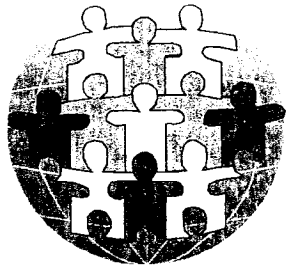

POLICY
Project

Legal and Regulatory Framework for Family Planning and Reproductive Health in Ukraine

A Report to the POLICY Project

By

Volodymyr Rudiy

June 1999

The Futures Group International
in collaboration with:
Research Triangle Institute (RTI)
The Centre for Development and Population Activities (CEDPA)

POLICY is a five-year project funded by the U.S. Agency for International Development under Contract No. CCP-C-00-95-00023-04, beginning September 1, 1995. The project is implemented by The Futures Group International in collaboration with Research Triangle Institute (RTI) and The Centre for Development and Population Activities (CEDPA).

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EXECUTIVE SUMMARY

In Ukraine, the POLICY Project works to improve the policy environment for family planning (FP) and reproductive health (RH) by increasing political support for RH and improving the capability of national and oblast officials to plan FP/RH programs. As a part of its USAID-supported program in Ukraine, the POLICY Project enlisted local expert Dr. Volodymyr M. Rudiy to assess all existing laws, acts, and regulations that relate to FP, RH, and population issues at the national level in Ukraine. This review of the legal and regulatory framework is designed to provide a foundation on which FP and RH policies and programs can be improved. The conclusions are those of the author and do not necessarily reflect the views of the POLICY Project or the funding organization.

Article 49 of the constitution supports a government role in providing health services. Other articles of the constitution ensure equal rights for men and women, protect the population from harmful work, and address relations in families and marriage. Reproductive health rights and maternal and neonatal health are further elaborated in the Fundamentals of Health Legislation in Ukraine.

The National Family Planning Program (NFPP) created in 1995 is the primary vehicle for public sector delivery of RH services. One of the NFPP's goals is to create a network of FP centers to provide quality services and information, increase the awareness and acceptability of modern contraceptive methods, reduce the number of undesired and high-risk pregnancies, reduce reliance on surgical abortion as a primary means of birth control, and provide information and services to adolescents. The NFPP also seeks to increase domestic production and imports of numerous contraceptive methods. A lack of funding, however, from national and regional budgets has inhibited the effective implementation of the program, which expires in 2000.

The review of the legal and regulatory framework confirms that all methods of contraception are legal in Ukraine but require registration by the Ministry of Health (MOH). Imports account for the entire contraceptive supply, with the exception of some condoms. Pharmaceutical contraceptives are exempt from entrance duties, and the tariff for condoms is 5 to 10 percent of their customs value. No method is subject to government price controls, and all contraceptive products and RH services are exempt from the value-added tax. However, the advertising of pharmaceutical contraceptives, like other prescription medicines, is prohibited, possibly contributing to the public's low level of knowledge about and confidence in these methods.

Medical services, including RH services, are provided free in public health care facilities. However, a number of barriers to access remain. The use of pharmaceutical contraceptives requires a prescription from an obstetrician-gynecologist (Ob-Gyn). Women in rural areas do not have access to the specialists who provide certain services such as insertion of intrauterine devices (IUDs). The requirement for minors to receive parental consent for medical interventions may restrict adolescents' access to services such as prescriptions for oral contraceptives.

Abortion is legal at accredited facilities in Ukraine, although the number of restrictions increases as the term of pregnancy lengthens. Again, parental consent is required for adolescents. Obstetric, gynecologic, and FP services are provided through public sector facilities and a small number of licensed private practitioners. However, a number of services—including abortion, treatment of sexually transmitted diseases (STDs), obstetric care, and prenatal care—can only be received at public sector facilities. Compared to state-owned facilities, there are few private practices, and the role of nongovernmental organizations (NGOs) in health care is negligible.

Legislation and programs, such as the NFPP, the Fundamentals of Health Legislation of Ukraine, and the Law on the Prevention of AIDS, contain information and education components, most of which

have been poorly implemented. In order to increase general health and FP/RH knowledge among the youth, a comprehensive course on the fundamentals of valeology[1] has been developed for secondary schools, but the course is optional and infrequently included in school curricula.

The government also attempted to mitigate the adverse effects of unfavorable occupational and environmental factors on health, with special emphasis on RH. Regulations protect women and children from difficult and harmful labor practices and provide further protections for pregnant women. Environmental law and industrial safety standards safeguard environmental health and have devoted special attention to the potential impacts of the Chernobyl disaster on RH.

The author believes that, by and large, the legal and regulatory framework is favorable for FP and RH in Ukraine. Adequate funding remains the primary challenge, particularly for the NFPP and any successor program. The information and education components of RH policies also need to be fully implemented. The legal and regulatory framework reveals room for improvement, and the author draws the following conclusions:

- The complex procedure to register pharmaceutical and barrier methods should be streamlined and should conform more closely to that of the European Union.
- Qualification requirements for specialists in the field of obstetrics, gynecology, and FP should be updated and elaborated. In particular, more opportunities to provide FP services should be given to paramedics and midwives.
- The requirement mandating a doctor's prescription to purchase oral contraceptives should be revised.
- Limitations on advertising modern contraceptive methods should be revised.
- Appropriate educational programs should be promoted at secondary schools, and the valeology course should be mandatory. Also, programs at training institutions for physicians, midwives, and educational workers should be updated.
- The role of nongovernmental and charitable organizations should be enhanced and further specified in the legal system so that these organizations can take on activities in providing information to the public on FP and RH and provide vulnerable groups with contraceptives.
- The NFPP should be fully funded in the budget, and appropriate laws should be passed to create a favorable climate for Ukrainian, foreign, and international investments from charitable and humanitarian organizations.
- The government must ensure effective compliance with national RH legislation and oversee the accountable use of the limited resources allocated for FP programs.

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[1] Special health education course; title does not translate directly into English.

BACKGROUND

According to the definition in the *Programme of Action* approved at the International Conference on Population and Development (ICPD), which took place in Cairo in 1994, reproductive health is a state of full physical, mental, and social well-being, and not just the absence of disease relating to the reproductive system. It includes a satisfying and safe sexual life, the capacity for reproduction, and the right to determine the number, timing, and spacing of one's children. According to this definition, reproductive health includes sexual health. This implies the right of men and women to information and access to safe, efficient, and convenient methods of birth control at an affordable price. The *Programme of Action* also confirms the right to appropriate health care services and seeks to reduce maternal, infant, and child mortality.[2]

Reproductive health is closely linked to the family—a primary unit of society—and to FP, which enables individuals to exercise their reproductive rights (i.e., to make their own decisions regarding the size of their family and the intervals between the birth of their children). Reproductive health envisages control of reproductive behavior, including contraception, healthy fetal development and childbearing, as well as access to abortion.

Contraceptive methods allow women to delay or avoid pregnancy. Traditional methods include periodic abstinence from sexual activity (biorhythm or calendar method), withdrawal, and vaginal douching. Modern methods include pharmaceuticals such as oral contraceptives (the pill), foams, jellies, sponges, and injectables; barrier methods such as diaphragms, intrauterine devices (IUDs), and condoms; and male and female sterilization.[3]

One priority of a democratic, socially-oriented state is to encourage conditions and mechanisms that promote the RH of its citizens. Given the historical inequality of rights and status of women in society, full RH cannot be achieved without improvements in women's status. The development of a healthy, happy, and productive population depends on the achievement of full RH, which is wholly compatible with national goals for sustainable development.

Ukraine is one of the largest countries in Europe. As of January 1, 1998, it had a population of 50.5 million persons, over half of whom (27.3 million) were women. There were 12.8 million women of childbearing age (15–49 years), three quarters of whom lived in urban areas. Three and a half million women lived in rural areas. For several decades, abortion has been a primary method of birth control for women in Ukraine. It also appears to be a leading cause of maternal mortality, sterility, and the high incidence of gynecological diseases. The abortion rate in Ukraine is one of the highest in the world, 56 per 1,000 women of reproductive age in 1996.

According to the Health-1996 Sociological Survey,[4] the most commonly used contraceptive methods were IUDs (24%), condoms (20%), and biorhythm (20%). Only 5 percent of women used oral

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[2] ICPD *Programme of Action* paragraph 7.2.

[3] Foams, jellies, and sponges employ a local barrier mechanism and are frequently categorized as barrier methods. However, because they contain pharmaceutical agents, they are considered pharmaceuticals under Ukrainian law and are subject to the same regulations as oral contraceptives and injectables. For the purposes of this paper, they are categorized among pharmaceuticals.

[4] Survey results published in *The Health of Women and Children in Ukraine, 1997* by the Cabinet of Ministers and the Ministry of Health, et al.

contraceptives, and use of injectables was negligible. The survey showed that 11 percent of women prefer not to use any contraceptives. The respondents considered the most convenient and reliable methods to be the IUD (37%), condoms (22%), and biorhythm (15%). Only 8 percent of the women polled considered oral contraceptives to be reliable and convenient. Almost one-third of men preferred not to use any contraceptives at all (30%), 21 percent preferred IUDs, and 18 percent preferred condoms.

The current study provides an assessment of all existing laws, acts, and regulations (as well as pending legislation) that relate to FP, RH, and population at the national level in Ukraine. It examines the current legal and regulatory framework and factors that can regulate or influence the availability and acceptability of contraceptives and FP/RH service delivery in order to reveal possible constraints limiting or preventing the full integration of FP into the health sector. The study is followed by conclusions regarding the potential for RH improvements based on this regulatory and policy framework.

LEGAL AND REGULATORY FRAMEWORK FOR FAMILY PLANNING AND REPRODUCTIVE HEALTH

A. Reproductive Health Care in the Constitution of Ukraine and Fundamentals of Health Legislation

The Constitution of Ukraine[5] does not directly address FP and RH; however, a number of its provisions, particularly Article 49, lay a foundation for government to act on health, RH, and gender issues. The constitution guarantees equal rights to men and women as citizens and spouses, protects the population from harmful work, and provides the government a role in health care.

Article 24 proclaims equality of citizens' constitutional rights and freedoms and equality of citizens before the law. This article prohibits discrimination on the basis of sex, as well as race, color, political, religious, and other convictions, ethnic and social origin, property status, place of residence, and language. The equality of rights of men and women is ensured by

- providing equal opportunities in participating in public, political, and cultural activities, pursuing education and occupational training, and securing employment and remuneration for work;
- outlining special protective measures related to women's health care and labor, and pension benefits;
- creating conditions that make it possible for women to combine work and maternity; and
- providing material and moral support for mother and child, including paid leave and other benefits for pregnant women and mothers.

Article 43 regulates the right to work and prohibits women and minors from work that may be hazardous to their health.

Of particular importance to the topic of this paper, Article 49 proclaims that the state shall create conditions for efficient and accessible medical care for all citizens, and that medical services shall be free of charge in state and communal health care institutions.

Article 51 states that marriage is based on the consent of both the man and the woman, and each spouse has equal rights and obligations in marriage and family. Family, childhood, motherhood, and parenthood are protected by the state.

The primary legislative act related to protecting health and the delivery of medical care is the Fundamentals of Health Legislation in Ukraine.[6] Section VII addresses maternal and child health, and Article 57 proclaims that motherhood shall be protected and encouraged by the state. This protection is ensured by a wide network of maternity, medical-genetic, and other consultations; maternity homes, sanatoria, and holiday homes for pregnant women and mothers with children; nurseries, kindergartens, and other children's institutions; leave for pregnancy and childbearing, social insurance benefits, and breastfeeding breaks at work; prohibition of hard and harmful work for women; improvement and sanitation at work and life conditions; removal of hazardous environmental factors; and state and public support to families. Article 57 also guarantees a woman's right to freely decide whether to have children, and the number, timing, and spacing of her children.

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[5] The Constitution of Ukraine was enacted by the Parliament *(Verkhovna Rada)* on June 28, 1996.

[6] Approved by Parliament on November 19, 1992.

Article 58 of the Fundamentals of Health Legislation proclaims that public health care institutions will offer services to monitor pregnancy, provide hospital care during childbirth, and provide care to newborns and their mothers.

B. National Family Planning Program

The Cabinet of Ministers approved the National Family Planning Program[7] (NFPP) in 1995, enacted through 2000, in hopes that the government of the Autonomous Republic of Crimea, Kyiv, and Sevastopol administrations would develop similar programs for their regions by January 1996. The NFPP states that every year when developing budgets, funds for regional programs and for NFPP measures will be allocated depending on available resources.

The purpose of the national program is to provide health services for both parents and children, provide appropriate contraceptives, and assist with childbearing and birth spacing. Its main tasks are to

- form government bodies to deal with FP issues;
- study medical and social hygienic FP problems and introduce results into practice;
- implement research results in the RH and planning of modern families;
- monitor development of the FP process;
- train medical and pedagogical staff to work in the FP field;
- establish a national provider training system in FP centers;
- meet the population's needs for contraceptive methods;
- create a mechanism for treatment of infertility;
- reduce the number of undesired and high-risk pregnancies;
- promote modern relations between men and women in family life and childbearing;
- improve the demographic culture of the population,[8] in particular FP culture;
- improve familiarization with modern methods of FP and RH;
- familiarize the population with modern reproductive behavior and contraceptive issues through the creation of an information system. Involve mass media to cover FP and sexual culture problems, marriage counseling, and the preparation of children, adolescents, and youth for family life; and
- ensure quality of information and education in the FP field.

To achieve these goals, the government plans to

- form a network of FP centers and counseling rooms at the national and regional levels;
- develop training programs for minors, students, health care providers, and teachers;
- organize domestic production of barrier methods and increase production of condoms;
- purchase pharmaceutical contraceptives produced by leading foreign companies;
- provide free contraceptives through FP centers to adolescents, to women for whom pregnancy may pose health problems, and to women who are victims of the Chernobyl accident; and
- promote a healthy way of life, including modern FP methods, through FP centers.

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[7] Cabinet of Ministers Resolution #736, September 13, 1995.

[8] The concept of demographic culture comes from the National Family Planning Program. The author's interpretation of demographic culture implies world outlook, traditions, and behavioral stereotypes of the nation regarding reproduction, not only of an individual or a family taken separately, but preservation and recovery of the nation, of the work force potential, etc.

National Family Planning Program Financing in National and Local Budgets, 1996-1998
(preliminary data from the Ministry of Finance)
In Millions of Hryvnyas

Years	State Budget		Local Budgets	
	Plan	Actual Data	Plan	Actual Data
1996	1.7	-	2.5	1.5
1997	1.7	-	3.5	1.5
1998	1.2	0.23	N/A	N/A

C. Legislation and Accessibility of Modern Contraceptive Methods

1. Legal Methods

As mentioned above, Article 57 of the Fundamentals of Health Care grants women the right to freely decide if and when to have children. There is no legislation in Ukraine that limits the use of certain kinds of contraceptives. In principle, every modern method of contraception—including pills, IUDs, injectables, barrier methods, and sterilization—is accessible.

According to Article 49, a person can choose sterilization by voluntary agreement and can have the procedure performed in an accredited medical institution if he or she meets the medical criteria established by the MOH. A 1994 ministerial order[9] lists approved medical indications and a procedure for voluntary surgical sterilization of women and men.

2. Registration of Contraceptives

Although all modern methods of contraception are legal in Ukraine, they are only available after appropriate registration. Registration is required for both pharmaceuticals (pills, injectables, foams, jellies, sponges, etc.) and barrier methods (IUDs, condoms, diaphragms, etc.).

Article 9 of the Law of Ukraine on Pharmaceuticals[10] states that pharmaceuticals must be registered in conformity with procedures outlined in a 1998 Cabinet of Ministers resolution.[11] The MOH Pharmaceuticals Registration Bureau registers the product based on an application submitted by the manufacturer or organization licensed to produce the pharmaceutical. The application includes information on the manufacturer, the name of the pharmaceutical (including its trade name), the names of active ingredients and their synonyms, the form of production, the complete composition of the pharmaceutical, indications and contraindications, dosage, conditions of production, methods of administration, terms and conditions of storage, information on packaging, and data concerning

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[9] Ministry of Health Order #121, Use of Methods for Sterilization of Individuals, July 6, 1994.

[10] Approved by Parliament on April 4, 1996.

[11] Cabinet of Ministers Resolution #569, Procedure of Registration (Re-Registration) of a Pharmaceutical and Fee Rates for State Registration (Re-Registration) of a Pharmaceutical, April 27, 1998.

registration of the pharmaceutical in other countries. Materials on preclinical study, clinical tests, an article or documents relating to pharmaceutical quality control methods, draft technological rules or information on production technology, samples of the pharmaceutical, its packaging, and a document confirming payment of the registration fee are attached to the application.

The bureau considers materials submitted by an applicant within one month. However, the one-month period does not include time for carrying out a specialized assessment or additional examination of materials on the preclinical study or clinical trials, if deemed necessary. The Pharmacological and Pharmacopoeia Committees of the MOH conduct a specialized assessment of materials after payment of a fee determined by the MOH. If necessary, materials concerning registration or re-registration of a pharmaceutical can be referred for an additional examination, and the pharmaceutical itself can be sent for additional clinical trials. Payment for these procedures is made in advance according to the terms agreed upon by the applicant and the examining body or specialized medical institution where clinical trials are carried out.

The Pharmacological and Pharmacopoeia Committees submit their conclusions and recommendations to the bureau, which decides whether or not to register the pharmaceutical. In the event of an affirmative decision, the pharmaceutical is included in the State Register of Pharmaceuticals of Ukraine. The bureau then awards the applicant a registration certificate, which allows the pharmaceutical to be used in Ukraine for the period of five years, after which it must be re-registered. Currently, the re-registration procedure is identical to the original registration procedure.

The maximum registraton fee for any pharmaceutical is 1,000 euros (approximately US$1,000) for each therapeutic form and 100 euros (approximately US$100) for every subsequent dosage and packaging of the pharmaceutical. The re-registration fee is smaller and depends on re-registration conditions. As of March 1999, 19 contraceptive methods, mostly oral contraceptives, were registered as medicinal agents (see Appendix 2).

IUDs, condoms, and other barrier methods must also be registered, according to the procedure outlined by regulations in a ministerial order.[12] The Ministry of Health New Medical Technologies Committee (NMTC) is responsible for registration. Every domestic and foreign technology approved for use in medical practice by the Nomenclature of Products for Medical Purposes is included in the State Registry. The Nomenclature, itself, is an annex to the Regulation on the State Registry of Products for Medical Purposes. The Nomenclature, inter alia, includes hygienic and pharmaceutical rubber articles[13] and contraceptives.[14]

The NMTC conducts an examination of each application to determine

- the product's properties and any adverse effects for human beings or the environment;
- the necessity of carrying out medical, biological, and technical trials; and
- the scope of the trials and the number samples necessary to carry them out.

As a rule, technical trials are not carried out when an internationally acknowledged certificate already exists for the product. Biological and medical trials are conducted in almost every case. The

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[12] Ministerial Order #74, Regulation on the State Registry of Products of Medical Technologies in Ukraine and the Regulation on the Procedure of Registration of Products of Medical Technologies in Ukraine, April 26, 1995.

[13] Code 4014 of the Nomenclature of Products for Medical Purposes.

[14] Code 401410000 of the Nomenclature of Products for Medical Purposes.

decision to register the product depends on approval of the application and required test results. A registration certificate is issued to the applicant as the sole document authorizing use of the product in Ukraine. The registration fee for barrier contraceptives, like the fee for any other health care product, is US$500. Analysis of available price information suggests that an assortment of condoms from at least nine different firms is on sale in Ukraine.[15]

3. Customs, Tax, Licensing, and Price Policy of Pharmaceuticals

With the exception of condoms, there is currently no domestic production of contraceptives in Ukraine. Article 7 of the Law on Pharmaceuticals permits the import of pharmaceuticals registered in Ukraine if the producer presents a certificate of quality. Pharmaceutical quality is controlled by the State Inspection on Pharmaceutical Quality Unit within the MOH, while the State Customs Service of Ukraine determines the legality of imports.

According to a 1997 ministerial order,[16] unregistered pharmaceuticals cannot be sold, but may be brought into the customs' territory of Ukraine for

- preclinical or clinical trials;
- registration in Ukraine;
- demonstration at shows, fairs, conferences, etc.;
- an individual's personal use;
- use in case of natural disaster, catastrophe, or epidemic, provided an appropriate MOH resolution and documents confirming the product's registration in its country of origin are available.

Pharmaceuticals are listed as goods subject to licensing, which are reviewed by the MOH on an annual basis. The Cabinet of Ministers approved the 1999 list in January.[17]

In accordance with the Single Customs Tariffs of Ukraine,[18] all pharmaceutical products[19] (including contraceptives) imported to Ukraine are exempt from entrance duty. Condoms[20] are an exception to full customs tariffs and are subject to a preferential rate of 5–10 percent of their declared customs value.

According to Article 5 of the Law on Value-Added Tax,[21] pharmaceuticals and medicinal goods registered in Ukraine are exempt from value-added tax (VAT). Subsection 5.1.8 exempts health care services delivered by licensed health care institutions. A Cabinet of Ministers resolution confirms that RH care services are no exception and are also exempt from the VAT.[22]

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[15] *Apteka* weekly.

[16] Ministerial Order #143, Procedure of Importing Unregistered Pharmaceuticals to Ukraine, May 15, 1997.

[17] Cabinet of Ministers Resolution #15, List of Goods, Imports, and Exports Subject to Quotas and Licensing Procedures in 1999, January 4, 1999.

[18] Decree of the Cabinet of Ministers #4-93, Single Customs Tariffs of Ukraine, January 11, 1993.

[19] Group 30 of the Harmonized System of Commodities Description and Code.

[20] Group 40 Hygienic Hard Rubber Products of the Harmonized System of Commodities Description and Code.

[21] The Law on Value-Added Tax , April 3, 1997.

[22] Cabinet of Ministers Resolution #1602, October 5, 1998.

According to a Joint Order of the Ministry of Health and Ministry of Economics,[23] no contraceptive method, neither pharmaceutical nor barrier, is on the list of domestic and imported pharmaceutical and medicinal products subject to government price controls.

4. Pharmaceutical Advertising

According to Article 26, Part 3 of the Law on Pharmaceuticals, the Law on Advertising governs the advertising of pharmaceuticals. Article 20, Part 2 prohibits advertising medicinal agents that are available only by doctor's prescription or that contain narcotic or controlled substances. According to a ministerial order,[24] all pharmaceutical contraceptives are available from pharmacies only with an Ob-Gyn's prescription. Therefore, advertising pharmaceutical contraceptives to the general public is prohibited, although recommending these and other drugs to medical and pharmaceutical workers is legal.

In addition to the Law on Pharmaceuticals and the Law on Advertising, a 1997 ministerial order pertaining to children and adolescents[25] also bars public advertising of prescription-only pharmaceuticals. This limitation unquestionably hinders public awareness of hormonal contraceptives. There are no limits, however, to advertising condoms and other barrier methods of contraception under Ukrainian law.

In accordance with Article 19 of the Law on Pharmaceuticals and the Rules of Retail Pharmaceutical Sales,[26] businesses and individuals can sell pharmaceuticals with a special permit. Those who have appropriate training and meet certain qualification requirements, such as individuals who have pursued a pharmaceutical degree at a foreign university, are eligible to sell registered pharmaceuticals at the retail level. The permit costs 35 Hryvnyas (approximately US$9) for individuals and 200 Hryvnyas (approximately US$50) for businesses. The permit must be issued within 30 days.[27]

5. Obstacles to Contraceptive Access

Article 49 of the Constitution of Ukraine envisages that the state will create conditions for efficient and accessible medical care for all citizens and that medical services shall be free in state and communal health care institutions. These measures also pertain to gynecological, obstetric, and FP services.

The only obstacle adults encounter to using pharmaceutical and other contraceptive methods in Ukraine is obtaining a prescription from an Ob-Gyn. This does not hold true, however, for sexually active adolescents who need contraception to prevent unwanted pregnancies. Without parental consent, their access is limited to over-the-counter methods, such as condoms.

Oral contraceptives may be regarded as a medical intervention. According to Article 43 of the Fundamentals of Health Legislation, medical intervention requires informed consent of the patient. If a patient is under the age of 15 or has been found incompetent by the court, medical intervention is

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[23] Joint Order of Ministry of Health and Ministry of Economics of Ukraine #265/101, August 1, 1997.

[24] Ministerial Order #233, Lists of Pharmaceuticals Registered in Ukraine, July 25, 1997.

[25] Ministry of Health Order #177, Procedure of Coordination of Information to be Included in Advertisements for Children and Adolescents, and Issuing Permits on Advertising Pharmaceuticals for Children and Adolescents.

[26] Cabinet of Ministers Resolution #447, May, 12 1997.

[27] Cabinet of Ministers Resolution #1020, Procedure of Licensing Entrepreneurial Activities, July 3, 1998.

impossible without the consent of a parent or legal guardian. Medical interventions for minors (those aged 15 to 18) or those found partially competent, require their consent and that of their parents or guardians. Therefore, persons under 18 can only use oral contraceptives with the consent of their parents or legal guardians.

Contraception is also less accessible to women who live in rural areas. For instance, to insert an IUD, a woman from a rural area without a gynecologist has to travel to a clinic where such a specialist is available. Primary health care workers—paramedics and midwives—cannot legally perform the procedure. Women may also have to travel to obtain a prescription for pharmaceutical contraceptives.

D. Abortion

According to Article 50 of the Fundamentals of Health Legislation, an operation that artificially interrupts a pregnancy—a vacuum aspiration, a "miniabortion," or a suction curretage abortion—can be carried out according to a woman's wish at an accredited health institution when gestation does not exceed 12 weeks. MOH regulations require that abortions be performed only at an accredited in-patient facility by an obstetrician-gynecologist, under mandatory anesthesia.[28]

Between the 12th and 28th week of pregnancy, an abortion can be carried out in certain cases described in a Cabinet of Ministers resolution.[29] These cases are based on medical indications (a number of severe infections, somatic and mental conditions accompanying the pregnancy) and social grounds (three or more children, divorce at the time of pregnancy, husband's death during pregnancy, pregnancy resulting from rape, confined spouse, annulment of parental rights; having a disabled child; or severe disease or injury of husband that rendered him disabled at the time of his wife's pregnancy). Abortion between the 12th and 28th week of pregnancy may also be carried out when the aforementioned conditions are absent but when childbearing or the continuation of a pregnancy threatens the woman's health or life.

For those under 18 years of age, an abortion can be performed with the consent of the parents or guardian. In special cases, such as in urgent cases that threaten a patient's life, consent is not required.

Ukrainian law assigns criminal responsibility for illegal abortion, which is an abortion that does not meet the aforementioned requirements.[30] An abortion carried out by a physician is deemed illegal if

- there are medical contraindications to abortion, irrespective of the gestation term;
- the abortion is performed outside of an accredited health care facility;
- the abortion is carried out without filling out special documents;
- the abortion is carried out using unauthorized or banned means;
- the abortion is performed between the 12th and 28th weeks of pregnancy, but the social or medical criteria have not been met;
- the abortion is performed after the 28th week, unless it is due to an extreme need.

Penalty for committing the above actions includes corrections work of up to two years or payment of a fine equal to 100-120 percent of minimum wages. Article 109 of the Criminal Code also punishes illegal abortions performed by a person without a special medical background (imprisonment

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[28] Ministerial Order #111, Regulations on Artificial Interruption of Early Pregnancy by Vacuum Aspiration, June 28, 1994.

[29] Cabinet of Ministers Resolution #926, November 12, 1993.

[30] Article 109 of the Criminal Code "Carrying Out an Illegal Abortion."

and/or corrections work for one to two years) and for an illegal abortion that resulted in long-term disability or death (imprisonment for up to six years).

E. Obstetric/Gynecological Care and Family Planning Services

In Ukraine, persons with special qualifications and medical training as Ob-Gyns, midwives, or paramedics offer obstetric and gynecological care and FP services. A 1993 ministerial order[31] stipulates that an Ob-Gyn specialist must know how to use modern contraceptive methods and must carry out educational work to increase knowledge on preventing unwanted pregnancy. A gynecologist specializing in the treatment of children must work to educate parents and teenagers. The qualifications fail to describe the specific skills necessary to prevent unwanted pregnancy using modern contraceptive methods.

Qualifications for paraprofessionals whose work includes obstetric and gynecologic services are listed in an annex to the Ministerial Order on Attestation of Paramedics[32] addressing paramedics and midwives (ambulance paramedic, paramedic, hospital midwife, women's consultation center midwife). Only midwives working in women's consultation centers are required to have specific FP/RH knowledge, specifically of modern contraceptive methods, prevention of unplanned pregnancy, and HIV/AIDS prevention.

Ukraine has a vast network of state-owned and community-owned medical facilities, which can offer obstetric, gynecological, and FP services. According to official government statistics, in 1997, state-owned and community-owned health care sectors included

- 2,006 women's consultation centers or outpatient centers with women's consultation facilities;
- 16,574 paramedic stations in rural areas;
- 14,345 maternity houses;
- 12,989 Ob-Gyns (4.8 per 10,000 women); and
- 31,731 midwives (11.8 per 10,000 women).

Private practice is legal with a license. As of March 25, 1999, 976 licenses for private practice gynecology have been issued by the MOH. Of these, 187 licenses belong to individuals and 789 to group practices. There are limits to private gynecological practice. In particular, licensed Ob-Gyns are not permitted to provide follow-up care for pregnant women, treat complications during pregnancy, or perform surgical interventions, including abortions. These procedures must be performed at accredited state-owned and community-owned medical institutions. The rules for issuing licenses for private medical practice, like licenses for the retail sale of pharmaceuticals, are regulated by a Cabinet of Ministers resolution[33] and the corresponding Guidance of the Ministry of Health and Ministry of Economics License Chamber.[34]

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[31] Ministerial Order #208, Provisional Qualification Characteristics of Specialists Who Are Physicians, September 20, 1993.

[32] Ministerial Order #146, Attestation of Paramedics, October 23, 1991.

[33] Cabinet of Ministers Resolution #1020 on Licensing Entrepreneurial Activities, July 3, 1998.

[34] Joint Order #LP-6/60 of the License Chamber attached to the Ministry of Economics and the Ministry of Health, Procedure of Issuing Special Permits (Licenses) to the Subjects of Entrepreneurial Activities to Practice Medicine, Physical, Psychiatric and Forensic Examination; Conditions and Rules of Such Activities and Oversight of Compliance Therewith, March 22, 1996 (enacted May 3).

The Cabinet of Ministers regulates the rules of state accreditation for health care facilities.[35] All health care facilities, public or private, are subject to accreditation on a triennial basis. Ministerial Order #2 of January 12, 1998, contains the standards of accreditation for primary health care facilities and units.

The role of NGOs in health care on the whole, and in FP services in particular, has been insignificant so far. NGOs operate according to their statutes of association, the Law on Associations of Citizens, and the Law on Charity and Charitable Organizations. The Law on Charity mentions assistance in health care development, participation in health care delivery, promotion of maternal and child health, and social care of patients.

The Red Cross Society of Ukraine is the largest and the most influential NGO in the health care field with about 5.3 million members, about 70 percent of whom are women. Currently, a new, long-term humanitarian program is being initiated through which the Ukrainian Red Cross, with aid from the International Red Cross and Red Crescent, will be conducting a number of activities to combat tuberculosis, STDs, and HIV/AIDS. Specifically, the Red Cross will be focusing its efforts on educating the community to prevent HIV/AIDS and STDs and will be assisting the government in providing the most vulnerable population groups with means of prevention, including condoms. Short-term activities will last three years, and long-term activities will last 10-15 years.

Although no law precludes the Ukrainian Red Cross from owning hospitals, outpatient facilities, or pharmacies, the organization currently does not own any due to its dire economic condition. The Parliamentary Committee on Health Care, Motherhood, and Childhood is working jointly with the National Red Cross Committee of Ukraine on a draft law that would allow on the Red Cross of Ukraine to set up hospitals, pharmacies, shelters, and canteens for the poor.

F. STD, HIV, and AIDS Prevention

In accordance with the rules governing private medical practice,[36] only specialized state-owned and community-owned health care facilities can treat STDs, including AIDS. There have been attempts to change this rule and allow all forms of health care institutions to treat infectious diseases.

Parliament enacted the Law on AIDS Prevention on March 3, 1998.[37] On February 12, 1999, Parliament read the draft bill on the protection of the population against infectious diseases, which contains norms on health care for patients with STDs.[38] Article 4 of the Law on AIDS Prevention declares that the government will

- guarantee the accessibility, quality, and effectiveness of medical examinations for HIV (including anonymous testing) and provide consultations;
- provide regular and comprehensive information to the public, via mass media, on the causes of HIV infection and preventive measures to avoid infection and to limit its spread;

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[35] Cabinet of Ministers Resolution #765, The Procedure of State Accreditation of Health Care Facilities, July 15, 1997.

[36] Joint Order #LP-6/60.

[37] Law on the Acquired Immune Deficiency Syndrome (AIDS) Prevention and Social Protection of Population, March 3, 1998.

[38] Reading a bill is one of the many stages a bill must pass through before it is signed into law. At this point, the bill may be introduced to the Parliament's agenda and discussion of its merits begins.

- introduce special topics on HIV/AIDS prevention in the curricula of educational institutions;
- provide access to methods to prevent against HIV/AIDS transmission through sexual intercourse;
- promote safe sexual behavior; and
- promote charity aimed at HIV/AIDS prevention.

Article 12 reads that health care is provided to patients with AIDS without discrimination according to the procedure established by the law and corresponding international treaties of Ukraine.

Recently, the Cabinet of Ministers passed two important orders on the issues of STDs and AIDS: Cabinet of Ministers Resolution #357 on Comprehensive Measures to Prevent Sexually Transmitted Diseases of March 23, 1998, and Cabinet of Ministers Resolution #341 on The Program of AIDS and Pharmaceutical Addiction Prevention for the Years 1999–2000. These orders include measures for information and professional training for specialists and various segments of the public to produce and supply methods to prevent unwanted pregnancy, STDs, and HIV/AIDS, and to improve the quality and accessibility of medical services.

G. Information and Education in Family Planning and Reproductive Health

A number of Ukrainian legislative and normative acts address the need to inform and educate various segments of the public on FP and RH issues. Article 32 of the Fundamentals of Health Legislation mandates that the government promote healthy living by disseminating scientific knowledge on health care, organizing medical, environmental, and physical training, and improving the public's knowledge of health matters.

The Law on the Prevention of AIDS outlines a number of steps to disseminate RH information. Also, the NFPP includes a number of informational and educational activities, but in practice, the educational measures are not widely implemented because of a lack of funding.

Reproductive health and FP issues are included in the mandatory human biology course that is taught in the eighth and ninth grades of general education schools. They have not, however, been introduced as special subjects in the curricula of secondary and higher educational institutions. In 1996, the Ministry of Education developed informative and comprehensive courses on the fundamentals of valeology[39] for secondary schools, lyceums, and gymnasia (special comprehensive schools). The course begins in the sixth grade (children aged 11–12) and addresses a number of issues related to RH, STD and AIDS prevention, FP, and contraception. Because the course is an optional component of the general curriculum of secondary schools, the pedagogical council and directorate of each school decide whether or not to introduce it.

H. Reproductive Health, Labor, and Environmental Protection

Current unfavorable occupational and environmental factors have had an impact on health in general and on RH in particular. Ukrainian legislation pays significant attention to mitigating this impact.

Ukraine's Code of Laws on Labor prohibits those younger than 18, pregnant women, and women who have children younger than three years old from working at night or working overtime (Articles 55,

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[39] Special health education course offered as part of a pilot project.

63 and 175). Article 56 of the code permits pregnant women to excuse themselves from a complete working day or week. A separate chapter, Women's Labor, limits women's work at night (Article 175); prohibits business trips for pregnant women (Article 176); transfers pregnant women to easier work (Article 178); provides leave for pregnancy, childbirth, and care (Article 179); provides breaks for breastfeeding (Article 183); and prevents pregnant women from being discharged from work (Article 184).

The Parliament enacted the Law on Labor Protection in 1992, which prohibits work under unsafe and hazardous conditions or underground, or work requiring women to lift and move heavy items. The MOH has issued two related orders,[40] and the Cabinet of Ministers has approved another.[41]

Environmental legislation, and especially the Law on Environmental Protection enacted in 1991, establishes a new system of environmental health (ambient air standards, maximum permissible concentrations of hazardous substances in water and soil; maximum permissible levels of acoustic, electromagnetic, and other hazardous environmental effects, maximum permissible concentrations of noxious substances in food). There is also a system of occupational health and safety standards, which comprises maximum permissible concentrations of hazardous substances indoors and in the workplace, and maximum permissible levels of other noxious factors at work.

When setting up environmental and industrial safety standards, it is necessary to research the agent's effect on the reproductive function of laboratory animals, with extrapolation of the results to human beings in order to protect human RH. Such research is regulated by special guides approved by the MOH of the former Soviet Union, to which Ukraine is a successor state.

Taking into account the body of research that shows a trend of reproductive loss[42] and a rise in genetic burden,[43] and the increased role heredity plays in infertility, spontaneous abortions, and birth defects, the Target Comprehensive Program of Genetic Monitoring in Ukraine for the Years 1999–2003 was approved by presidential decree. The implementation of this decree will fulfill Article 16 of the Constitution of Ukraine to provide a safe environment and overcome the aftermath of the Chernobyl disaster.

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[40] Order #256, List of Rough Labor and Work under Unsafe and Hazardous Condition of Work where Women's Labor Is Prohibited, December 29, 1993 and Order #241, Marginal Norms for Lifting and Moving Heavy Things by Women, December 22, 1993.

[41] Order #381, Program of Releasing Women from Work Connected with Rough Labor and Hazardous Conditions as well as Limitation of Their Work at Night for the Years 1996–1998.

[42] Reproductive loss should be understood as birth rate reduction and increased mortality. These are losses incurred by the community in the course of population recovery due to the aforementioned processes.

[43] Genetic burden is understood as an increased rate of hereditary diseases.

CONCLUSIONS

The legal and regulatory framework for FP and RH in Ukraine is favorable on the whole. Law guarantees equal rights for men and women and women's rights to decide if and when to bear children. Laws and regulations seek to provide accessible health care, including Ob-Gyn and FP services. There are no major legal hurdles to using any method of contraception, and laws concerning abortion describe the circumstances for safe, legal abortions, holding physicians criminally liable for illegal abortions. Labor, occupational safety, and environmental laws reduce the incidence of detrimental occupational and environmental factors on RH in addition to protecting the fetus. In principle, customs and tax policies on pharmaceuticals and medical goods establish no barriers to accessing contraceptives.

Though the legal and regulatory framework is favorable, implementation of FP and RH measures is not always effective. As a result of Ukraine's current financial and economic crisis, FP and RH programs are not adequately financed. Moreover, additional changes to the legal and regulatory framework would be beneficial.

The procedure for registering pharmaceuticals and medical goods is rather complex and needs to be streamlined. Obviously, experts' suggestions for a trade licensing system to replace the pharmaceutical registration system deserve attention. This will bring legal requirements closer to those of the European Union. The repeat registration procedure for pharmaceuticals also needs to be streamlined, since current requirements are the same as the initial registration requirements.

Service provider training programs fulfill the requirement for information dissemination by teaching medical students and other health care providers about various services. Students learn about up-to-date, modern contraceptive methods and how to provide counseling on their use. There is still a need, however, to update and thoroughly define the qualifications for specialists in the obstetrics, gynecology, and FP fields and to give more opportunities to paramedics and midwives to provide FP services. Such a decision has yet to be approved by the appropriate authorities within the MOH. The clauses requiring a prescription from an Ob-Gyn to purchase oral contraceptives and limiting the advertising of modern contraceptive methods also need to be analyzed and revised.

Both service providers and the public would benefit from further implementation of the educational and informational components of government RH policies as well. These components could be further implemented by promoting appropriate educational programs in secondary schools and by updating programs at training institutions for physicians, midwives, and educational workers. Educational FP/RH programs should be introduced earlier in secondary schools by making the optional valeology course a mandatory part of the curriculum earlier in the course of studies. The valeology course provides more detailed information for youth on issues of public and individual health in general, and on FP/RH issues in particular.

NGOs and charitable organizations play an important role in informing the public about FP/RH issues and in providing the most vulnerable groups with contraceptives and RH services. This role should be strengthened and the organizations' effectiveness enhanced. FP/RH should be a top priority for investment, and these organizations must be encouraged to devote their attention to FP/RH issues over other public health issues.

It is imperative that the government provide immediate and adequate funding in the budget for the NFPP. The government also needs to attract Ukrainian, foreign, and international investments from charitable and humanitarian organizations. Appropriate laws must also be passed to create a favorable

climate for such investments. In addition, recipients must be held accountable for their use of the limited resources allocated by national and local governments for FP programs.

A comprehensive approach is most helpful when considering all the factors that inhibit the abilities of NGOs and private organizations to provide quality products and services to FP clients in Ukraine. The government must ensure effective compliance with the national RH legislation, specifically with respect to protection of women's labor and health care delivery.

Obstacles outside of the regulatory framework that prevent effective implementation of FP/RH policies must also be addressed. Such obstacles include local traditions, possible misinterpretation of the national law at the local level; cultural and religious norms; inadequate information, education and professional training for service providers; and imperfect standards regulating their activities.

Addressing the aforementioned recommendations would be helpful in the development of the program that will succeed the current National Family Planning Program, which expires in 2000.

APPENDIX 1

List of Legislative and Regulatory Acts on Family Planning and Reproductive Health in Ukraine

1. The Constitution of Ukraine, adopted by Parliament June 28, 1996.

2. Fundamentals of Health Legislation in Ukraine, November 19, 1992.

3. Cabinet of Ministers Resolution #736, The National Family Planning Program, September 13, 1995.

4. Ministerial Order #121, Application of Methods for Sterilization of Individuals, July 6, 1994.

5. The Law on Pharmaceuticals, April 4, 1996.

6. Cabinet of Ministers Resolution #569, Procedure of Registration (Re-Registration) of a Pharmaceutical and Fee Rates for State Registration (Re-Registration) of a Pharmaceutical, April 27, 1998.

7. Ministerial Order #74, Regulation on the State Registry of Products of Medical Technologies in Ukraine and the Regulation on the Procedure of Registration of Products of Medical Technologies in Ukraine, April 26, 1995.

8. Ministerial Order #143, Procedure of Importing Unregistered Pharmaceuticals to Ukraine, May 15, 1997.

9. Cabinet of Ministers Resolution #15, List of Goods, Imports and Exports which is Subject to Quotas and Licensing Procedures in 1999, January 4, 1999.

10. Decree of the Cabinet of Ministers #4-93, Single Customs Tariffs of Ukraine, January 11, 1993.

11. The Law of Ukraine on Value-Added Tax, April 3, 1997.

12. Cabinet of Ministers Resolution #*1605*, Health Care Services Provision thereof by Health Care Facilities is Exempt from Value-Added Tax, October 5, 1998.

13. Joint Order of Ministry of Health and Ministry of Economics #265/101, List of Pharmaceuticals the Price thereof is Controlled by the Government, August 1, 1997.

14. The Law on Advertising, July 4, 1996.

15. Ministerial Order #233, Lists of Pharmaceuticals Registered in Ukraine, July 25, 1997.

16. Ministerial Order #177, Regulations on Pharmaceuticals Advertising, June 10, 1997.

17. Cabinet of Ministers Resolution #447, Ordering Work of Pharmaceutical Facilities and Approval of Rules of Retail Sale of Pharmaceuticals, May 12, 1997.

18. Cabinet of Ministers Resolution #1020, Procedure of Licensing Entrepreneurial Activities, July 3, 1998.

19. The Code on Marriage and Family in Ukraine, with numerous amendments, June 20, 1968.

20. Ministerial Order #111, Regulations on Artificial Interruption of Early Pregnancy by Vacuum Aspiration, June 28, 1994.

21. Cabinet of Ministers Resolution #926, Procedure of Artificial Interruption of Pregnancy of 12 to 28 Weeks, May 1997.

22. The Criminal Code of Ukraine, December 28, 1960; key amendments dated January 12, 1983, and February 8, 1995.

23. Ministerial Order #208, Provisional Qualification Characteristics of Specialists Who Are Physicians, September 20, 1993.

24. Ministerial Order #146 Attestation of Paramedics, October 23, 1991.

25. Joint Order #LP-6/60 of the License Chamber attached to the Ministry of Economics and the Ministry of Health, Procedure of Issuing Special Permits (Licenses) to the Subjects of Entrepreneurial Activities to Practice Medicine, Physical, Psychiatric and Forensic Examination; Conditions and Rules of Such Activities and Oversight of Compliance Therewith,'' March 22, 1996.

26. Cabinet of Ministers Resolution #765, Procedure of State Accreditation of a Health Care Facility, July 15, 1997.

27. Ministerial Order #2, Standards for Accreditation of Health Care Facilities in Ukraine, January 12, 1998.

28. The Law on Charity and Charitable Organizations, September 16, 1997.

29. The Law on Acquired Immune Deficiency Syndrome (AIDS) Prevention and Social Protection of the Population, March 3, 1998.

30. Draft Law on Protection of Population from Infectious Diseases, October 19, 1998.

31. Cabinet of Ministers Resolution #357, Comprehensive Measures to Prevent Sexually Transmitted Diseases of March 23, 1998.

32. Cabinet of Ministers Resolution #341, Program of AIDS and Pharmaceutical Addiction Prevention for the Years 1999 - 2000.

33. The Code of Laws on Labor, December 10, 1971.

34. The Law on Labor Protection.

35. Ministerial Order #241 Marginal Norms for Lifting and Moving Heavy Things by Women, December 22, 1993.

36. Ministerial Order #256, List of Rough Labor and Work Under Unsafe and Hazardous Condition of Work Where Women's Labor Is Prohibited, December 29, 1993.

37. Cabinet of Ministers Resolution #381, Program of Releasing Women from Work Connected with Rough Labor and Hazardous Conditions as well as Limitation of Their Work at Night for the Years 1996-1998, March 27, 1996.

38. Presidential Decree on Target Comprehensive Program of Genetic Monitoring In Ukraine for the Years 1999-2003.

APPENDIX 2

Contraceptive Methods Registered in Ukraine

(as of March 1, 1999 according to Liky Ukrainy State Association)

NAME AND FORM	MANUFACTURER
Anteovine pills #21, #21x3	Chemical Works of Richter Gedeon Ltd, Hungary
Vilonet, dragee #61, #63	Leipziger Arzneimittelwerk GmbH of Wyeth Group Concern, Germany
Depo-Provera 150 water suspension for injections in 1 ml vials	Pharmacea and Upjohn, USA
Diane-35 pills, #21	Shering AG, Germany
Marvelon, pills #21	N.V. Organon, the Netherlands
Minizistron dragee #21	Jenapharm GmbH, Germany
Mirena #1	Leiras Oy, Finland
Non-Ovlon, dragee #21	Leiras Oy, Finland
Ovidon-Richter, pills #21	Chemical Works of Richter Gedeon Ltd, Hungary
Postinor pills, #4	Chemical Works of Richter Gedeon Ltd., Hungary
Regulon, pills #21, #21 x 3	Chemical Works of Richter Gedeon Ltd., Hungary
Rigevidon, pills, #21	Chemical Works of Richter Gedeon Ltd., Hungary
Cilest, pills, #21, #63	Cilag, Switzerland
Tri-regol, pills, #21x3	Chemical Works of Richter Gedeon Ltd., Hungary
Trisiston, dragee #21	Jenapharm GbmH, Germany
Triquilar, dragee, #21, #6, #5, #10	Shering AG, Germany
Trinovum, dragee, #21, #63 (21x3)	Janssen-Cilag, Belgium, Switzerland
Pharmatex sachets 18.9 mg #10 pills 20 mg #12, creme 72 g, sponge #2	Innotex, France
Femoden, dragee, #21	Shering AG, Germany