importers, rather than shipment-by-shipment licensing;
- Create a list of established, registered drugs and brands that do not need to be tested on a shipment-by-shipment basis;
- Rationalize the fees charged for licenses and necessary importation certificates;
- Eliminate the Ministry of Trade's involvement in import licensing for pharmaceuticals; and
- Segment the pharmaceutical and contraceptive market between the public and private sectors.

Based on an analysis of the evaluation data, the consultant recommends the following mechanisms to alleviate the current constraints to conducting business in the commercial pharmaceutical sector:

- Improve liaison between the United States Agency for International Development's (USAID) social transition projects and USAID's market transition projects,
- Improve government-to-government advocacy,
- Strengthen selected nongovernmental organizations (NGOs) as advocates for change, and
- Provide technical assistance to the MOH to develop and implement a segmentation strategy for providing pharmaceuticals and contraceptives.

1. INTRODUCTION

The Reproductive Health Services Expansion Program (RHSEP) for Central Asia was initiated by USAID in 1993. The purpose of this program is to reduce dependence on abortion for fertility control by promoting safe, modern contraception. The RHSEP has been implemented through a team of five global population contractors: Association for Voluntary and Safe Contraception (AVSC), the Johns Hopkins Program for International Education in Reproductive Health (JHPIEGO), Johns Hopkins University Population Communication Services (JHU/PCS), Options for Population Policy (OPTIONS), and Social Marketing for Change (SOMARC).

SOMARC designed and implemented a contraceptive marketing project, the Red Apple Project, which is the main component of USAID/Central Asian Republic's (CAR) contraceptive reproductive health program. USAID/CAR has invested heavily in SOMARC's project to increase the availability of contraceptives through the private sector and, to ascertain the project's success, has requested that the Population Technical Assistance Project (POPTECH) field a two-part evaluation of the Red Apple Project. The first part of the evaluation focused on the technical and marketing aspects of the Red Apple Project to date. Believing that "further progress in contraceptive marketing in Central Asia is hindered by the lack of a legal and regulatory climate conducive to market expansion and the development of a viable commercial sector," USAID/CAR requested that the second part of the Red Apple Project evaluation provide "an update of the legislative environment and the potential for the commercial sector, especially in marketing of contraceptives, in Kazakstan and Uzbekistan."

The following chapter, which represents the results of the second part of the Red Apple Project evaluation in Kazakstan, is organized into three major sections: (1) a description of the laws and regulations that govern the commercial pharmaceutical sector, (2) a discussion of the significant regulatory constraints to growth of contraceptive sales in the commercial sector, and (3) recommendations for interventions to resolve existing legal and regulatory constraints.

2. METHODOLOGY

The sources of information on which this study is based include personal interviews; translations and summaries of relevant laws, orders, and decrees of the Republic of Kazakstan; and reports and assessments prepared by USAID's contractors and/or various international donor agencies.

The consultant conducted personal interviews with MOH officials—especially in the areas of maternal and child health and pharmaceutical control; a leading family planning service provider within the government system; private pharmacy owners; commercial-sector pharmaceutical importers; staff of local management consulting firms; and USAID staff, consultants, and contractors working in legal reform, commercial law, taxation, pharmaceuticals, contraceptive marketing, and healthcare reform.

The consultant reviewed Kazakstan's laws, orders, and decrees, which had been collected by the Carana Corporation. (See Appendix E.) The consultant also reviewed customs classifications and fee schedules. (See Appendix F.)

The consultant also reviewed documents that were prepared by USAID offices and by USAID's contractors working in privatization, contraceptive marketing, and women's reproductive health. (See Appendix B.)

3. LAWS AND REGULATIONS GOVERNING THE COMMERCIAL PHARMACEUTICAL SECTOR

Considerable change has occurred in the pharmaceutical sector since the early 1990's when the Government of Kazakhstan (GOK) authorized private operation of pharmacies and private importation and sale of pharmaceutical products. For example, of the 1,083 pharmacies in the country (Carana report, 9 August, 1996) perhaps as many as 90 percent are now privately owned. (The Red Apple evaluation team estimated that perhaps 1,400 or more pharmacies are operating in Kazakhstan.) Methods of retail operation and product distribution, however, still function largely as they did in the Soviet era. In its 1996 analysis, the Carana Corporation gives a clear picture of the current pharmaceutical system in Kazakhstan. The experts interviewed by the consultant indicated that the picture presented in Carana's 1996 analysis is still accurate. (See Appendix G.)

The laws and regulations that govern the operation of Kazakhstan's commercial pharmaceutical sector generally focus on the following areas:

- Licensure and inspection of retail pharmacies,
- Licensure to conduct business in the pharmaceutical sector,
- Registration of pharmaceutical products and brands,
- Licensure of pharmaceutical companies for each shipment to be imported,
- Quality assurance and compliance of imported pharmaceutical products and brands,
- Application or non-application of customs tariffs to pharmaceutical products, and
- Application of VAT to pharmaceutical products.

The Carana Corporation collected and summarized Kazakhstan's laws and regulations regarding the operation of the pharmaceutical sector for inclusion in its "Pharmaceutical Information Packet" (Section 6, June 1996). (See Appendix E.) The process of licensing and importing pharmaceutical products for distribution and sale in Kazakhstan is outlined in the Carana report, "Kazak Pharmaceutical System Analysis." (See Appendix G.)

4. CONSTRAINTS TO GROWTH OF CONTRACEPTIVE SALES IN THE COMMERCIAL SECTOR

The consultant assessed the constraints to increased sales of contraceptives in Kazakhstan's commercial sector on the basis of experience from USAID/CAR's Red Apple contraceptive marketing project, the evaluation team's analysis of the Red Apple project (outlined in the first report), and interviews with commercial sector companies. Based on this assessment, it appears that the major constraints are (1) the impact of relatively low contraceptive demand—caused primarily by consumer and provider resistance to hormonal contraceptives—on retailers' and importers' use-of-cash-for-product-purchasing decisions; and (2) the absence of a pro-active promotional and sales infrastructure within the distribution chain. That is, marketing constraints rather than legal and regulatory constraints appear to have had the most negative impact on Red Apple project sales performance and on overall commercial contraceptive sales in Kazakhstan.

4.1 Legal and Regulatory Constraints

There are, however, some legal and regulatory constraints involving commercial sector pharmaceuticals that do prevent the commercial sector from operating optimally—with greatest ease and at lowest cost—to ensure a consistent supply of high quality contraceptives in the Kazakhstan marketplace. These constraints do not appear to be focused on contraceptives per se; they apply to all pharmaceutical products and operations.

All governments that consider safeguarding the public health a responsibility, initiate a system of laws and policies that regulate the availability and distribution of pharmaceutical drugs. These regulatory systems are not necessarily an undue constraint on the ability to conduct business in the commercial pharmaceutical sector; they may, however, be considered constraints on the reasonable ability to conduct business in the commercial pharmaceutical sector (1) where they do not or are not necessary to protect the public health, (2) where the bureaucratic implementation processes for these laws cause unnecessary delays and/or product shortages, (3) where the fees charged for required certificates and licenses exceed their reasonable value, and (4) where inconsistent implementation of the regulations—through either lack of knowledge or corruption—deleteriously increase the time, costs, and risks of conducting business.

Tax and tariff laws and regulations, when designed and implemented without considering their impact on the availability and affordability of essential pharmaceutical products, may also unduly constrain the commercial-sector's participation in the delivery of pharmaceutical products to the public.

4.2 Primary Legal and Regulatory Constraints in the Commercial Pharmaceutical Sector

In Kazakstan, the primary legal and regulatory constraints to optimal operation of the commercial, pharmaceutical sector appear to be the following:

- The inconsistent application—through either lack of knowledge or corruption—of the existing regulatory framework, particularly in the customs area;
- The 20 percent VAT applied to pharmaceutical products including contraceptives;
- The number of government agencies and ministries involved and the lack of transparency in the process of issuing import licenses and certificates of compliance necessary for importation; and
- The absence of a segmentation policy within the MOH to provide free or low-cost contraceptives to potential users through public-sector outlets.

4.2.1 *Inconsistent Implementation of the Regulatory Systems, Particularly Customs*

Although there are no import duties levied against pharmaceutical products (including contraceptives), the pharmaceutical distributors and USAID's contractors working in the area of customs reform think that the difficulties in dealing with the customs and importation system are, perhaps, the primary problem in conducting business.

The inconsistent implementation of regulations in the customs system is widely thought to be because of (1) extremely low salaries for inspectors, supervisors, and other officials; (2) fees and taxes that are perceived as so excessive that bribes are considerably cheaper than compliance; (3) rapid change in regulatory requirements; (4) unclear regulations; and (5) inefficient communication of regulations and changes to customs officials throughout the system and country, as well as to importers.

Regardless of the cause of this inconsistent implementation of customs regulations, it adds considerably to the importers' business costs—which are, of course, passed along to wholesalers, retailers, and consumers through product prices—as well as to the likelihood that products will not be consistently available in the marketplace.

Following are examples of the constraints caused by the current customs regulations and/or their inconsistent implementation:

- (1) Customs Fees. The law requires that a customs inspector accompany any road shipment of imported product from its point of entry into Kazakstan to Almaty,

where the goods pass through customs. The inspector's presence ensures that the goods are not diverted before the customs duties are assessed. The inspector who accompanies the truck is paid 100 ecu if he travels only within his district and 200 ecu if the trip to Almaty requires that he pass out of his district. In practice, an inspector joins the truck at the border and rides with it just until it passes out of his district, whereupon he collects 200 ecu and departs. A second inspector then gets on the truck and rides it just until it passes out of his district. He collects 200 ecu and departs. This process continues until the truck reaches Almaty. Instead of paying one 200 ecu fee for a customs inspector to accompany the imported shipment to Almaty, an importer may pay up to ten of these fees, depending on where his truck entered Kazakhstan. The law does not specifically forbid this practice, so the importer has no legal recourse.

- (2) The Local Communications System. The inadequacies in Kazakhstan's communications systems cause delays in the dissemination of information. It can take months for information on a change in the customs regulations to reach certain border outposts. Although the importers using those entry points may know of these changes, the customs inspectors do not and will, therefore, require the importers to follow the obsolete rules.
- (3) Storage Fees. The rate charged by customs to importers to store goods while they await customs clearance is 10 cents per kilogram per day. (The first three days of storage are free.) A shipment weighing 2,500 kilograms that is held in customs for even 10 days beyond the initial free period will cost the importer approximately US\$2,500 in storage fees. An importer is, therefore, willing to bribe customs officials to move goods speedily through the customs process, because the amount of the bribe required is considerably less than the potential storage fee.
- (4) Changing Customs Regulations. A pharmaceutical importer recently attempted to import a shipment of goods into Kazakhstan. The importer obtained and paid for the required licenses and certificates, but by the time the goods arrived at Almaty, the customs regulations had changed. The importer was told that he would have to re-do his completed paperwork (i.e., pay for new certificates and licenses) because the change had occurred after he started the importation process.

Retail pharmacy owners reported having difficulty conducting business because of the opportunities for irregular payments that are created by mandated health, sanitary, and fire inspections of their pharmacies. Carana's report, "Kazak Pharmaceutical System Analysis," (see Appendix G) contains detailed examples of such occurrences. According to a number of sources, the threat of a visit from the tax inspector is used to encourage business owners to pay these irregular "fees" to health inspectors and/or the police and to prevent business owners from reporting the corrupt officials.

4.2.2 Value Added Tax Especially as Applied to Pharmaceutical and Contraceptive Products

In Kazakstan, the prevailing 20 percent VAT is a major constraint on the ability of many importers to conduct business. It appears to especially constrain smaller companies without special privileges.

The rate and amount of the various taxes that must be paid on pharmaceuticals and contraceptives are major constraints from a public health standpoint because of the impact that these taxes have on the price to the consumer. The higher the taxes, the higher and less affordable the consumer price becomes, and, therefore, the less accessible the product is in the commercial marketplace. Additionally, as the product's cost to the importer increases, its final profitability becomes increasingly important. At current levels of demand, contraceptives do not yield a large profit to importers; consequently, importers may be more likely to invest their available cash in products that will bring a quicker, larger profit.

In a country like Kazakstan, where the MOH plainly states that it cannot afford to continue to provide free health services and pharmaceuticals to the entire population, the ability of a growing number of consumers to afford the healthcare (including pharmaceuticals) that they need from the commercial sector is increasingly important. For many consumers, a 20 percent higher price may constitute a serious constraint to their access to essential pharmaceuticals and contraceptives in the commercial sector. (It would be interesting to compare the costs to the MOH of providing free contraceptives to "middle income and upper lower income" consumers who might purchase contraceptives in the commercial market at a 20 percent reduction in price, to the revenue that would be lost by the government if the 20 percent VAT were not levied on contraceptives.)

In many countries, the levying of VAT replaces an increase in unpopular income taxes or allows for a decrease in politically unpopular income tax rates. Kazakstan's 20 percent VAT is comparable to the VAT of a number of developed countries. (It does not appear, however, that the population of Kazakstan is as able to pay a 20 percent tax on virtually all consumer goods as are the populations of developed countries.) Pharmaceuticals sold in Great Britain, for example, are not exempted from the VAT, nor are they sold at a reduced VAT rate. In Kazakstan, pharmaceutical products—specifically contraceptives—are not exempted from or assessed a lower than 20 percent VAT, although some types of goods, such as "school aids," are exempted from the VAT.

Tax experts (USAID contractors and consultants) explain that a reduced rate (i.e., 10 percent) or a "zero rate" VAT for particular types of goods is more financially advantageous to the importer than is exemption from the VAT for the goods in question. This zero rate is advantageous because importers can claim taxes paid on VAT zero-rated goods, but not on VAT-exempted goods. According to commercial pharmaceutical importers, the Pharmacists Association has written a letter to the MOH requesting relief from the VAT for pharmaceuticals in general. However, the current status of that request is unknown, since the MOH has not yet formally responded.

The difficulties caused for pharmaceutical importers by the amount of the VAT that they must pay are compounded, for some, by the fact that they must pay the tax when the goods enter Kazakhstan, not when they sell them into the distribution system. Since most pharmaceutical importers sell their products into the marketplace on consignment, it can be over 30 days before they begin to receive payment from their customers. The pharmaceutical importers must, therefore, pay the 20 percent VAT on the goods before they realize any revenue from the importation.

The regulations concerning this VAT payment are not completely clear, however. According to USAID's contractor that works on VAT issues, pharmaceutical and other importers do not have to pay the VAT until the end of the month in which the goods enter the country. However, according to USAID's contractor that works in customs reform, that delay in payment is granted only to pharmaceuticals that fall within the customs classification numbers 3000 to 3004; hormonal and spermicidal contraceptives are classified as number 3006.6 and, therefore, are not eligible for delayed VAT payment. (At least one importer confirmed that this was his company's experience.) A major pharmaceutical importer indicated that he has a special letter from the GOK that gives him three months from the time of import to pay the VAT. He stated that such a letter is available to any company that meets certain conditions, but that most pharmaceutical importers do not know about this possibility.

4.2.3 Regulatory Layers in the Importation Process

According to most companies that import pharmaceuticals, delays and inconsistencies in the regulatory process controlling importation hamper their ability to operate efficiently in the marketplace. However, importers occasionally admit that they are able to "find ways" to deal with these constraints.

The following five agencies are involved in regulating the importation of pharmaceuticals:

- The MOH
- The Ministry of Industry and Trade (MOIT)
- Medstandart
- A foreign contractor (previously Societe Generale de Surveillance, S.A.) that validates the price of goods in the country of export
- The customs service

Each of these agencies issues certificates or licenses of some kind for each imported shipment of goods; each of these agencies also charges fees for each certificate or license issued.

There are numerous instances of lack of transparency in this process and of requirements that are not necessary for the protection of the public's health. These regulatory constraints and suggestions for their change are discussed at some length in the Carana study, "Kazak

Pharmaceutical System Analysis." (See Appendix G.) The most problematic of these constraints are as follows:

- (1) Agency Disagreement Over Proper Certificates. The MOH, Medstandart, and the JSC Standarty disagree over which agency is legally competent to certify pharmaceuticals. Medstandart requires importers to obtain certificates from (and pay fees to) JSC Standarty, but the MOH will not accept these certificates.
- (2) License Fees. The MOIT charges approximately US\$131 to issue an import license for every pharmaceutical shipment. Since the customs service collects information on quantity, type, and value of all imported articles, there is no apparent reason for the MOIT to charge fees and issue licenses to collect the same information.
- (3) "Pre-registration" of Pharmaceutical Shipments. The "pre-registration" of pharmaceutical shipments by a foreign contractor to confirm invoice prices and specifications adds considerably to the time required to import product into Kazakhstan. Customs officials often make these same checks when the product enters the country.
- (4) Importation Licenses. An importer must obtain an import license for each shipment brought into the country. If the regulatory intent is to ensure the trustworthiness of the importer, an annual license should suffice.
- (5) Certification of Medicine. Each type of medicine in a shipment must be certified—at a fee of US\$48 per type of medicine. These laboratory examinations seem unnecessary when evaluating long-established brands whose formulations have not changed over many years and whose safety has been verified by the country of origin.

The license and certificate fees charged by the government for importation of pharmaceuticals into Kazakhstan are considered by importers, as well as by USAID ex-patriate advisors, to be well above the costs to the government of issuing them. (See Appendix F.) According to USAID's contractor that works in customs reform, the process of Kazakhstan's entering the World Trade Organization (WTO) may ameliorate these irrational fees (perhaps within the next six months), since the WTO requires a justifiable, rational fee structure for membership.

4.2.4 Absence of a Ministry of Health Policy for Segmentation of the Contraceptive Market which can be Implemented

Segmentation of any market means division of the total market population into subgroups that are identified by selected characteristics such as gender, age, income and ability to pay, geographic location, and lifestyle. Successful market segmentation allows for maximized efficiency of marketing activities (through targeting advertising messages, prices, or other elements of the marketing mix to the concerns, desires, and needs of specific groups) as well as maximized efficiency of product and service delivery channels (through eliminating unnecessary overlap of delivery systems). In a world where public sector resources are finite, segmentation of the contraceptive market appears to be essential to the long-term sustainability of any women's reproductive health program.

Kazakstan's public sector provides contraceptive services and products—to the extent that they are available—to any woman who comes to a public sector healthcare outlet to obtain them. These goods and services are provided free or at a low cost to all—when providing product or services no distinction is made in regard to a woman's ability to pay. That is, there is no significant segmentation of the contraceptive market by the public sector according to the consumer's ability to pay.

The commercial sector's ability to increase its participation in the delivery of contraceptives to women who want or need them (i.e., to expand sales) is limited, at least in part, by the extent to which commercial products and prices must compete with free products or low-cost medical services provided by the public sector to women who could otherwise afford to buy them in the commercial sector. Constraints on demand for contraceptives in the commercial sector are especially important in marketplaces, like Kazakstan, where the level of product demand plays an important role in the purchasing decisions made by importers, distributors, and retailers with limited cash reserves.

It is difficult to ascertain the size of the market segment in Kazakstan that is reasonably able to pay for its contraceptive needs in the commercial sector. In many markets, it is difficult to differentiate between consumers' ability to pay and their willingness to pay for contraceptive products. It is especially difficult in a contraceptive market like Kazakstan where consumers have multiple sources of income (most of them "unofficial") that, in order to evade taxes, are not always correctly reported and where reliable databases on household income and expenditures do not appear to exist.

5. RECOMMENDATIONS FOR RESOLUTION OF EXISTING CONSTRAINTS

5.1 Recommended Changes in Current Laws and Regulations

The two most important legal and regulatory constraints to business owners' ability to conduct business efficiently in the commercial pharmaceutical sector appear to be the inconsistent implementation of the regulatory framework and the VAT. These constraints, especially in the areas of customs and importation, may not be easily changed by short-term interventions. (This does not mean, however, that these issues should not be addressed wherever possible.) While the chances for success are difficult to predict, opportunities for short-term intervention to resolve at least some of the constraints presented by the VAT and its collection do appear to exist. Other constraints—such as the number of government agencies and ministries involved in the importation process and the absence of an implementable segmentation strategy within the MOH to provide contraceptives—may also be changed through short-term interventions.

The consultant recommends that the following efforts be made to change current laws, regulations, and policies that affect commercial, pharmaceutical-sector operations:

- Reduce (i.e., to 10 percent or to 0 percent) the VAT on all pharmaceuticals or at least on contraceptives;
- Include contraceptives in any existing opportunities for delayed payment of the VAT that are open to other types of pharmaceuticals;
- Clarify the authority to certify drugs for importation (Medstandart or Standarty);
- Implement annual licensing of importers, rather than shipment-by-shipment licensing;
- Create a list of established, registered drugs and brands that do not need to be tested on a shipment-by-shipment basis;
- Rationalize the fees charged for licenses and certificates necessary for importation;
- Eliminate the Ministry of Trade's involvement in import licensing for pharmaceuticals; and
- Segment the pharmaceutical and contraceptive market between the public and private sectors.

5.2 Recommended Mechanisms for Achieving Change

Based on an analysis of the information gathered for this evaluation, the consultant recommends the following mechanisms to change current constraints to conducting business in the commercial pharmaceutical sector:

- Improve liaison between USAID's social transition projects and USAID's market transition projects;
- Improve government-to-government advocacy;
- Strengthen selected NGOs as advocates for change; and
- Provide technical assistance to the MOH to develop and implement a segmentation strategy to provide pharmaceuticals and contraceptives.

5.2.1 *Improved Liaison Between the United States Agency for International Development's Social and Market Transition Projects*

Despite the past levels of liaison among USAID's projects, it appears that renewed opportunities for sharing of information and priorities are needed. Some of the technical assistance and advice given to various agencies of the GOK by some of USAID's market transition projects (in legal reform, trade and investments, or commercial law, for example) may not have fully taken into account the social or health needs and objectives identified by USAID's social transition projects. By the same token, some social transition projects seem to be unaware of the regulations being developed with assistance from the market transition projects and of the information and/or advocacy opportunities offered by these projects. USAID's existing market transition projects are already addressing or can address issues such as reduced VAT rates for pharmaceuticals and contraceptives, inconsistent implementation of regulations, excessive fees for licenses and certificates, and unwieldy importation processes.

Additionally, in the consultant's opinion, the policy and regulatory issues that prevent effective operation of the commercial pharmaceutical and contraceptive sector cannot be successfully addressed unless one agency or contractor is made explicitly responsible for coordinating and initiating activities in this area.

The consultant, therefore, specifically recommends the following actions:

- Identify one USAID contractor (perhaps Abt, SOMARC, or the Policy Analysis, Planning, and Action project [POLICY]) to develop and implement a strategy and work plan to change the policies and regulations that constrain the commercial pharmaceutical and contraceptive sector;

- Identify one USAID contractor (perhaps Abt or SOMARC) to work as an advocate and raise awareness of the policy and regulatory needs of the commercial pharmaceutical sector—and specifically contraceptive availability in the commercial sector—among USAID's other projects that are providing relevant legal and regulatory technical assistance to the GOK;
- Implement quarterly meetings of USAID's social and market transition projects to discuss current activities, to identify policy and regulatory needs and concerns, and to develop areas of collaboration to achieve USAID's goals; and
- Identify one USAID contractor (perhaps the American Bar Association (ABA) through an "information coordinator") to alert (while there is still opportunity for comment and input) all USAID-funded agencies and contractors to developing legislation and to circulate copies of all new legislation to each of USAID's CAs.

5.2.2 Government-to-Government Advocacy

Depending upon its policy priorities and decisions, USAID/Almaty management may decide to present selected constraints of greatest importance to the Ambassador or other appropriate high level official for discussion on a government-to-government level. In the opinion of the consultant, a 10 percent or 0 percent VAT for pharmaceuticals, particularly contraceptives, should be considered by USAID management as one such constraint. USAID should also consider discussing at a government-to-government level the effect of widespread corruption in the regulatory system on the overall development of the national economy.

5.2.3 Strengthening of Selected Nongovernmental Organizations as Advocates for Change

Kazakhstan's developing NGOs are speaking out on issues that are relevant to their constituencies. Among these NGOs are two associations of "pharmacists": one for importers, distributors, and retailers in the pharmaceutical sector and one for domestic pharmaceutical manufacturers. These local associations serve a critical function in sustaining advocacy for the commercial pharmaceutical sector. In fact, the Pharmacists Association, discussed earlier in this paper, has already written to the MOH requesting relief from VAT for pharmaceuticals. The "Pharmacists Newspaper"⁷⁷⁷ is reportedly a vehicle for editorial comment as well as for publication of new laws and regulations that govern the pharmaceutical sector and its publisher is said to be an active member of the Pharmacists Association.

⁷⁷⁷This newspaper is said to have a contract with the MOH to publish new regulations relevant to the pharmaceutical sector.

NGOs like the Consumers Union may also represent sustainable advocacy for consumer interests such as the affordability of necessary pharmaceuticals, like contraceptives, within the commercial sector.

On the basis of these observations, the consultant recommends the following actions to strengthen existing NGOs as advocates for change in the pharmaceutical sector:

- Develop a list of NGOs that could reasonably advocate for availability and affordability of pharmaceuticals and contraceptives in the commercial sector; and
- Identify a USAID contractor (perhaps SOMARC or POLICY) to design and implement a plan to provide technical assistance to selected NGOs in areas that strengthen their capabilities as advocates for change, such as media training, strategy development, advocacy techniques including use of the media, and development of local constituencies and funding.

5.2.4 Technical Assistance to the Ministry of Health

While efficient segmentation of the contraceptive market among public, private and non-profit, and private and commercial sectors will probably not be actualized in the short term, the need for segmentation of the contraceptive market is sufficiently important to long-term sustainability of any women's reproductive health program in Kazakhstan that the foundations for segmentation should be laid as quickly as possible.

The consultant recommends, therefore, that USAID provide technical assistance (perhaps through Abt or POLICY) to the MOH to develop a segmentation strategy to provide contraceptives and contraceptive services.

Effective segmentation of the contraceptive market in Kazakhstan should provide, as it does in other countries and markets, opportunity for increased commercial-sector participation in contraceptive delivery and contraceptive services as well as more equity in the public sector system for healthcare service delivery.