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O'Hanlon Consulting

Recommended Citation

Armand, Francoise, Cuellar, Carlos, and O'Hanlon, Barbara. January 10, 2005. Assessment of Private Sector for Reproductive Health and Family Planning Products and Services in Ukraine. Bethesda, MD: Private Sector Partnerships-One project, Abt Associates Inc.

Assessment of
Private Sector
Prospects for
Reproductive
Health and Family
Planning Products
and Services in
Ukraine

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Funded by: U.S. Agency for International Development



Mission

Private Sector Partnerships-*One* (PSP-*One*) provides technical leadership to promote and expand the private sector's interest, ability and direct involvement in the delivery of quality reproductive and other health products and services.

To increase private and commercial sector participation in the sustainable provision of reproductive and other health products and services PSP-*One* works to:

- ❖ Advance private sector programming knowledge and practices
- ❖ Facilitate public/private alliances
- Pursue optimal market segmentation
- Promote behavior change through targeted health communications
- Upgrade private provider performance
- Expand financial mechanisms to improve access to health products and services
- Improve policy and regulatory environments
- Scale up proven private sector models and strategies

Contract/Project No.: GPO-I-00-04-00007-00

Submitted to: Tim Clary, Senior Advisor for HIV/AIDS, Infectious Diseases and Reproductive

Health. Office for Health and Social Transition. USAID/Ukraine

United States Agency for International Development

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Acronyms

BCC behavior change communication

FP family planning

GDP gross domestic product

HIV/AIDS human immune deficiency virus/acquired immune deficiency virus

IEC information, education, and communication

IUD intra-uterine devices

JSI John Snow, Inc.

MOH Ministry of Health

NGO nongovernmental organizations

NRHP National Reproductive Health Program

OC oral contraceptive
OTC over-the-counter

PDG policy development group

PSP-One Private Sector Partnerships-One project

RH reproductive health

STI sexually transmitted infections
UNFPA United Nations Population Fund
UNICEF United Nations Children's Fund

USAID United States Agency for International Development

Acknowledgments

The PSP-*One* team would like to acknowledge the support it received from the USAID/Ukraine staff in conducting this assessment. We wish to express our gratitude to Mr. Andriy Huk, of the POLICY project, for graciously providing our team with logistical and technical assistance, and Ms. Nadiya Zhylka, Deputy Head Maternity and Childhood Health Care Department of the Ministry of health, for supporting this initiative. We also wish to thank the Ukrainian representatives of pharmaceutical companies, local and international NGOs, private sector clinics, and various divisions of the Ministry of Health, for sharing valuable insights with the PSP-*One* team.

Executive Summary

Ukraine is a middle-income country with increasing economic prospects, a thriving private sector market, and widespread access to health services. The country is, however, experiencing reproductive health issues similar to those of other former Soviet republics. Among these are the limited use of modern contraceptive methods, high method failure and abortion rates, a growing incidence of sexually transmitted infections, and critical information gaps among providers and potential users alike.

Ukraine is also a country characterized by a wide-reaching health sector with a highly medicalized approach to reproductive health. In contrast to services, however, pharmaceutical products are almost exclusively accessed through private sector pharmacies and there is no systematic policy of providing free or subsidized contraceptives to the public. To help inform future reproductive health interventions, the USAID/Ukraine mission requested from the PSP-*One* project an assessment of the private sector's contribution to reproductive health/family planning (RH/FP) needs, particularly in the area of contraceptive product supply.

In addition to assessing the current supply of contraceptive products and services, the PSP-*One* team set out to analyze the factors that are known to predict contraceptive security, such as the demand for products, the effectiveness of commercial distribution channels, the role of service providers, the level of effort invested in consumer campaigns, and public sector policies as they affect private sector performance.

The team's analysis resulted in the following key findings:

Policy environment

The PSP-*One* team conducted a legal and regulatory assessment of market conditions for the private sector provision of RH/FP products and services. Despite the constitutional article guaranteeing free medical health care through the public sector, the legal and regulatory framework and policy environment create positive incentives for private investments, encouraging the entry and sustained presence of private sector suppliers in the RH/FP marketplace. The policy environment, however, has traditionally not been supportive of nongovernmental organizations (NGOs) as providers of RH/FP products and services. Although NGOs have recently been granted the right to provide RH/FP clinical services, it is highly unlikely that many will take advantage of this change because they are prohibited from charging fees and have limited access to capital.

Some regulations exist that may restrict access to prescription drugs, limit the provision of RH/FP information to minors, and prevent consumer-directed advertising campaigns. More significant than laws and regulations, however, may be the impact perceptions and practices have on consumer and provider behaviors. For example, youth do not spontaneously seek counseling and services from public clinics; consumers routinely obtain products without prescriptions; and pharmaceutical companies typically prefer dealing with providers than consumers. Furthermore, while policies and regulations do not restrict any particular FP contraceptive method, provider practices and user preferences have resulted in a skewed method mix that relies heavily on abortion, traditional methods, and, increasingly, hormonal contraceptives.

Product supply

The current range of modern contraceptive products available on the Ukrainian commercial market includes condoms, oral and injectable contraceptives, and intra-uterine devices, with hormonal contraception representing the fastest growing segment of the market. While products are available at different prices, the saturation of the supply side of the market and increased competition for market share have led pharmaceutical companies to focus on their core consumer group and loyal providers rather than potential new users. Contraceptive manufacturers have played a critical role in increasing provider confidence in hormonal contraception, notably by supporting continued education for health providers. The general public, however, is seldom the focus of information and public relations campaigns, which in turn contributes to the sluggish demand for contraceptives.

Commercial contraceptive brands are distributed through a vast network of wholesalers and retailers whose potential reach extends to all regions of Ukraine, including rural areas. The industry is undergoing a consolidation phase characterized by wholesaler closings, but the number of pharmacies remains high. Pharmaceutical sales are a profitable business in Ukraine, fueled by a growing demand for products that must be met almost exclusively by the private sector. This market, however, suffers from a lack of reliable data about contraceptive product sales, market share, consumer trends, and distribution coverage.

RH/FP services

The Ukrainian RH environment is characterized by the public sector's continued dominance in the area of services. The relationship between public sector providers and the pharmaceutical industry is rarely supervised, which may have led to unethical behaviors by some pharmaceutical companies. This close relationship also appears to have fostered a growing preference for prescribing oral contraceptives and a decreasing reliance on other methods such as IUDs and injectables.

Few incentives exist for the provision of RH services through privately owned practices and clinics. Although patients' direct payments to public sector providers have created an informal private sector within the Ministry of Health (MOH), they have also reduced incentives for doctors to set up their own practice, which involves considerable risks and costs. Providers working in private sector clinics tend to concentrate on profitable services and leave preventive services, such as FP, to the public sector. Furthermore, few Ukrainians are able to afford private sector service fees, which are considerably higher than informal payments in public clinics.

With the bulk of RH services currently provided by public sector facilities, and the concentration of product supply in the commercial sector, there is limited room for nonprofit organizations to play a significant role in RH. Although a recent law has made it possible for NGOs to provide contraceptive services and products to patients, it appears only a limited number of organizations in Ukraine have the human, technical, and structural capacity to become service providers. NGOs, however, can play a critical role in addressing the need for RH/FP information in the general population through consumer-directed campaigns and other communication activities.

In light of the above findings, the team offered the following conclusions:

There is no pressing contraceptive security problem in Ukraine where products are concerned, as the commercial market caters to a large proportion of the user population and the sustained presence of affordable brands does not appear to be threatened.

- The lack of research data leaves some contraceptive security questions unanswered. The ability of rural residents, young people, and the urban poor to access and afford contraceptives can only be determined through quantitative research.
- Widespread access to contraceptive products and services does not extend to accurate and reliable
 information on RH/FP. Public and private sector providers, as well as oral contraceptive
 manufacturers, agree that lack of information and education among potential users is the biggest
 barrier to increased use of modern methods.
- The current method mix is driven by industry focus and provider attitudes rather than public health goals, resulting in a trend toward a limitation of options for Ukrainian women.
- Currently, efforts to bolster the development of private sector practices are unwarranted, because the current division of responsibilities between the public and private sectors is unlikely to change. Policy efforts should therefore focus on correcting problems rather than changing the status quo.

Consequently, PSP-*One* recommends avoiding supply-side activities that may have a counterproductive effect on the commercial contraceptive market, focusing instead on increasing demand for products and services among key target groups. This can be achieved in collaboration with contraceptive manufacturers that are actively investing in the contraceptive market. PSP-*One* also recommends addressing misconceptions among service providers, and supporting more ethical practices between pharmaceutical companies and doctors. Potential gaps in contraceptive supply remain to be identified through quantitative research and should be addressed through carefully targeted public sector or NGO programs.

In order to increase sustained private sector participation to RH/FP goals, the PSP-*One* team advocates a dual strategy of public/private partnerships and public sector policies that facilitate and complement the activities of the private sector.

Proposed illustrative partnership activities include the following:

- Working with the pharmaceutical industry to design and implement consumer campaigns, increase distribution coverage in underserved areas, and ensure the wide availability of affordable products
- Supporting ethical provider outreach activities by pharmaceutical companies, including public relations campaigns, expanded pharmaceutical detailing, and controlled product sampling programs
- Supporting and expanding the activities of NGOs with technical expertise and experience in dealing with target groups, as well as those involved in advocacy and provider training

Proposed illustrative policy interventions include the following:

- Helping the MOH formalize public/private partnerships through a memorandum of understanding and the development of a national self-reliant contraceptive strategy
- Conducting a segmented market analysis to identify key characteristics of potential users and underserved groups and strategies to meet their needs

- Designing a commodities distribution program to be channeled through select public outlets and providing technical assistance to the MOH in targeting commodities to priority populations
- Supporting large-scale contraceptive technology updates for MOH gynecologists, obstetricians, and family medical doctors, and encouraging a more balanced method mix through evidencebased prescribing practices

1. Background

1.1 Country Overview

Ukraine, a country of 48.4 million people¹ with an annual gross domestic product (GDP) per capita of \$5,400², faces reproductive health challenges similar to those of other countries in the former Soviet Union. In spite of an improving economic situation, fertility rates have been low, contributing to a decline in population of more than 2 million people from 1991 to 2001. Maternal and infant mortalities have decreased recently, though rates are still high compared with those of other European countries, and the spread of sexually transmitted infections (STI) and HIV/AIDS is on the rise. Other major reproductive health issues include a low use of modern contraception methods and a high level of unintended pregnancies and abortions³.

A number of programs have been implemented to address these problems since the collapse of the Soviet Union, many of them supported by USAID/Ukraine. In 1995, the Ministry of Health (MOH) launched the Women's Reproductive Health Initiative to carry out provider training, information, education, and communication (IEC) activities, policy improvement initiatives, and commodities procurement. USAID also supported the Policy Development Group (PDG) and the Ukraine Reproductive Health Network, and funded a five-year National Reproductive Health Program (NRHP) and the 1999 Ukraine Reproductive Health Survey, which remains the most recent reliable source of RH information⁴. Among other donor organizations currently working in the area of reproductive health/family planning (RH/FP) in Ukraine are the United Nations Population Fund (UNFPA), the European Union, the United Nations Children's Fund (UNICEF), and the Canadian International Development Agency.

Efforts to improve the RH/FP situation in Ukraine have contributed to a high overall contraceptive prevalence (68 percent). The use of modern methods, however, remains low with only 38 percent of couples using such a method. Other areas of concern include high abortion levels (the NRHP estimates that 1.2 abortions are performed for each birth⁵), high contraceptive failure and discontinuation rates, and inconsistent RH/FP knowledge among both the general population and provider community. The 2003 POPTECH assessment also pointed to "missed opportunities" in the area of postpartum and post-abortion counseling, and unmet RH needs in the youth population.

Ukraine's high abortion rate and low use of modern contraceptive methods are sometimes interpreted as a consequence of limited access to contraceptives. In particular, the lack of a sustained subsidized commodities program is often cited as a significant barrier for low-income and hard-to-reach groups. Another concern is access to reliable information, since many people obtain contraceptive products directly from pharmacies, where little RH/FP counseling is provided. Previous assessments have offered various recommendations for improvement, including increased private sector involvement as a way to ensure sustainable contraceptive supply and increase the use of modern methods in Ukraine.

¹²⁰⁰¹ Census

² Purchasing power parity, 2004 estimate. CIA World Factbook

³ POPTECH Assessment of Reproductive and Maternal Health in Ukraine, LTJ Associates, Inc. December 2003

⁴ POPTECH 2003

⁵ National Reproductive Health Program 2001-2005, December 2000

1.2 Objectives of the Assessment

The USAID/Ukraine mission requested technical assistance from the private sector program core task order (Private Sector Partnerships-*One* project [PSP-*One*]) in assessing the ability of the private sector to ensure sustained contraceptive supply in Ukraine. In particular, the PSP-*One* team was expected to address the current and estimated future availability, affordability, and accessibility of contraceptives in the private sector. This report presents the team's findings, provides recommendations for activities and policies that can increase private sector engagement in the contraceptive field, identifies specific population groups not likely to be adequately served by the private sector, and suggests strategies to meet their needs while avoiding negative impact on the growing contraceptive market.

1.3 Approach

The PSP-*One* team first sought to identify and interview key players in the private contraceptive market, including pharmaceutical manufacturers, distributors, wholesalers and retailers, and private medical providers. In addition, the team explored the impact of public sector policies and practices, as well as the activities of nonprofit organizations, on the demand for and supply of contraceptive methods. Because for-profit companies in particular tend to react to market conditions as they evolve, the team aimed to fully understand current and future governmental policies in order to predict likely responses in the private sector.

The PSP-*One* team adopted a holistic approach to assessing sustained access to contraception. The availability and affordability of contraceptive methods in a given country are directly influenced by the following factors:

- The current demand for products and services at commercially sustainable prices
- The competitive landscape for contraceptive products and services
- The size and complexity of the commercial distribution infrastructure
- The availability and affordability of health services related to contraceptive methods
- The attitudes and behaviors of key influencers, such as the medical community
- The level of effort invested in demand-building activities such as generic and branded advertising, and targeted behavior change communication (BCC)
- The availability of free and/or subsidized products and services in the country

In determining realistic strategies to maximize private sector involvement and meet contraceptive needs in Ukraine, the team also considered corporate interests and priorities, user preferences, and financial sustainability requirements

2. Market Analysis

2.1 Policy Environment and Its Impact on the Private Sector

The PSP-*One* team culled through the literature and policy documents to identify any policy barriers to private sector provision of RH/FP products and services. In addition, team members conducted interviews to identify any departure from laws, policies and regulations, and practice. The results of this analysis are presented in Annex A – Legal and Regulatory Assessment of Market Conditions for Private Sector Provision of RH/FP Products and Services. Highlights of the analysis are discussed in the following paragraphs.

Overall, the legal and regulatory framework and policy environment are very favorable to the private sector. Major laws and regulations that influence the supply of RH/FP products are very liberal, creating positive incentives for the commercial sector to invest in RH/FP activities. Policies in the areas of tax and import policies; product approval, licensing, and registration; price controls and profit limits; and advertising and promotion regulations are market oriented and do not present barriers to private sector entry and sustained presence in the RH/FP marketplace.

Policies and regulations do not restrict any FP contraceptive method, allowing for a balanced method mix. By law, every modern method—pills, intra-uterine devices, injectables, barrier methods, and sterilization—must be accessible. Actual contraceptive practice, however, has resulted in a skewed method mix that relies heavily on abortion, traditional methods, and hormonal contraceptives. A key factor contributing to women's limited choice in contraceptive methods is provider bias, combined with selective marketing by the pharmaceutical companies and unreliable product supply in the public sector.

Regulations governing the supply of RH/FP services, such as certification of private providers, private practice, and clinics, strongly support a growing private health sector. As a result, individual and group private practice is on the rise, albeit only in lucrative health services like dentistry, ophthalmology, and curative medicine. A limited number of private gynecologists offer family planning as part of a larger portfolio of RH services, such as diagnostics, gynecological and fertility treatment, and abortion. Although a few policies may constitute barriers to access and merit further analysis, in many instances, efforts to change existing practices might be more effective than new laws or regulations.

Several inhibiting factors prevent NGOs from becoming service providers. Recently the government changed the laws governing NGOs' activities so that they may provide RH/FP clinical services. Although this change is significant, it is unlikely that many NGOs will take advantage of it soon because few incentives exist for them to become service providers. On the contrary, NGOs are not permitted to charge for services or donated products, they have limited access to capital to establish private practice, and there is very little international funding to support them. Further analysis is required to determine whether the overall RH/FP marketplace would benefit from a greater NGO role in service provision, and whether allowing them to charge for services and products is feasible. A mechanism to help NGOs secure a steady funding base would also have to be identified.

Prescription norms may present a barrier to access, primarily for rural women who rely on Feldshers⁶ for primary health care. Although Ob-Gyns can prescribe FP methods, most Feldshers do not have a gynecologist or family medical doctor, requiring a rural woman to travel to obtain FP counseling/services and to purchase contraceptives. The reasons why rural women do not use contraceptives, however, are unclear. Does the prescription norm create a true barrier to access? Or does the lack of FP information prevent these women from demanding services? Further analysis is needed to determine whether changing the prescription norm is an appropriate intervention.

Adolescents face barriers in accessing FP information, products, and services. The age adolescents become sexually active has dropped to approximately 14-years old in urban areas⁷, which makes early RH/FP counseling particularly critical in this age group. According to the health law, youth under 18 years must have parental consent to receive RH/FP services. In practice, however, adolescents are not prevented from accessing FP services and information through MOH facilities. Interviews conducted with MOH providers revealed that doctors typically do not require parental approval for youth counseling and services. Most youth, however, do not spontaneously go to the MOH for their RH/FP needs. NGOs for their part respect the law and restrict their activities to youth older than 18 years. Despite the abundant supply of condoms and other FP methods at kiosks and pharmacies, there is a widespread assumption that young people cannot afford them. Again, further research is required to determine whether changing the law is the appropriate "trigger" to address these barriers, or whether well designed, youth-friendly NGO programs might be more effective.

It is important to note that two key practices affect access to quality RH/FP products, services, and information, but do not necessarily impact the private sector directly. These are operational barriers to the efficient and equitable provision of RH/FP services and inadequate funding allocation to the national reproductive health program. These barriers, which affect the entire RH/FP sector, can only be addressed through major reforms that are beyond the scope of a private sector initiative.

2.2 Contraceptive Product Supply

The current range of modern contraceptive products available on the Ukrainian commercial market includes condoms, oral contraceptives, injectable contraceptives, and intra-uterine devices (IUDs). Condoms are available in a variety of features (e.g., classic, lubricated, ribbed, studded, ultra-thin, ultra-strength) and at different prices (from US\$0.38 to \$2.00 for a pack of three condoms). Condoms are for the most part imported from Western Europe or Asia and distributed through pharmacies, grocery stores, and kiosks. One Ukrainian company (LATEX) packages imported condoms locally and offers some of the lowest priced brands. The range of brands and features decreases outside urban areas and is limited to a few low-priced products in rural areas, as predicated by consumer demand and average purchasing power.

A growing market for hormonal contraception

Oral contraceptives (OCs) constitute a growing and dynamic segment of the contraceptive market. While condom brands are merely imported by local distributors and sold to wholesalers and retailers with limited advertising and promotional support, hormonal contraceptive brands benefit from the marketing and financial capacity of pharmaceutical companies with a vested interest in the Ukrainian market. These companies include Organon (Netherlands), Schering (Germany), Richter Gideon (Hungary), Pfizer (USA), and Janssen Cilag (a subsidiary of Johnson & Johnson). The team focused on understanding the respective

⁶ Rural health stations

⁷ POPTECH 2003 page 20.

corporate strategies of these pharmaceutical companies and their impact on the country's current and future contraceptive supply. Table 1 presents pharmaceutical companies that are active on the contraceptive market, their product portfolio, and their price range.

Table 1. Contraceptive Brands Sold in Ukraine

Manufacturer	Schering	Organon	Richter Gedeon	Janssen Cilag	Pfizer
Products	Combined OCs:	Combined OCs:	Combined OCs:	Combined OCs:	Injectable:
	Diane 35	Marvelon	Lindinet	Cilest	Depo Provera
	Jeanine	Mercilon	Novynette	Pending:	
	Logest	Laurina	Ovidon	Ortho Evra	
	Microgynon	Tri-merci	Regulon	contraceptive patch	
	Minisyston	Progestin-only:	Rigevidon	pateri	
	Ovlon	Excluton	Emergency		
	Triquilar	IUD:	Contraception:		
	Trisiston	Multiload	Postinor		
	Yirina	Pending:			
	IUD:	NuvaRing vaginal			
	NovaT	ring			
	Mirena (hormone releasing)				
OC prices	\$1.45 - \$10.50	\$5.50 - \$9.00	\$0.90 - \$5.00	N/A	N/A
IUD prices	\$5.00 - \$100.00	\$15.00 - \$20.00	N/A	N/A	N/A
Other products	N/A	Nuva-Ring: \$12.00	Postinor:	Patch: Undisclosed	Depo-Provera: \$6.00 - \$8.00

As a general trend, contraceptive manufacturers are adopting an innovation-driven approach to the Ukrainian market, concentrating on middle and upper class, educated consumers who demand increased method choice. Schering's *Mirena*, a hormone-releasing IUD retailing for US\$100; *NuvaRing*, a combined hormonal vaginal ring developed by Organon soon to be launched in Ukraine; and Janssen Cilag's combination contraceptive patch, which is pending registration, reflect a strategy of expansion through innovative, high-priced products. These companies are targeting the most dynamic consumer segment for hormonal contraception: young, upwardly mobile women living in urban areas. While this strategy does not imply that the availability of lower priced products is being threatened, it suggests that communication and promotional investments by pharmaceutical companies focus almost exclusively on the most profitable products and consumer segments.

The size of the contraceptive market in Ukraine is estimated at about US\$ 6 million CIF⁸ (sales of manufacturers to local wholesalers). Although it has been growing steadily, the contraceptive market appears to be reaching a plateau, which indicates a saturation of the supply side and typically results in increased fighting for market share and/or reaching out to potential new users. Efforts to broaden the market by reducing consumer prices appear to have failed: One pharmaceutical supplier reportedly experimented with a 70 percent price reduction of its lower end brand and noticed no change in sales. At the higher end, the introduction of a third-generation OC, had a cannibalizing effect on the company's

⁸ Cost, insurance, and freight included

other brands and failed to increase the market. Consequently, manufacturers are aiming for increased market share by launching innovative products and concentrating their efforts on the most profitable targets: at the consumer level, that would be young, urban-living middle and upper class women (especially students), and at the provider level, trusted doctors who are loyal to a company's brands.

The symbiosis between suppliers and service providers

Contraceptive manufacturers implement research and marketing activities through fully owned affiliates based in Kiev. These representative offices employ large teams of medical representatives (typically called detailers) who regularly visit public and private providers to promote company products and provide technical support. These teams, which constitute the pharmaceutical industry's most important marketing tool and absorb a large part of its operating costs, have played a critical role in increasing provider confidence in hormonal contraception. It is estimated that pharmaceutical detailers cover 95 percent of gynecologists in the country. This level of attention, however, is rarely extended to general practitioners and family doctors.

The close collaboration between pharmaceutical companies and public sector health providers has been facilitated by a relatively open-minded attitude from the MOH and medical associations. Pharmaceutical companies, for example, support continued education for health providers through conferences and workshops on specific topics (including contraception). Direct-to-consumer communication efforts, however, are limited by the prohibition of branded advertising for prescription drugs. Although registering OCs as over-the-counter (OTC) products can circumvent this law, manufacturers have minimal interest in developing large-scale consumer campaigns. As a result, while providers have substantially benefited from public and private efforts to increase the use of modern contraception, potential users remain relatively uninformed about these methods.

Because the Ukrainian government is known to adopt a "hands-off" attitude towards the private sector, the pharmaceutical industry is largely self-regulated. The tightening of the market has led to a number of unethical practices (not limited to the contraceptive segment) that cause distortions in normal supply and demand patterns. For example, at least one pharmaceutical company is reportedly paying doctors to prescribe its products. In addition, there are widespread complaints that providers demand free samples in return for favoring a company's products, and then sell these samples to their patients. These and other unethical practices are of great concern to the Health Care Committee of the European Business Association, an industry group working on improving health regulations and marketing ethics in Ukraine.

A well-developed commercial distribution

Commercial pharmaceutical suppliers sell a wide range of mostly low-dose OCs, including so-called third-generation pills, a progestin-only pill (Organon's *Excluton*), and an emergency contraception pill (Richter Gideon's *Postinor*). These products are distributed through a vast network of wholesalers and retailers whose potential reach extends to all regions of Ukraine, including rural areas. In the absence of distribution surveys or industry-generated information (such as the list and location of registered pharmacies), it is impossible to estimate actual distribution coverage for contraceptives, which are often resold to several wholesalers before they reach retail outlets. Although pharmaceutical distributors typically claim to carry a wide range of products and serve a wide geographic area, there are reasons to believe that the range of available contraceptives diminishes drastically outside urban areas. Nevertheless commercial suppliers contend that most Ukrainian women can access contraceptives if they want them, and that limited product availability simply reflects a lack of demand and a preference for low-cost brands. The proliferation of pharmacies and wholesalers indeed supports this theory. In areas where few pharmacies are established (as

in villages with fewer than 5,000 inhabitants), rural feldshers are known to maintain a stock of essential drugs (including contraceptives when requested) that they order from the nearest pharmaceutical outlet.

An industry in transformation

The continued availability of contraceptives is subject to the overall availability of pharmaceutical drugs in Ukraine. This market has experienced an explosive increase in the number of pharmaceutical wholesalers and retailers in the past decade that has produced high competition and lower margins (limited to 10 percent by law but typically as low as 3 percent). This sector is currently undergoing a consolidation phase characterized by the closing of wholesalers. According to the representative of a prominent pharmaceutical chain in Kiev, 260 of the 300 wholesalers have closed their operations in the past year. The industry welcomes this consolidation, however, because it favors the creation of larger, well-financed wholesale groups with broader reach. The closing of unprofitable wholesalers is unlikely to affect product availability, and the number of pharmaceutical retail outlets is actually growing. The number of pharmacies has increased from about 6,000 a few years ago to about 15,000 today. Pharmaceutical sales remain a highly profitable business in Ukraine, fueled by a growing consumer demand for products that must be met almost exclusively by the private sector.

A lack of market research data

Despite the proliferation of research firms in Ukraine, it is difficult to access reliable data about contraceptive product sales, market share, consumer trends, and distribution coverage. One company, Business Credit, currently collects comprehensive sales and distribution data through periodic surveys of pharmaceutical outlets. This research firm, however, does not sample condoms and does not monitor products wholesalers sell directly to consumers or providers (as is often the case for IUDs). In addition, some client pharmaceutical firms have questioned the accuracy of available pharmaceutical sales data.

Consumer research relating to the contraceptive market also appears to be scant. The absence of an up-to-date national reproductive health survey creates an information vacuum that is not compensated by private sector market research. Pharmaceutical company affiliates do not usually invest in quantitative studies but rather in qualitative research such as focus groups and in-depth interviews. More resources are invested in provider research, including surveys of up to 100,000 physicians at a time. This information, however, is very costly and strictly proprietary. To date there has been no spontaneous effort among pharmaceutical companies to join forces and fund research that could benefit the entire industry.

A dearth or consumer-directed information

Although health providers have benefited from the MOH and pharmaceutical industry's training and communication efforts, the general public is seldom the focus of information and behavior change campaigns, which in turn contributes to the sluggish demand for contraceptives. The majority of persons the assessment team interviewed both in the private and public sectors identified the lack of public information as a priority to be addressed for contraceptive prevalence to increase significantly. Several inhibiting factors appear to be at work: limited public funding affects the ability of the MOH to communicate with potential users; the absence of consumer research makes it difficult to design effective programs; real or self-imposed limitations on brand advertising discourage manufacturers from communicating with consumers; and legal restrictions on messages targeted at minors hinder public education campaigns. Beyond its impact on product demand (and indirectly, the growth of contraceptive supply), the lack of programs directed at high-risk groups, especially youth, constitutes a public health concern.

2.3 Reproductive Health and Family Planning Services

Traditional reliance on the public sector

The public sector is clearly the dominant provider of RH/FP services. The MOH offers RH/FP services and counseling through multiple facilities under its countrywide service delivery network. Facilities include maternity centers, outpatient clinics, women's consultation centers, RH/FP centers, and family medical centers, and the MOH has trained Ob-Gyns and family medical doctors in the provision of RH/FP services and counseling. The challenges associated with public sector provision of FP services are well documented in other reports (see POPTECH 2003 Assessment, Deliver Project Assessment 2004, POLICY Project Operational Policy Barriers Analysis 2003). The following is a discussion of public sector practices and behaviors that affect contraceptive security.

The fluid and close relationship between pharmaceutical companies and public sector physicians influences prescription practices and therefore contraceptive choices. Public providers displayed a preference for OCs, for example, reflecting intensive marketing activity by pharmaceutical companies, as well as provider training efforts in the public sector. All public sector providers interviewed consistently said that they believe older generation and generic hormonal contraceptives are "inferior" products and tend to prescribe expensive, latest-generation pills. This may present a problem if a large percentage of women cannot afford the newest pills. Public providers also like to prescribe OCs for a host of RH problems. For example, several physicians use *Regulon*—a product marketed by Richter Gedeon—to regulate a woman's menstrual cycle after an abortion. In contrast, these providers generally reported a lack of interest in prescribing injectable contraceptives, which have the reputation of causing undesirable side effects. This attitude is reflected in turn in the market for *Depo Provera*, considered negligible in comparison with the OC market.

There is minimal interest among public providers in promoting the use of IUDs. According to many informants, the use of IUDs has decreased dramatically in the last five years (some reported prevalence to be as low as 10 percent). Explanations vary as to why IUD use is declining, but some providers may be applying overly stringent eligibility criteria that are not evidence based. As a result, abortions may be more accessible to women than IUDs. Public health providers are also known to prescribe excessive testing that is not medically indicated according to international norms, and represents an additional cost for users.

Despite the constitutional right to obtain free medical services in the public sector, almost all patients find themselves having to purchase drugs and supplies from pharmacies, as well as to make direct, informal payments to public sector health providers. Facilitated by the MOH's interpretation of Article 49 allowing facilities to charge patients for "products" (defined as medicines and medical supplies such as syringes and bandages), informal payments have created a "shadow" private market that is highly advantageous to providers. Prices are commensurate with a provider's professional degree and reputation, and therefore vary from provider to provider, and facility to facility. Providers are hesitant to discuss prices directly with their patients or anyone else, so prices are typically communicated through word-of-mouth. It is unclear whether the existence of informal payments is preventing low-income clients from seeking FP services. The most detrimental impact of this shadow market, however, may be that it discourages public sector providers from setting up their own practice, which always involves high costs and considerable risk.

The informal payment structure is so entrenched that the provider community is likely to offer strong resistance to any initiatives to change the status quo (see Operational Policy Barriers Study for further details). On the positive side, the informal payment system has made clients accustomed to paying for services. Among the hardest transitions from universally free health care to a fee-for-service system is getting clients accustomed to having to pay for services and products. Ukraine does not face this barrier.

Except for vulnerable population groups, everyone pays something for medical services, thereby creating an informal private practice of fee-for-service within the public sector.

An emerging private health sector with limited FP/RH focus.

While the number of providers working in private sector clinics part or full time appears to be increasing, these providers tend to concentrate on profitable services such as dentistry, ophthalmology, oncology, diagnostics, outpatient surgery, and gynecology. This pattern in private health care follows past trends in other Eastern European countries where liberalization policies attempted to foster private sector growth after the fall of communism. FP and other RH services eventually followed, and the marketplace matured. With a dominant public sector offering "free" FP services, there is simply no economic incentive for private providers to offer these preventive services.

Consequently, private providers working in the RH area focus on the most profitable gynecological services, such as ultra-sound and other gynecological tests, abortion, hormonal replacement therapy, and infertility treatment. A quick review of the prices charged for services suggested that only higher income groups could be expected to afford private health care. At the three sites visited (Isida, Medikom, and Boris clinics), however, 50 to 75 percent of patients carried employer-paid private medical insurance that help defray the cost of services and some drugs. Private health insurance schemes tend to cover almost all gynecological services, including FP consultations, hormonal products used for RH treatment (not contraception), IUD insertions (excluding product costs), and abortions.

Private provider attitudes toward RH vary greatly, but at least one prominent gynecologist reported attending international conferences on contraceptive technology and stocking IUD brands not available in Ukrainian pharmacies. Private providers exhibit the same attitudes and practices toward contraception as public sector providers, with a clear preference for OCs, and a limited interest in prescribing injectable contraceptives or IUDs to their patients.

Limited potential for the NGO sector.

With the bulk of services currently provided by public sector facilities, and the concentration of product supply in the commercial sector, there is little room left for nonprofit organizations to play a significant role in reproductive health. Because of legal restrictions on their ability to provide products and services, NGOs tend to focus exclusively on advocacy and education. Some NGOs are essentially professional associations pursuing a specific agenda, or para-statal organizations created to circumvent rigid regulations of provider activities in the public sector. There is evidence, however, that some NGOs, particularly those belonging to the Reproductive Health Network, have played a key role in changing provider attitudes and lobbying for improvements in the quality of services in the public sector. Although a recent law has made it possible for NGOs to provide services and products to patients, few seem to have the human, technical, and structural capacity to become service providers. Moreover, NGOs are not permitted to charge for services and products, which limits their ability to recover costs. NGOs, however, can play a critical role in addressing the persistent lack of knowledge about contraception among Ukrainian women through direct-to-user communication campaigns.

2.4 Public vs. Private Sector Roles

A "double" monopoly of RH/FP services and product supply

Table 2 demonstrates that the supply of RH/FP products is essentially dominated by the commercial sector through private pharmacies whereas the supply of RH/FP services is ensured by the public sector. NGOs are increasingly taking a lead role in activities not monopolized by the public or private sectors, such as information campaigns directed at consumers.

	Supply	Demand
Services	Public Ambulatory Clinics (w/Family Medicine MDs) FP Centers at Women's Health Centers with OB/Gyns Maternity Hospitals – limited post-partum care	NGOs through IEC, counseling and referrals
Products	Private Pharmaceutical manufacturers Wholesalers Private and semi-private pharmacies	NGOs through IEC materials and activities Public providers through counseling & prescriptions Pharmaceutical companies through promotional materials and detailing

Table 2. Overview of Private/Public Mix

There are few incentives for the "pure" private sector to increase its provision of RH services. As Figure 1 demonstrates, the combined advantage of the large volume of patients using public sector facilities and the existence of informal payments in these facilities makes private practice attractive only for those providers who cater to a small, wealthy clientele. Until steps are taken to eliminate informal payments in the public sector, private sector service provision will not increase significantly and most couples will continue to seek RH/FP services at public clinics. The few doctors in the private sector who have a progressive approach toward contraception are more likely to play a role as opinion leaders than as service providers for the average Ukrainian. Moreover, the bulk of patients with unmet health needs are likely to be found in the lower income and rural segments of the population who cannot access private sector clinics and must be served by the MOH.

Public/private relationship in the supply of products

Figure 1 illustrates the unique relationship that has developed between the public and private sectors with respect to the supply of RH/FP products. The attitudes and practices of public sector providers, who represent the largest body of service providers, strongly influence the demand for contraceptive methods and in turn the availability of these methods in the commercial market. The absence of consistent product supply in public clinics has resulted in a virtual supply monopoly in the private sector, and public sector providers and private sector suppliers find themselves in a mutually dependent relationship that has had

both positive and negative influences on the availability of contraceptive products. On the positive side, the close collaboration between pharmaceutical companies and public sector providers has led to a substantial change in attitudes towards hormonal contraception. On the negative side, a program dedicated to those unable to afford or access commercial products is clearly absent, and there are ethical questions regarding the objectivity of the product information provided to patients. While services remain relatively easy to access and free of charge (at least in principle but not in practice), there is some concern that even the cheapest condom or OC brands might be too expensive for low-income Ukrainians.

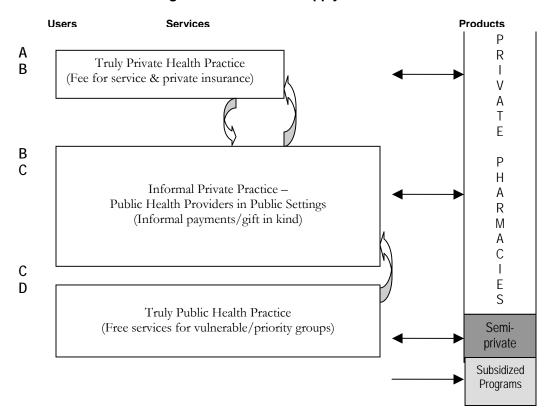


Figure 1. Overview of Supply Sources and Users

3. Conclusions

The PSP-*One* team's analysis of the policy environment, market conditions, and medical practices resulted in the following key conclusions:

There does not seem to be a pressing contraceptive security problem in Ukraine where products are concerned. Although there is insufficient research to determine with certainty whether all consumers have access to affordable products, there is no obvious supply crisis in Ukraine. Ukraine has a well-developed commercial market that caters to average consumers, not just the elite. While pharmaceutical companies tend to invest marketing resources in high-margin products, they are careful to keep low-cost brands in their portfolio. The sustained presence of affordable OCs on the market does not appear to be threatened as long as there is demand for these products. In addition, wholesalers that depend on a high-volume business are careful to maintain a wide and diversified portfolio in order to maximize revenue.

The lack of research data however, leaves some contraceptive security questions unanswered. The extent to which consumers located outside urban areas have easy access to contraceptive products can only be determined through quantitative consumer or distribution surveys, which are not currently available in Ukraine. In addition to people living in rural areas, young people and the urban poor may not be able to afford commercial contraceptive products. Only quantitative research, however, can provide an estimate of the size of the underserved population. The POLICY Project's upcoming willingness-to-pay survey should provide insight into the affordability issue, but more segmentation-type research may be needed.

Widespread access to products and services does not extend to accurate and reliable information about RH/FP. Public and private sector providers, as well as OC manufacturers, agree that lack of information and education among potential users is the biggest barrier to increased use of modern methods. Information and education are needed to turn unmet need into potential demand and eventually into increased use of modern methods. Ukrainian men and women may have ample access to products and services but their need for basic information and counseling is not adequately met by the public, private, or NGO sectors.

The current method mix is driven by industry focus and provider attitudes rather than by public health goals. Contraceptive security implies a choice of methods and counseling that is based on patients' needs and preferences. While the current method mix reflects a reduction in the use of abortion and a higher reliance on hormonal methods, the difficulties associated with obtaining an IUD and the limited availability of injectables reflect a trend toward a limitation of options for Ukrainian women. This trend is likely the result of pervasive misconceptions about these methods, as well as the industry focus on OCs.

Efforts to bolster the development of private sector service providers are currently unwarranted. Because the public sector reaches deep into the various Ukrainian oblasts, services channeled through this sector are likely to reach all population groups and they are more likely to be affordable than those channeled through the burgeoning private sector. Likewise, the national product supply is best served by the commercial distribution, which is both more efficient and more financially sustainable than distribution programs channeled through public sector outlets. As a result, policy efforts should focus on correcting problems (such as provider education or ethical issues surrounding pharmaceutical activities) and designing a national contraceptive security strategy that makes the most of the capabilities of each sector (public, private, and NGO).

4. Key Recommendations

Based on the findings and conclusions of the market analysis in Ukraine, the PSP-*One* team offers the following recommendations:

Avoid supply-side activities that could have a counterproductive effect on the commercial contraceptive market

It may be tempting to increase contraceptive supply in Ukraine by introducing free or subsidized products on the market, through either public or private sector channels. Doing so without considerable investments in targeted IEC activities, however, may have the effect of competing with commercial suppliers for existing consumers. When such competition occurs, commercial suppliers typically react by limiting their product portfolio to a few high-price brands targeted at a small, upper income user group. In the long run, this may lead to a rarified commercial contraceptive supply that no longer serves the needs of average consumers.

Identify priority groups for demand-building activities

Despite the lack of research data, it is possible to infer from interviews of contraceptive suppliers and service providers that users of OCs tend to be young, middle class urban women; condom users tend to be young urban men; and IUD users, older, low to middle income women. Pharmaceutical companies have identified female university students as their fastest growing customer segment and are investing the bulk of their resources on this core group. Students are most likely to have reservations about abortion, harbor fewer misconceptions about hormonal contraceptives, and have easy access to counseling through campus clinics. Other key target groups for expanding the contraceptive market are post-partum women and post-abortion patients. As previously noted in the 2003 POPTECH report, this group represents a "missed opportunity," because women who deliver or abort are most likely to need FP counseling, yet rarely receive it. Finally, adolescents should be considered a priority group because they are at high risk of contracting STIs and having repeat abortions. This group, however, is less likely than older women to adopt contraception and may require intensive communication efforts.

Work with pharmaceutical manufacturers that have an interest in the contraceptive market

The efforts of pharmaceutical companies to market hormonal contraceptives to providers can be supported and expanded. A social marketing intervention based on a partnership with one or several manufacturers could have a substantial impact on both the demand and supply sides of the market. When market conditions are right, as is the case in Ukraine, manufacturers can be persuaded to increase their investment in distribution and promotional activities in response to large-scale campaigns directed at consumers and other supportive activities. Should research demonstrate that a large percentage of the population is unable to afford commercial contraceptives, manufacturers may agree to decrease the price of some of their brands. It is important to recognize, however, that partnerships with commercial providers work best when they are targeted at the core consumer group (in the case of Ukraine, young, middle class urban women). For high-risk and low-income groups, activities channeled through the public sector or NGOs are more appropriate.

Address gaps in knowledge and misconceptions among service providers

Because public sector providers have substantial influence on the method mix available in Ukraine through their counseling and prescription practices, it is necessary to renew and sustain their training to increase the use of modern methods. Providers have substantial influence on the method mix available in Ukraine through their counseling and prescription practices There is some evidence that intensive marketing activities conducted by some pharmaceutical companies are skewing provider preferences toward OCs, particularly more expensive third-generation pills. Because access to other methods such as IUDs and injectables is a condition for contraceptive security, it is important to ensure that the information and training doctors receive does not emanate exclusively from pharmaceutical companies. Consequently, renewed training in contraceptive technology is recommended, possibly to be conducted by NGOs that enjoy a close relationship with service providers, such as the Ukraine Family Planning Association. Activities involving private sector providers are not recommended at this time as these providers only cater to a small percentage of the Ukrainian population.

Encourage improved linkages between product suppliers and service providers

Potential users of FP methods are typically prescribed a brand of contraceptives that they must then purchase in a pharmacy. This is often the only link between suppliers and providers. Unfortunately, the relationship between these two groups has been marred by abuses, such as providers reselling free samples, or pharmaceutical companies bribing doctors. One company, however, is undertaking a new initiative (previously tested in Russia) that consists of providing doctors with one free sample per patient, a coupon for three months of free products for each patient, and a toll-free number where patients can be referred to a participating pharmacy. This system allows for better linkages between doctors, pharmacies, and consumers; more efficient sampling programs; and improved monitoring of both patient and doctor behaviors. Such initiatives by pharmaceutical companies should be supported and perhaps expanded to include a wide range of products.

Identify underserved groups and address their contraceptive security needs

The private sector cannot be expected to reach all consumers if it is not profitable to do so. It remains, however, essential to meet the needs of all potential users in Ukraine. Because the industry and MOH generate very little consumer research, it was not possible to obtain a definite estimate of the proportion of the population that can afford commercial products, though physical access seems adequate for the majority of users. As a result, the team did not eliminate the possibility of a dedicated program that could make free or subsidized products available to specific groups, particularly adolescents and rural and low-income women. The distribution of these products, however, should take place in the context of a targeted strategy and be supported by effective logistical and monitoring systems. The MOH will likely need technical assistance to minimize leakages in the commercial distribution and target commodities to those who need them the most.

5. Proposed Strategy to Increase Private Sector Participation in RH/FP Goals

The private sector is already an important player in the RH/FP arena. In addition to its contribution to contraceptive security through sustained product supply, private sector efforts have been a factor in achieving broader public health goals, such as increases in contraceptive prevalence and the reduction of abortion rates. This contribution can be maximized through a dual strategy of public/private partnerships and public sector policies that facilitate and complement the activities of the private sector. A strategy to strengthen the private sector's role in the RH/FP marketplace is presented in the following paragraphs. Figure 2 provides a visual overview of the PSP-*One* proposal.

5.1 Partnership activities between public and private sectors

A sustained effort to communicate the benefits, effectiveness and safety of contraceptive products (especially hormonal methods) is necessary to achieve substantial growth in the use of modern methods. Although pharmaceutical companies have demonstrated a willingness to invest in this market, their focus is likely to remain on service providers. To complement these efforts, we recommend implementing a large-scale behavior change initiative targeted at specific target groups among the most likely adopters of modern methods. The goals of this intervention would be to reinforce the efforts of the private sector in growing its core consumer groups (young, urban women, especially the student population), address the unmet needs of post-partum and post-abortion patients, and reach out to high-risk groups such as adolescents.

Partnerships with commercial manufacturers can take different forms but typically include a commitment by both parties (the public and private entity) to invest in activities that can substantially grow the contraceptive market. Such activities may include:

- Designing and implementing consumer research, mass media advertising, product sampling, and public relations campaigns
- Increasing distribution coverage for contraceptive products in under-served areas
- Ensuring the wide availability of affordable products (the upcoming Willingness to Pay Survey conducted by the POLICY project will help determine whether a reduction in price is needed in order to reach lower-income users)
- Increasing provider outreach activities by pharmaceutical companies, including high-profile
 events public relations campaigns, expanded pharmaceutical detailing, and controlled product
 sampling programs
- Supporting and expanding the activities of NGOs with technical expertise and experience in dealing with target groups, as well as those involved in advocacy and provider training
- Training providers in the special needs of adolescents and supporting the creation of youth-friendly counseling programs in collaboration with NGOs
- Coordinating partnership activities with public sector programs (see next section)

5.2 Policy activities to support public/private partnerships

The public sector plays a critical role in the well being of the private sector. We propose working closely with the MOH to facilitate and complement private sector initiatives while at the same time, achieving important public health goals such contraceptive security, increases in the use of modern contraceptive methods and a reduction in abortion rates.

The focus of the second strategy should be to assist the MOH in taking a leadership and oversight roles in partnerships between public, private, and NGOs engaged in FP/RH activities. A possible strategy would be to help the MOH formalize the partnership between these stakeholders by drafting a memorandum of understanding (MOU), facilitating regular coordinating meetings and developing a work plan of activities that conform to public and private agendas. As a group, the public and private sector partners could develop and implement a National Contraceptive Security Strategy as their first initiative together.

Targeting subsidized commodities is a critical strategy to ensure that under-served populations have access to FP information and modern methods. Under-served potential users include several population groups: those who want to adopt modern methods but have limited access to commercial pharmacies; those with limited access to information and counseling services, and those who cannot afford commercial contraceptive brands. In addition, individuals at high-risk of unwanted pregnancies, repeat abortions and/or STI infections and HIV/AIDS should be considered under-served because they lack the information and motivation to adopt safe behaviors. It is important, however that the MOH implement this subsidized commodity program with care so to not harm the vibrant commercial supply of FP/RH products. Proposed activities include:

- Conducting a market segmentation analysis to identify under-served groups (such as low-income peri-urban and rural populations, youth, etc)
- Identifying geographic areas where demand for contraceptive products is not satisfied because of limited access to commercial products (using consumer research, a distribution survey or other assessment tools)
- Identifying socio-economic groups with unmet demand for contraceptive products (using the upcoming willingness to pay survey)
- Designing a commodities distribution program to be implemented by select public outlets
- Providing technical assistance to the MOH in targeting commodities to priority groups
- Coordinating with private sector initiatives to develop and implement a BCC program targeted at priority groups

A final area where the public sector can play a lead role is in improving the attitudes and practices of services providers and encouraging greater use of modern methods. Given the MOH's limited resources, both pharmaceutical companies and NGOs can assist in carrying out the proposed activities. Greater MOH involvement and direction in these activities, however, will ensure a more balanced perspective on contraceptive methods. Activities may include:

- Supporting large scale contraceptive technology updates targeting MOH gynecologists, obstetricians and family medicine doctors
- Encouraging providers to offer a more balanced method mix through better prescribing practices
- Training providers to manage the side effects of hormonal methods, particularly injectable contraceptives

Figure 2: Illustrative FP/RH Strategy for Ukraine

Goals	Strategy	Objectives	Proposed Activities
REDUCE INCIDENCE OF ABORTION	#1 Increase demand for RH/FP products and services among target groups	Objectives Increase the use of modern methods among target groups Take advantage of the growing commercial market for contraceptive products Support the efforts of dedicated but underfunded NGOs	Proposed Activities Establish partnerships between MOH and contraceptive manufacturers and distributors Design program to support and complement industry efforts (consumer research, mass media advertising, controlled sampling programs, and expanded provider detailing) Support increased distribution coverage of contraceptive products. Support and expand NGOs activities (ie. advocacy, PR campaigns, interpersonal communication, and referrals to trained health providers) to reach target groups.
INCREASE USE OF MODERN METHODS	#2 Improve the attitudes and practices of service providers	Objectives Increase providers' attitude toward multiple methods Encourage providers to prescribe more balanced method mix Increase provider awareness of the health consequences of repeated abortions	Proposed Activities Support large-scale contraceptive technology updates targeting gynecologists, obstetricians, general practitioners, and family doctors Train providers to manage the side effects of hormonal methods through expanded detailing activities Train providers in the special needs of adolescents and support the creation of youth-friendly counseling programs in collaboration with NGOs Establish FP links with post-partum and post-abortion services, train these providers in contraceptive technology
	#3 Target subsidized commodities to under-served potential users	Objectives Improve access to under-served groups with unmet demand Address the unmet needs of groups at highrisk of repeat abortions or STIs Limit distribution of free or subsidized commodities	Proposed Activities Id under-served groups (such as low-income, and rural populations) Id geographic areas with limited access to commercial products (using consumer research, a distribution survey or other assessment tools) Design commodities distribution program to be channeled through select public outlets Provide TA to MOH in targeting commodities to priority populations Develop BCC program targeted at high-risk groups

Annex A: Legal/Regulatory Assessment of Market Conditions for Private Sector Provision of RH/FP Products & Service

Regulatory/Policy Area	Description	Authority Responsible	Issues/Outcomes			
	Regulations that Govern Contraceptive Options					
Contraception Choice (Availability of Specific Methods)	There is no legislation that limits the use of certain kinds of contraceptives. Article 49 allows a woman/man to choose sterilization by voluntary agreement and can have the procedure performed in an accredited medical institution (including private sector, as demonstrated by Medicum clinics). A 1994 ministerial order approved medical indications for voluntary surgical sterilization for women and men.	Ministry of Health: Article 57 of the Fundamentals of Health Care; Norms and Standards	In principle, every modern method – pills, IUDs, injectables, barrier methods, and sterilization – is accessible. Provider bias, combined with aggressive marketing by the pharmaceutical companies, has resulted in a skewed method mix. Historically, Ukraine providers steered women away from older generation of OCs and women used IUDs. Today, providers are more comfortable with newer generation of OCs and more women are using the pill. Also, IUDs are on the decline. Sterilization, used occasionally, is rarely discussed by providers or patients despite the liberal normative provisions governing sterilization.			
	There are restrictions on who may receive FP methods; in particular adolescents. According to Article 43 of the Health Legislation, OC is regarded as a medical intervention. As such, a medical intervention requires the informed consent of the patient. If the patient is under 18 years of age, they require parental and/or legal guardian approval. This restriction, however, does not apply to condoms and other barrier methods.	Fundamentals of Health Legislation, Article 43	According to the Health Code, adolescents (youth under 18) cannot access FP information, products and services without parental consent. NGOs are the primary source of FP info for adolescents. These NGOs have applied this restriction to the provision of FP information and counseling, and restrict their materials and activities to older young adults. However, they acknowledge that there is great need among younger adolescents (13 to 18 years). It is interesting to note that the MOH providers interviewed do not require parental consent to provide FP info and services. The problem is MOH is not the "preferred" source of FP info and services by adolescents and they do not actively go to MOH facilities.			
Prescription and dispensing	According to an MOH Ministerial Order, all pharmaceutical contraceptives require a prescription from an obstetrician or gynecologist. Businesses and individuals can sell pharmaceuticals with a special permit. Those who have appropriate training and can meet certain qualifications and education requirements are eligible to sell registered pharmaceuticals at the retail level. Permit costs are minimal (approximately \$10 for an individual and \$50 for a business). The permit is issued within 30 days. There are no restrictions on who can dispense condoms.	Ministry of Health: Ministerial Order #233, Lists of Pharmaceuticals Registered in Ukraine, '97 Article 19 of the Law on Pharmaceuticals and Rules of Retail Pharmaceutical Sales: Ministerial Order #447, '97 Ministerial Order #1020, Procedure of Licensing Entrepreneurial Activities, '98	The prescription norm may present a barrier to access, primarily for rural women who rely on Feldshers for primary health care. Although Ob-Gyns can prescribe FP methods, gynecologists are the principle health care providers of RH/FP and the ones most likely to prescribe an FP method. Increasingly family medical doctors also prescribe contraceptive methods and insert IUDs. However, Feldshers often do not have a gynecologist or family medical doctor, requiring a rural woman to travel to obtain FP counseling and services, and to purchase a FP method. The reasons why rural women do not use FP methods are unclear. Does the norm on prescriptions create a true barrier to access? Or is the reason why rural women not use FP methods/services because they lack sufficient information on and are unaware of FP's benefits? The laws and norms are supportive of individuals and businesses that wish to sell pharmaceuticals such as contraceptives given the robust number of kiosks, pharmacies, and other outlets offering contraceptives.			

Regulatory/Policy Area	Description	Authority Responsible	Issues/Outcomes
	Regulations that Gove	ern Contraceptive Options (co	ntinued)
Product Approval; Licensing; Registrations	Registration is required for both pharmaceuticals (pills, injectables, foams, jellies, sponges, etc.) and barrier methods (IUDS, condoms, diaphragms, etc). Article 9of Law of Pharmaceuticals states that all pharmaceuticals must conform to the procedures outlined in Cabinet of Ministers Resolutions #569: Procedure to Register and Re-register Pharmaceuticals. Oral contraceptives are registered as medicinal agents. IUDs, condoms, and other barrier methods are registered as medical technologies.	Ministry of Health: State Registrar of Pharmaceuticals, Pharmaceutical Registration Bureau, Pharmacological and Pharmacopoeias Committees, Dept. Control over the Quality of Medicines & Pharmaceuticals (Local FDA equivalent), New Medical Technologies Committee '98 Law of Ukraine on Pharmaceuticals Cabinet of Ministers Resolutions #569: Procedure to Register and Re-register Pharmaceuticals Ministerial Order #74, Regulations of State Registry of Medical Technologies Products	Pharmaceutical Registration Bureau registers any product based on an application submitted by the manufacturer. The bureau reviews each application within a month. However, this time period does not include any specialized assessments (including clinical trials). As a rule, clinical trials are not carried out when an internationally acknowledged certificate exists for the product. Biological and medical trials are conducted in almost every case. Registration fee for any pharmaceutical is 1,000 Euros for each therapeutic form and 100 Euros for each subsequent dosage. This fee does not include additional cost for specialized assessments, which can be considerable. Registration process is shorter and requires a smaller fee. IUDS, condoms, and other barrier methods also must be registered through the New Medical Technologies Committee. Conversations with pharmaceutical manufacturers suggested that the registration process and fees are neither excessive nor cumbersome.
	Regulations	that Govern RH/FP Providers	
Certification of Private Providers/Private Practice/Clinics	Private practice is legal with a license. A Cabinet of Minister Resolution regulates private medical practice and licenses for retail sales of pharmaceutical products. The Cabinet of Ministers also regulates the state accreditation for all – public and private – health facilities. All health facilities are subject to accreditation every three years.	Ministry of Health and Ministry of Economics: License Chambers Cabinet of Minister Resolution #1020 on Licensing Entrepreneurial Activities, '98. Cabinet of Minister Resolution #765, The Procedure of State Accreditation of Health Care Facilities, '97.	Private practice – both individual and group practice – is on the rise. This trend follows similar trends in other Eastern European countries that have liberalized medical practices: initially private practices are in dentistry, ophthalmology, and preventive medicine because they are the most lucrative medical services. There are very few Ob-Gyns who offer RH/FP services. There are some restrictions on private Ob-Gyns. They are not permitted to provide follow-up care for pregnant women, treat complications during pregnancy, or perform surgical interventions (including abortions) unless they are performed at an accredited stateowned medical institution.

Regulatory/Policy Area	Description	Authority Responsible	Issues/Outcomes			
	Tax and Import Policies					
Sales/Value Added Taxes	According to Article 5 of the Law on Value-Added Tax, pharmaceuticals and medicinal goods in Ukraine are exempt from VATs. Private health care services delivered by licensed health care institutions are also exempt from VAT. Another resolution further clarified this provision stating specifically that RH/FP services are exempt from VAT.	Finance Ministry Law on Value Added Tax, '97 Cabinet of Ministers Resolutions #1602	These favorable terms exempting pharmaceuticals and medical goods, including condoms, from VAT do not create a disincentive. Also, VAT exemption for private sector medical services, particularly RH/FP services, will help stimulate the eventual expansion into this health area.			
	Regulations	that Govern RH/FP Providers				
	Article 7 of the Law of Pharmaceuticals permits the importation of contraceptives in Ukraine if the manufacturer presents a certificate of quality. Quality is controlled by State Inspection on Pharmaceutical Quality Unit. All pharmaceuticals are subject to licensing, which is reviewed by the MOH annually. All imported pharmaceutical products, including contraceptives, are exempt from entrance duty. Condoms are exempted from full customs tariffs and are subject to preferential rate of 5% to 10% of their declared custom value.	Ministry of Health: State Inspection on Pharmaceutical Quality Unit Ministerial Order #143, Procedure of Importing Unregistered Pharmaceuticals Cabinet of Minister Resolution #15, List of Goods, Imports, and Exports Subject to Quotas and Licensing Procedures	Customs procedures and import tariffs do not represent a barrier for the commercial private sector entrance to the Ukrainian market.			
	Advertising	and Promotion Regulations				
Advertising and Promotion	Article 26, Part 3 of the Law on Pharmaceuticals, the Law of Advertising governs pharmaceutical advertising. Article 20 Part of the Law of Advertising prohibits advertising to the general public of medicinal agents that (i) are available only by a doctor's prescription, (ii) are a controlled substance, or (iii) contain a narcotic. There are no limits on advertising condoms, other barrier methods, and over –the-counter (OTCs) products.	Ministry of Health: Health Regulations Law on Pharmaceuticals, Article 26, Part 3 Law of Advertising, Article 20	Although there are advertising restrictions on prescription drugs, this is not the biggest barrier to providing information directly to consumers. All the pharmaceutical companies in Ukraine have OTC pills, permitting them to go around this advertising restriction if they so desire and there are no restrictions on providing generic messages. The primary reasons for limited consumer advertising are (i) the lack of MOH resources, (ii) lack of MOH capacity to design public awareness campaigns, and (iii) pharmaceutical companies' preference for communicating with providers. The pharmaceutical companies provide (through detailing materials) what little information women/couples receive on FP methods.			

Regulatory/Policy Area	Description	Authority Responsible	Issues/Outcomes		
Other Regulations Affecting the Commercial Sector					
Regulations affecting the commercial sector and market place		Ministry of Economics	Most of the representatives from the pharmaceutical companies interviewed stated they consider the Ukrainian market to be conducive for business. Launching "higher end" products and increasing the number of staff working with contraceptives are signals demonstrating their commitment to stay in the Ukrainian marketplace. Of the five pharmaceutical companies interviewed, only one expressed concern about the overall legal/regulatory environment. One manufacturer was worried that the current favorable environment would change if the Government of Ukraine adopts EU regulations that might impose further restriction on advertising and price controls.		
Regulations affecting the commercial sector and market place		Ministry of Economics			
Price Control	According to a Joint Order from the Ministry of Health and Economics, contraceptive methods—either domestic or imported—are not subject to government price controls.	The Ministry of Health and Ministry of Economics Joint Order of MOH and MOE #265/101, '97	The Constitution and Health Legislation are silent on price controls for the private and commercial sectors. As a result, the nascent commercial sector is able to charge any prices for services. Prices are targeted for upper middle and upper classes. Consumers pay for the cost of these services through private health insurance schemes or out-of-pocket payments.		
Caps on Profit Margins	The law restricts profits margins on pharmaceuticals. Wholesale profit margins are capped at 10 percent while those for retail are capped at 40 percent.		Currently, the cap on profits is not a constraint because profit margins for wholesalers and retailers are both below the legal limit: 10% and 40% respectively.		
	Other Regulations Affe	cting the Commercial Sector (co	ontinued)		
Fee for Service	Article 49 proclaims that the state shall create conditions for efficient and accessible medical care for all citizens. The most important provision of this Article is "medical services shall be free of charge in state and communal health care institutions." The NFPP admonishes the MOH to provide free contraceptives through FP centers to key target groups: adolescents, women with high-risk pregnancy, Chernobyl victims.	The Ministry of Health and Ministry of Economics Joint Order of MOH and MOE #265/101, '97 Ministry of Health: Fundamentals of Health Legislation ('92) Article 49 of Ukraine Constitution ('96)	There are no restrictions on what the private sector can charge for services. There are, however, clear restrictions on charging for services in the public and NGO sectors (see below NGOs). Despite the constitutional right to free medical services in the public sector, almost all clients have to purchase drugs and supplies for the medical care as well as make direct, under-the-table payments to health care providers. Payments are made discreetly in cash or in-kind directly to the service provider. In some cases, the added cost has prevented clients from seeking FP services. The "shadow market" in the public sector has created several outcomes – both negative and positive. On the negative side, it is difficult to ensure quality services. Formal payments would be more convenient for the client. On the positive side, almost everyone pays for services and has become accustomed to paying for services and products. Except for the vulnerable population groups, everyone pays for something for medical services, thereby creating an informal private practice —fee-for-service—within the public sector. The informal payment structure is so entrenched that providers strongly resist any initiatives to changes this system.		

Regulatory/Policy Area	Description	Authority Responsible	Issues/Outcomes
	Restrictions Affecting Non	profits and Nongovernmental C	Organizations
NGOs	Law on Associations of Citizens, Law on Charity and Charitable Organizations govern the health NGOs. Until recently, NGOs in the RH/FP arena limited their activities to advocacy and information and counseling due to the legal restrictions on their scope. In 2004, the laws changed to expand NGOs' role, now permitting NGOs to provide RH/FP services and products.	Ministry of Health Department of Social Services	The recent change in law expanding NGOs' scope is important but it is highly unlikely that many will take advantage of these changes soon. Although NGOs can legally offer services, the MOH has yet to create the mechanisms to accredit and license NGOs so they can actually provide medical services. Also, NGOs will not be allowed to charge for services or donated products. With limited international funding to support NGOs, this restriction has effectively squashed any incentive for an NGO to transition from FP advocacy/information activities to FP services. As one successful NGO director said, "Why should I take on the risk to create a medical practice when I cannot recoup any of my investment or costs?" Another commented, "Why should I try to compete with the MOH monopoly?" Also, other NGO directors said it is very difficult to raise capital needed to establish a medical practice.

Annex B: Key Informants

Sector	Organization	Individual/Title
Donor Sector	USAID	Tim Clary, Senior Advisor for HIV/AIDS, Infectious Diseases and Reproductive Health
Public Sector	Ministry of Health of Ukraine	Nadiya Zhylka, Deputy Head Maternity and Childhood Health Care Department
		Mikola Georgiovitch, Deputy Chief of Legal Administration
		Vladimir Golovakov, Deputy Head Anesthesiologist, Zhitomir Oblast
		Grygory Lysenko , Head of the Family Medicine Department Kiev Medical Academy of Postgraduate Education.
		Inna Demchenko, First Deputy Director, Government Service of Medicines and Medical Supplies
		Boris Ventskivskiy , Head of Department of Obstetrics and Gynecology No. 1
Private Medical	ISIDA Clinic	Viktor Viktorovith, IVF Department Deputy
Providers	Medikom Clinic	Volodymyr Bannikov, Obstetrician-Gynecologist
		Rimarenko V.
	Boris Clinic	Serdyuk V.
Pharmaceutical Manufacturers	Azko Nobel Organon	Konstantin Zubovskiy, Managing Director, Russia, Ukraine and Kazakhstan
		Roman Bishovets, Head of Ukraine Office
	Schering	Vladimir Redko, Business Unit Director
		Dr.Victoria Timoschenko, PR Manager
		Mariya Zimovets, Business Development Manager
Pharmaceutical	Richter Gedeon	Janos Szabo, Head of Representative Office
Manufacturers		Alexander Gorbenko, Product Manager
		Andreiy Obrizan, Product Manager
	Pfizer Corporation	Ibor Nykyforchyn, Marketing Manager
	Yanssen Cilag	Alexander Melnik, Marketing Director
Pharmaceutical distributors	VVS Medical Supply	Elena Andrushchenko, Business Manager
	Protek-Pharma	Tetyana Mikolaivna, Marketing Director
	Nevid Pharmacy Chain	Elena Ivanova, Manager
Research Firms	Masmi Rating	Stanislav Chiglintsev, Director
		Andrey Borovskiy, Director
		Vladiimir Bogdan, Research Director
	Business Credit Co.	Dr. Ludmila Sassina, Marketing Director

NGOs and Associations	Association of OB/GYN	Boris Ventskivskiy, President
	Pharmacists Association	
		A. Spizhenko
	Association of Family Medicine	Grygoriy Lysenko, President
	Ukrainian Family Planning Association	Irina Vovk, Chief Specialist
	Association	Emilia Nepochatova, Kiev branch
	European Business Association	Alexander Markov, Executive Director, Health Care Committee
	Women's Health and Family Planning	Galina Maistruk, Chief of Board
	Women in Ukraine	Tatyana Dolishna, Chief Magazine Editor
USAID Contractors	The Futures Group	Andriy Huk, Country Director
		Elena Truhan, NGO coordinator, POLICY Project
	JSI Mother and Infant Health Project	Helene Lefevre-Cholay, Chief of Party