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PROJECT PERFORMED FOR
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**Deloitte &
Touche**



Deloitte Touche Tohmatsu International

In association with

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**MARKETING ASSESSMENT FOR
THE SALE OF
CONTRACEPTIVES IN THE
PRIVATE SECTOR
ROMANIA**

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Prepared for:
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EXECUTIVE SUMMARY

The Romanian Reproductive Health Survey, conducted in 1993, revealed that despite high awareness of modern contraceptives among women in union (98%), contraceptive usage is dominated by traditional methods (43%) while use of modern methods remains relatively low at only 14.5%¹. Moreover four out of five traditional method users did not plan to change their current method. The heavy reliance on traditional methods is attributed to several factors. The most frequently mentioned are fear of side effects, partner preference, and lack of information. In addition, accessibility and cost were cited by one third of traditional method users as an important reason for not using modern contraceptives.² Even when it was illegal abortion was used for fertility control, and as a back-up to traditional methods. In 1990, after legalization, there were 992,265 reported abortions in Romania and according to the 1993 Reproductive Health Survey in 1992, there were 2.4 abortions for every live birth.

Recognizing the limited capacity to expand use of modern contraceptives through the public and NGO sectors, USAID/Romania requested assistance from the PROFIT Project in analyzing opportunities to promote the use of modern contraceptives through the commercial sector. A two-person consulting team analyzed the commercial/trade and legal/regulatory factors impacting commercial contraceptive importation, distribution, marketing and sales, and identified those factors that adversely affect the regular availability of contraceptives in the private sector. The consulting team was also asked to recommend additional analysis and technical assistance that might alleviate any impediments identified.

Except for the Ministry's pending training requirement for physicians wanting to provide family planning services, existing regulations were not found to be a significant barrier to availability of contraceptive services or products. Moreover, the team concluded that a potential exists for a significant portion of the Romanian population to shift to use of modern contraceptives through commercial channels, if sufficient information is provided on contraceptive products to allow for freedom of choice. Commercial constraints, such as access to foreign exchange and price controls, have had an impact on product availability by limiting available stock. However, the situation has improved as progressive economic measures have been adopted. For example, importers indicated that since the spring of 1994, when Romania adopted a liberalized exchange rate regime, foreign exchange was readily available. Lack of credit and business training has kept private distributors from investing in building a national distribution network and

¹ According to the "Reproductive Health Survey, Romania 1993" this 14.5% is split between the following methods: IUD 4.2%, Condom 3.9%, Pills 3.1%, Tubal Ligation 1.4%, Others 1.9%.

² See Appendix 1, Scope of Work provided by USAID/Romania on "Reproductive Health Survey, Romania 1993" Preliminary Report, January 1994: Institute for Mother Child Care, Ministry of Health and Division for Reproductive Health, Center for Disease Control and Prevention, Atlanta, GA.

pharmacists from carrying large inventories. While not a major barrier, these deficiencies do have an impact on supply of pharmaceutical products, including contraceptives.

However, by far the greatest obstacle to modern contraceptive usage is lack of correct information. There has been a severe restriction on information on modern contraceptives in Romania for over 20 years. Since the ban on contraceptives was lifted in 1989, no large scale educational effort has been undertaken. While manufacturers, distributors and retailers indicated that usage of modern contraceptives was increasing, that process would likely be greatly accelerated by a broad based educational campaign.

Based on these findings, the team recommends the following:

1. Develop a family planning competency exam to allow those already trained to bypass the training course proposed by the Ministry of Health. This is particularly important for private physicians who are less likely to take the time necessary to complete such a training program.
2. Support the development of private distribution and retail outlets to ensure an adequate supply of contraceptives. This might include providing funding for a select number of commercial distributors and their customers (pharmacies) to offer credit terms for the purchase and promotion of reproductive health products.
3. Offer business training to newly privatized pharmacies to improve inventory management and ordering systems. Business training could be offered either through the College of Pharmacy or the Pharmacists' Association, or as part of a larger training program for pharmacists in modern contraception that will be offered as part of the IEC campaign. The project would include the training of trainers (TOT) and the training of approximately 2,000 pharmacists and/or pharmacists assistants.
4. Conduct an educational campaign targeted directly to consumers and pharmacists. Since couples can purchase contraceptives at pharmacies without a prescription, this would be the most efficient method of increasing usage of modern contraceptives. Such a campaign would be relatively easy to implement since Romanians are well educated and the mass media is well developed.

In sum, these recommendations not only support the family planning/quality of life strategy of USAID/Romania, but also support privatization and women in development objectives since a majority of pharmacists are women.

SECTION ONE: BACKGROUND

I. Scope of Work

The Romanian Reproductive Health Survey, conducted in 1993, revealed that despite high awareness of modern contraceptives among women in union (98%), contraceptive usage is dominated by traditional methods (43%) while use of modern methods remains relatively low at only 14.5%.³ Moreover four out of five traditional method users did not plan to change their current method. The heavy reliance on traditional methods is attributed to several factors. The most frequently mentioned are fear of side effects, partner preference and lack of information. In addition, accessibility and cost were cited by one third of traditional method users as an important reason for not using modern contraceptives. Even when it was illegal abortion was used for fertility control, and as a back-up to traditional methods. In 1990, after legalization, there were 992,265 reported abortions in Romania and according to the 1993 Reproductive Health Survey in 1992, there were 2.4 abortions for every live birth.

In response to the low incidence of modern contraceptive usage and the high incidence of abortion, several donor agencies have launched reproductive health programs. By far the largest initiative is the World Bank-assisted Health Rehabilitation Project which includes a substantial family planning component. The reproductive health component of the project focuses on the provision of information, products and services through the public health system. To date the project has been slow in implementation. For example, the Family Planning Unit which has been established within the Ministry of Health (MOH) to coordinate family planning activities has yet to be fully staffed. Government procurement of contraceptives has been well below budget and none of the budgeted promotional funds have been expended.⁴ The government claims to have established 180 of the proposed 230 planned reproductive health centers; however, the Ministry of Health's Family Planning Unit was unable to provide statistics on activities for those centers in 1993.

The United States Agency for International Development (USAID) has focused its support on the provision of information and services through local family planning non-governmental

³ According to the "Reproductive Health Survey, Romania 1993" this 14.5% is split between the following methods: IUD 4.2%, Condom 3.9%, Pills 3.1%, Tubal Ligation 1.4%, Others 1.9%.

⁴ World Bank Romania Health Rehabilitation Project: Mid-Term Evaluation Report, March 1994.

organizations (NGOs). While the program has had notable success, the ability of the NGOs to reach the 5.3 million Romanian women of reproductive age is limited.⁵

Recognizing the limited capacity to expand use of modern contraceptives through the public and NGO sectors, USAID/Romania requested assistance from the PROFIT Project in analyzing opportunities to promote use of modern contraceptives through the commercial sector. Specifically, USAID requested assistance in analyzing the commercial/trade and legal/regulatory factors impacting commercial contraceptive importation, distribution, marketing and sales and identifying factors that adversely affect the regular availability of contraceptives in the private sector. The consulting team was also asked to recommend additional analysis and technical assistance that might alleviate any impediments identified. The full Scope of Work is presented in Appendix One.

II. Assessment Methodology

The assessment was completed by the PROFIT project during a two week period beginning June 27, 1994 and was staffed by Susan Mitchell, PROFIT's Marketing Director and Frank Feeley, Director of Operations, Boston University Center for International Health, a PROFIT project sub-contractor.

The team interviewed key individuals in the public and private sectors. This included the Ministry of Health, World Bank and United Nations Officials, local NGOs, representatives from pharmacist and medical associations, pharmaceutical importers and distributors, and market research and advertising companies. A full list of contacts is included as Appendix Two. In addition, the team met with USAID officials and participated in a family planning conference in Alba Iulia from June 27-29, 1994.

⁵ The largest of the two NGOs supported by USAID (S.E.C.S) has established 11 clinics serving a total of 3 - 4,000 women monthly.

SECTION TWO: FINDINGS AND RECOMMENDATIONS

The team's findings are presented in four sections that address the flow of contraceptives into the Romanian market. They include: importers/distributors, medical providers, retailers and consumers. Each section analyzes regulatory and commercial barriers and recommends strategies to increase the provision of affordable contraceptives through commercial channels.

I. Importers/Distributors

Since no contraceptives are currently manufactured in Romania⁶, the ability to import contraceptives with minimal delays is key to accessibility. With few restrictions on the establishment of private pharmaceutical importers/distributors, over 50⁷ have been established since the market opened in 1989. In addition, several of the former state pharmaceutical import/distribution companies have been, or are in the process of being privatized. Regulations pertaining to the licensing of distributors are discussed in detail in Appendix Three.

Contraceptive products are imported through the following three channels:

1. UNIFARM, the Ministry of Health parastatal, which handles the importation of products obtained through The World Bank/Ministry of Health Program;
2. NGOs import products through a system organized by the International Planned Parenthood Federation;
3. Private importers, who purchase and import product directly from the contraceptive manufacturers.

All contraceptives other than those designated for NGOs are distributed through pharmacies. While the World Bank program intended for contraceptives to be distributed to Ministry of Health Reproductive Health Centers, to date, products purchased through this program have been distributed through pharmacies.

Private importers/distributors handling contraceptive products include: Tamisa Trading, which imports and distributes Czech condoms and Hungarian pills manufactured by Gideon Richter; FARMEXIM, which imports and distributes pills and IUDs for the German pharmaceutical manufacturer, Schering; and Aectra, which imports and distributes pills, IUDS, condoms, diaphragms and spermicide for Ortho/Cilag, a subsidiary of the U.S. based Johnson and Johnson

⁶ Condoms were manufactured at one point in a plant in Timisoara. According to distributors in the Romanian market, local production has ceased.

⁷ Statistics provided by MOH as of May 1, 1993. See Appendix 8

Corporation. The team was told that Organon, the Dutch manufacturer of IUDs and pills, was no longer in the Romanian market.

All three private distributors of contraceptives indicated that product registration, the first step in importation, was a relatively simple process. This is consistent with the wide range of contraceptive products that have been registered. For example, there are currently thirteen brands of oral contraceptives registered in Romania. A detailed analysis of registration procedures, including testing procedures, is included in Appendix Four and a list of registered hormonal contraceptives is included in Appendix Five.

While it is difficult to verify exact quantities of commodities entering the Romanian market, it is estimated that in 1993, approximately 2 million cycles of pills, 100,000 IUDs and at a minimum, 1 million condoms were imported and distributed. If the donation made by Schering is excluded, the private sector (which includes imports through IPPF) provided half of all contraceptive pills entering the market, meeting a large portion of existing demand.⁸ Statistics for condoms are less readily available; however, it is estimated that the percentage of private sector participation would be similar. While several private importers carry IUDs, distribution through commercial channels has been limited. Table 1 on the following page provides a summary of estimated contraceptive imports for 1993.

⁸ According to the Reproductive Health Survey there are 5.3 million women of reproductive age. Of those women, 67.2% are married/in union, and of those women, 3.1% were pill users. Therefore contraceptive pill demand in 1993 would be estimated at 1.3 million cycles.

TABLE 1

Contraceptive Imports 1993

	Cycles of Pills	IUDs	Condoms
MOH (actual) ⁹	500,000	100,000	1,000,000
IPPF (actual)	73,000	none	3,900
Private Distributors ¹⁰ (estimated)	550,000	3,000	NA
Other ¹¹	300,000	none	none
Total	1,423,000	103,000	1,000,000+

Foreign exchange seems to have been the largest constraint faced by importers since markets were opened in 1989. Until recently (March 1994), access to sufficient foreign exchange to pay for imports was a major barrier. Importers indicated that at its worst, only 2-4% of required foreign exchange was available and it could take 3 - 6 months to obtain the foreign exchange allocation necessary to pay for imported products. However, recent economic measures, including the adoption of a liberalized exchange rate regime, have resulted in full access to foreign exchange. Importers indicated that, since March 1994, their requirements for foreign exchange were met within one week.

A key commercial constraint faced by distributors is price controls on pharmaceutical products. Price controls limit the combined wholesaler and retailer margin to between 12 - 33% over the import price of the product. These limits result in a reluctance on the part of distributors to

⁹ In 1993 the MOH ordered through the World Bank 1 million cycles of pills which were shipped in two installments: in November 1993 and January 1994; 100,000 IUDs which were shipped in two installments: July and December 1993; and 1 million condoms, shipped in September 1993.

¹⁰ The team met with the 3 major commercial pill and IUD importers who provided current estimates for sales of pills and IUDs. The quantities were discounted by 50% for the 1993 period. Since condoms are distributed both through pharmacies and cosmetic stores, a variety of companies are handling condom importation and distribution. Therefore, condom imports through commercial channels were not estimated.

¹¹ Schering made a one time donation of 400,000 units of Microgynon in 1990 of which 300,000 units were distributed in 1992/93.

make long term investments in upgrading their delivery systems or to provide credit terms to their customers. Moreover, instabilities in exchange rates have led distributors to limit inventories or withhold imported products from the market because the approved price in local currency (lei) was insufficient to replace the hard currency spent to purchase the product. They would wait until a price adjustment reflected the lower value of the lei before selling the product for local currency. However, exchange rates have stabilized recently, allowing importers and distributors to purchase larger inventories without facing the risk of currency devaluation. A detailed discussion of pricing, foreign exchange, duties and taxes is included in Appendix Six.

While no Western standard national distribution company exists combining sophisticated order processing, inventory management, transportation systems, sales and promotional activities, competition among the existing players may eventually lead to improvements in available distribution services. The team recommends that this process be assisted by providing funding to one or several of the key contraceptive distributors to upgrade distribution systems, encourage promotional efforts and increase the level of inventories maintained.

II. Medical Providers of Family Planning Services

Medical providers are typically the primary point of interface for women seeking information on family planning. However, in Romania, access to providers with knowledge of modern contraceptive practices is limited. This is the result of the policies of the Ceausescu government which prohibited the use of abortion and contraception from 1965 until 1989 when the regime was overthrown. Since a majority of health services continue to be provided through the public health system, the establishment of quality reproductive health care services within the Ministry of Health is key. The World Bank has provided a loan to the Ministry of Health to upgrade family planning services. Unfortunately, implementation of the World Bank program has lagged, leaving those seeking family planning information and services with few alternative options.

Moreover, draft standards for family planning training imply that physicians will be prohibited from providing family planning services until they have completed the Ministry of Health training program. As it currently stands, the training program will require physicians specializing in obstetrics-gynecology to undergo six weeks of training, and physicians specializing in general medicine to undergo six months of training before being permitted to provide family planning services. The Ministry of Health's draft training proposal is provided in Appendix Seven. While the standards were developed for the staff of the Ministry of Health Reproductive Health Centers, these standards are viewed as also governing the private provision of family planning services. It is therefore recommended that a competency exam be developed to allow those already trained to avoid attending the training course. This is particularly important for private physicians who can't afford to take the time necessary to complete the MOH program.

The public sector is not the only provider of family planning services. There are private medical providers offering family planning services through non-profit clinics established with the support of the international donor community. They include the Family Planning Movement (Vrancea), Marie Stopes, Medecins Sans Frontieres, and Societatea de Educatie Contraceptiva si Sexuala (S.E.C.S.). In addition, physicians are permitted to establish private practices on a for-profit basis. As of May 1993, 2,809 private medical practices had been established, of which 717 were in specialty areas including obstetrics/gynecology. Regulations pertaining to the establishment of a private practice and data on private practices are included as Appendix Eight. Discussions with the Ministry of Health indicate that the number of private practices is increasing. Nonetheless, most physicians are unwilling to leave the security of government service to venture into the private market. Those that do leave tend to take positions with pharmaceutical companies rather than take the risk of establishing a private practice. Therefore, it is unlikely that in the short-term, a wide range of family planning services will be provided through the private sector.

III. Retailers/Pharmacists

Given the limited involvement of medical providers in the delivery of family planning, retail pharmacies have emerged as the most important source of contraceptives for Romanians. According to the Reproductive Health Survey conducted in 1993, pharmacies are the source of contraceptives for 39% of women in union who use a contraceptive method. Pharmacies supply 59% of condom users, 42% of pills users and 16% of IUD users.

The team's informal survey of ten pharmacies in the Bucharest area and two pharmacies in Alba Iulia showed that a wide range of products at a variety of prices are available. (See Table 2 on the following page). All twelve pharmacies had at least one brand of oral contraceptives and ten of the twelve carried the low price pill brand, Rigididon, produced by the Hungarian manufacturer Gideon Richter. Retail prices for Rigididon ranged from 400 lei (US \$.26) for Ministry sourced product to 1,200-1,500 lei (US \$.80 - 1.00), for commercially sourced product. All twelve pharmacies carried condoms ranging from 250 - 1,500 lei (US \$.16 - 1.00) for a 3-pack. IUDs were only found in 6 of the 12 pharmacies with prices varying substantially from 1,000 -22,000 lei (US \$.66 - 14.66). Most of the pharmacies that did not carry IUDs noted that when the stock was depleted, they chose not to re-stock due to the low level of sales. Several pharmacies also carried Chinese made spermicidal film that sold for approximately 1,000 lei (US \$.66) a pack.

In conducting the pharmacy survey the team noted that prescriptions were not required for the purchase of contraceptive products. This finding was later confirmed by a senior official at the Ministry of Health. This is an important finding in that it provides an opportunity for women to purchase directly from pharmacies, by-passing the obstacle created by many of those in the medical community.

TABLE TWO

PHARMACY SURVEY - ROMANIA

BUCHAREST CONTRACEPTIVE PRICING (CITY)	(note: all prices in Romanian lei *)							(3 Pack) CONDOMS	IUDs
	ORAL CONTRACEPTIVES								
Private Downtown Pharmacies	Riglvidon	Trivadol	Diane 35	Triquilar	Microgynon	Ovidon	Trinouvum		
Farmacia Megheru			12,630	4,580	5,580			1,500	23,000
Farmacia Lutelia	1,500		12,660		4,580			1,200	5,500
Farmacia Balistel	400				5,000			1,077	
State Downtown Pharmacies									
State Pharmacy #1	400	400						321	
State Pharmacy #2	400			400				260	
BUCHAREST CONTRACEPTIVE PRICING (OUTSKIRTS) (private)									
Farmacia Fortuna	1,195							690	
Farmacia						2,055		711	
Farmacia Folbog (univ. hosp.)	400		12,600		4,800			600	2,000
Farmacia Panaceea	1,195		12,630			2,055	7,535	750	
Farmacia Beller	1,200					2,025		1,050	6,400
TRANSYLVANIA (Alba Iulia) PRICING (private)									
Pharmacy #1	1,185		12,630			2,060		420	1,000
Pharmacy #2	1,195					2,055		420	2,000

* Exchange Rate: 1500 lei = \$1.00

Pharmacies were one of the first industries to be privatized, with 2,100 (83%) of the 2,530 pharmacies currently under private ownership. Regulations pertaining to the establishment of a private pharmacy are no more onerous than in most Western countries and have not limited the creation of new pharmacies. There are, however, limits on the number of pharmacies that can operate in urban areas, but this has not been a deterrent to the establishment of new pharmacies to date. Appendix Nine provides a detailed discussion of regulations governing private pharmacies.

Although products were available, pharmacists indicated that inventories were kept low. The reasons cited include: lack of credit for drug purchases and cash flow constraints resulting from slow reimbursement for state-subsidized products. Although not generally cited as a problem, it is clear that the level of automation in retail pharmacies is low, and that this can contribute to cash flow problems, due to slow processing of subsidy claims, and to delays in ordering inventory. Pharmacists did report that government payments have improved recently, and some pharmacists claimed that they were getting paid within one or two weeks. However, it appears that these pharmacists have put substantial effort into better billing operations.

The team concluded that ensuring that retailers have sufficient access to cash to maintain adequate inventory levels is essential for continued access to contraceptive products through commercial channels. When stock-outs do occur they seem to be caused by cash flow constraints and poor inventory management systems. This situation could be improved by providing newly privatized pharmacies with a credit facility to help finance inventory, and with the provision of basic business training. The Pharmacists' Association indicated that The School of Pharmacy has shown interest in developing business courses geared to the newly privatized pharmacy and that assistance in this area would be welcomed by pharmacists.

Pharmacists also agreed that training in family planning would improve their ability to counsel women seeking to purchase contraceptives without a physician's consultation. In the event that a requested product is not available, updated information on contraceptive technology would have a positive impact on the pharmacist's ability to make an alternative recommendation.

While the team recommends conducting a more comprehensive retail audit to verify that a consistent and affordable supply of contraceptives is available through the national private pharmacy network, it seems reasonable to conclude that there are several factors that might confirm why a range of affordable contraceptive products seem to be more readily available than indicated in the earlier assessments conducted by SOMARC and Medecins Sans Frontieres.¹²

¹² An informal survey conducted by The Futures Group in May 1993 showed limited product availability in NGO clinics; in a survey of twenty pharmacies, no contraceptive supplies were available in the state pharmacies and a limited quantity of expensive orals, IUDs and condoms were available in privately owned pharmacies. A survey was also conducted by Medecins Sans Frontieres among 40 - 50 pharmacies, in 3 districts in Transylvania at three points in time: September 1991, February 1993, and July 1993. The range of available

Improvement in access to foreign exchange, which is relatively recent, could have significantly increased access to commercial supplies. In addition, a large number of pharmacies have been recently privatized. It is commonly believed that private pharmacies are more diligent than state run pharmacies in ensuring that a supply of a variety of products is maintained. Finally, the low priced contraceptive pill, Rigividon, which is priced comparably to widely sold consumer items such as cigarettes and soda, seems to be increasingly available in the market.¹³

IV. Consumers

The Reproductive Health Survey conducted in 1993 showed that while Romanian couples have a strong desire to limit family size, fertility is primarily controlled by use of traditional contraceptive methods and abortion. Use of modern contraceptives was found to be low, at 14%, with a significant factor being fear of side effects, partner preference or lack of information. Current data provided by the Ministry of Health on abortion trends points to increasing demand for more reliable modern methods of family planning. According to the Ministry, the number of reported abortions has been dropping steadily from a peak in 1990 of 992,265, the first year of legalization to 585,761 in 1993. This represents a three year decline of 41%. See Appendix Ten for detailed abortion statistics.

<u>Year</u>	<u>Total Abortion Reported</u>	<u>Percent Change</u>
1990	992,265	
1991	866,934	-12.6%
1992	691,863	-20.2%
1993	585,761	-15.3%

(Source: Ministry of Health - July 1994)

The decline seems to be too large and consistent to be explained entirely by reporting error, or a failure of the private sector to report abortions. While observers familiar with Romania believe that abortions are under-reported, the Reproductive Health survey of 1993 found a discrepancy of approximately 15% between the reported number of births and abortions and the numbers

products varied considerably over the three time periods. The more affordable contraceptive pill, Rigividon, was available in 38% of the pharmacies in September 1991, 73% of the pharmacies in February 1993 and in none of the pharmacies in July 1993.

¹³ For example: The average net income in Romania is \$70/month, one cycle of commercially sourced Rigividon is 1% of this wage. In the U.S., a secretary earns \$24,000 per year \$1,400 per month after taxes and health insurance. A cycle of pills sells for \$20 retail, 1.4% of monthly take home pay.

derived from the survey. The official reported number of abortions for 1992 which we obtained from the Ministry of Health would indicate a smaller discrepancy. We therefore conclude that it is valid to view the decline in abortions as real, and that this is an indicator of a trend among Romanian women. Since the number of women of child bearing age is relatively constant, and the effectiveness of traditional methods has not increased, it is reasonable to view this data as an indication that Romanian women, despite lack of information, are opting for more effective methods of contraception. Such a conclusion is consistent with a number of other observations including:

- High level of education
- The reported increase in private sector contraceptive imports
- The conclusion that products made available through the World Bank program were selling out rapidly.

In addition, the 1993 Reproductive Health Survey data is for women who are married or in stable union, thus not measuring the contraceptive patterns of younger women who are sexually active but not yet in a stable union. It is reasonable to hypothesize that younger women are more readily accepting modern contraceptives early in their sexual lives. If this is the case, the market for modern contraceptives will only increase as these women grow older and move into permanent unions.

Analysis of reported abortion trends and discussions with contraceptive distributors and pharmacists give promise to the idea that modern contraceptive usage is on the rise and can be improved significantly by correcting misconceptions and ensuring a constant supply of affordable product through private distribution channels.

The team recommends that an educational campaign be implemented, providing updated and correct information about modern contraceptives to consumers. The campaign should focus on reaching a large number of couples directly through mass media channels which are relatively well developed, (see Appendix Eleven for information on advertising and media). In addition, since women are by-passing physicians and buying contraceptives directly from the pharmacy, pharmacists can play a key role in correcting misconceptions by providing correct information on modern contraceptive usage.

V. Conclusion

Except for the Ministry's pending requirements of physician's delivery of family planning services, existing regulations are not a significant barrier to availability of contraceptive services or products. The potential exists for a significant portion of the Romanian population to shift to use of modern contraceptives through commercial channels, if sufficient information is provided on contraceptive products to allow for freedom of choice. Educating women about modern contraception through pharmacies can, ultimately, lead to a demand for improved women's health care. Such pressure could cause the government to reconsider its position on restricting the provision of family planning services to a limited number of obstetricians and general practitioners.

To achieve this goal USAID should focus its activities in three areas:

1. Developing a competency exam to allow physicians to avoid taking the six week/six month training program proposed by the MOH.
2. Ensuring that an adequate supply of contraceptives is available in the private sector by supporting the development of private distribution and retail outlets.
3. Providing consumers with correct information on the benefits of modern contraceptives.

These recommendations not only support the family planning/quality of life strategy of USAID/Romania, but also support privatization and women in development objectives since a majority of pharmacists are women.

SECTION THREE: PROJECT RECOMMENDATIONS

Based on the above, it is recommended that project activities focus on three areas:

1. Developing a preparatory course and a competency exam for physicians wanting to practice family planning without taking the MOH training course.
2. Providing business support at the distribution and retail level to ensure on-going supply of a range of affordable products through private distribution channels.
3. Launching a broad based information/education/communication (IEC) campaign to accelerate demand for modern contraceptives.

Details of the various project components are provided below. It is estimated that project development and implementation would be coordinated over a two-year period by a local project manager.

I. Market Research/Evaluation

Prior to launching the business assistance and family planning IEC program, a retail audit and survey should be conducted among a representative sample of pharmacies.

The audit would be conducted to confirm the following:

- Contraceptive products in stock and rate of out-of-stocks
- Contraceptive inventory and pricing levels
- Sales of contraceptive products

The audit would be supplemented by a brief questionnaire that would determine the following:

- Business constraints including credit needs
- Customer contraceptive buying patterns
- Pharmacy staff knowledge and attitudes to family planning

In addition, focus group research would be conducted with consumers prior to the development of an IEC campaign to determine attitudes towards modern contraceptives. This would be followed by the testing of materials developed for the campaign including television/radio spots and brochures.

The Program would be evaluated through several mechanisms. The business support fund and pharmacy training program would be evaluated both through actual sales and through the retail

audit which would confirm inventory levels once the business support fund was operational and pharmacists have been fully trained. The IEC campaign would be evaluated by conducting a baseline survey on awareness and attitudes towards family planning prior to the campaign. The baseline survey would then be compared to a survey conducted 9-12 months after the launch of the IEC campaign to measure shifts in awareness and attitudes.

II. Distributor/Retailer Business Support Fund

A. Assistance should be made available to one or several distributors to encourage the promotion of contraceptive products and to provide credit terms to newly privatized pharmacies for inventory with emphasis on reproductive health products. Specifically the team recommends:

- Provide funding to a select number of distributors to promote their reproductive health line with customers (pharmacies). This might include the creation of family planning centers at pharmacies. The centers would display reproductive health products such as condoms, pills, and pregnancy test kits. These activities would be coordinated with contraceptive manufacturers.
- The establishment of a coordinated credit facility implemented through one or more distributors that would allow their customers (the pharmacies) to purchase reproductive health products on credit.

B. Offer business training to newly privatized pharmacies to improve inventory management and ordering systems. Business training could be offered either through the College of Pharmacy or the Pharmacists' Association, or as part of a larger training program for pharmacists in modern contraception that will be offered as part of the IEC campaign. The project would include the training of trainers (TOT) and the training of approximately 2,000 pharmacists and/or pharmacists assistants.

III. Information/Education/Communication Campaign

A. Consumer Campaign

Launch a consumer advertising campaign to correct misconceptions about modern contraceptives. The campaign would take advantage of the broad reach of mass media and the fact that women can buy product directly from the pharmacy. The campaign would air on television and radio and would focus on correcting misconceptions about modern contraceptives. The campaign would be national in scope and implemented over a one-year period. The campaign would be complemented with a more in-depth message communicated through brochures and a public

relations program aimed at obtaining endorsement from key opinion leaders and coverage in newspapers and magazines.

B. Pharmacists' Campaign

Launch a campaign to educate pharmacists on modern contraceptive technology building on the module designed by The FUTURES Group. This would involve adapting the existing module, training local trainers and coordinating the training program through the national network of private retail pharmacies.

IV. Family Planning Competency Exam

Develop a competency exam and preparatory course to allow physicians who have already been trained in family planning to by-pass the MOH training course. This would involve assessing the existing curriculum, determining physician competency, development of two exams (one for Ob/Gyns and another for GPs) and designing a preparatory course for the exam. Negotiating with the MOH regarding permission for an equivalency exam is a crucial element which would need to be resolved prior to implementation of this project.

V. Vending Machine Distribution - Feasibility Study

A proposal was brought to our attention by the Director of a local NGO to install vending machines in locations frequented by young people so that they can have affordable and discreet access to contraceptives. While the idea has never been tested in a developing market, Population Services International (PSI) is testing the concept in the United States. An article on the program is attached.

Discussions with PSI indicate that there are several key elements:

1. Aggressively promoting the program with advertising.
2. Implementing the program with the collaboration of a youth group.
3. Ensuring the support of those who frequent the locations to minimize vandalism.

However, prior to the establishment of such a program in Romania, a feasibility study would need to be conducted. The study would include the following elements:

- Analyzing the viability of installing vending machines in Romania and identifying a system for the machines to be refilled.¹⁴
- Analyzing the financial viability of the venture.
- Conducting focus groups with young people to assess if condoms are a desired form of family planning and if discretion is an issue in purchasing behavior.

¹⁴ PSI indicated that vending machines would need to be adapted to fit Romanian coins and that a steady supply of one type of condom would need to be assured. PSI purchases vending machines for \$150 a piece but this does not include the cost of adapting the machine for local coins. PSI's initial program used approximately 200 machines.

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THURSDAY, JANUARY 28, 1993

Takin' it to the streets

Portland businesses that install condom vending machine deserve credit for helping to save teen lives

The AIDS epidemic is too lethal for the public or health officials to pull their punches. That's why the new Project Action campaign in Portland — which aims at encouraging condom use among sexually active teen-agers — deserves wholehearted support.

Project Action is a privately funded activity that hopes to show the nation how to get high-risk teen-agers to practice safer sex. Condom dispensers will be placed at various businesses around the city frequented by teens. Television public-service spots will tell teens, "Don't even think about sex without a condom." Follow-up surveys will attempt to determine whether the program is successful.

If education were all it took, Oregon's teens would be well-protected against AIDS. But research shows that while teens know the science of AIDS, they fail to translate that knowledge into life-saving action.

About half of Oregon teens practice abstinence, the surest form of AIDS protection. But the other 50 percent are sexually active. That number climbs to 75 percent by the time teens are high-school seniors. And fewer than 10 percent of those teens use condoms regularly.

For them, neither the "no sex" message of abstinence nor the "safer sex" message of condom use is getting through.

Project Action hopes to reach those high-risk teens by marketing condoms in new ways. Vending machines will sell individual condoms for 25 cents apiece, about one-half to one-third the retail price. The condoms will come packaged with illustrated instructions, in English and Spanish.

One of the biggest barriers to condom use may be breached — the em-

barrassment even the most uptight user feels while buying condoms from a store clerk. The machines also make low-cost but highest-quality condoms available at locations most accessible to teens, with more instructions for use than most manufacturers provide.

Is it really wise to encourage teens to use condoms? Yes. When used correctly, condoms are very effective at preventing HIV infection. Dr. Thomas Arrowsmith-Lowe, the federal Food and Drug Administration's expert on barrier contraceptives and HIV, came to Portland to support the Project Action kickoff. He told *The Oregonian*'s editorial board that FDA research shows that surgeon's gloves, which are used to protect medical and dental patients from possible HIV infection during treatment, are more likely to fall than correctly used condoms.

Project Action needs more than cooperation from public-health officials to succeed. It needs the owners of Portland businesses to step forward and agree to install condom dispensers. That's a big request. But business owners who can say yes without violating their own religious or moral codes are truly performing a public service: They are helping to save lives.

Ideally, teens would play it safe and avoid sex altogether. But many teens are sexually active. That was as true in the uptight '50s as it is in the free-for-all '90s. This stubborn reality underscores the need to take the pragmatic course in fighting today's AIDS crisis.

Aggressive, creative marketing of condoms makes sense. So does aggressive, creative marketing of abstinence. Teen-agers need to hear all the messages that might save their lives.

BEST AVAILABLE DOCUMENT

**SCOPE OF WORK FOR MARKETING ASSESSMENT FOR
SALE OF CONTRACEPTIVES IN THE PRIVATE SECTOR**

Background

There has been a remarkable decline of one-third in the total fertility rate of Romanian women - from 2.26 (87-90) to 1.56 (90-93). This change has been accompanied by an increased pregnancy rate and a more dramatic increase in abortion. The abortion to live birth ratio has increased from one abortion for every two live births in '88-'89 to 2.4 abortions for each live birth in 1992 (see Annex 1¹). At the time of the Romanian Reproductive Health Survey (RRHS), 57% of women in union (married and living in consensual union) reported using contraception: 43% traditional methods but only 14% modern methods. Thus, Romanian women are controlling their fertility largely through the use of abortion since only 14% were using effective contraception.

The RRHS revealed that despite high awareness of modern contraceptives among women in union (98%), there is also a high level of misinformation or fear contributing to the low use of modern contraception. Nearly two-thirds of women using traditional methods believed that their method was more effective than or equally effective as modern contraception. Two-thirds of women in union who were current users of traditional methods cited fear of side effects, partner preference and little knowledge about modern methods as very important or somewhat important reasons in their decision not to use a modern contraceptive method. Nearly 40% cited difficulty in obtaining modern methods and over a third cited the cost as a factor.

The Futures Group visit in May 1993 highlighted several problems in the availability of contraceptives. An adequate supply of contraceptive commodities to family planning clinics has been a problem since the inception of the Romanian Family Planning Project No. 186-0002 in 1991. Recent informal surveys reveal a continuing problem in the availability of contraceptives. Clinics have run out of contraceptives on several occasions, had to switch clients to other brands of oral contraceptives, or have been unable to provide certain methods. There is a limited method mix available.

Despite the fact that the RRHS revealed that government or private pharmacies are the primary source of contraception for 39% of women in union using modern methods, the Futures consultants found an unreliable supply in the pharmacies. The consultants completed an informal pharmacy audit in five cities, including Bucharest, covering about twenty pharmacies. No contraceptives

¹ Annex 1: "Reproductive Health Survey, Romania 1993, Preliminary Report" January 1994, Institute for Mother and Child Care, Romania Ministry of Health & Division for Reproductive Health, Centers for Disease Control and Prevention, Atlanta, GA.

whatsoever were available in state owned pharmacies, nor had any been available for the two months prior to the Futures visit. Privately owned pharmacies stocked limited amounts of expensive oral contraceptives, IUDs and condoms, but reported no difficulty in obtaining resupply from privately owned distributors. All pharmacists reported a significant demand for the products which is confirmed by the RRHS (nearly 65% of women in union do not want any more children or want to wait at least two years before having another child).

There is limited capacity to expand family planning services through the NGO or the public sector. The official mandate from the board of directors of SECS² (Society for Education in Contraception and Sexuality) is to promote educational activities, rather than to provide family planning clinic services. Other NGOs providing family planning services are even smaller than SECS. Government clinics are still struggling to initiate services.

The possibility of improving availability and use of modern contraceptive methods through the growing segment of private pharmacies could provide the greatest opportunity of an alternative to abortion. Such findings led the Futures consultants to recommend a marketing assessment to determine the feasibility of improving contraceptive access through the private sector pharmacies and the need for a family planning civic education program in Romania, using contraceptive social marketing program (CSM) techniques.

² SECS is the largest of two Romanian non-governmental organizations assisted through USAID funding.

Version incorporating suggestions of R&D/POP; 4/12/94

**Rumania
Private Sector Contraceptive Market Assessment
Scope of Work**

BACKGROUND

Unchanged from USAID/Rumania version.

SCOPE OF WORK

Suggest deleting paragraph three and what follows, and replacing it with the following:

"A two person team is requested to assess commercial/trade and legal/regulatory factors impacting on commercial contraceptive importation, distribution, marketing and sales, and identify any that adversely affect the regular availability of contraceptives in the private sector.

Specific areas and questions this team should look at include the following:

Regulatory and Trade Policies/Practices

- What is the legal and regulatory framework affecting importing and licensing of contraceptives? How is this affecting contraceptive prices? Assess and report on any relevant taxes applied to contraceptive commodities.
- Are there internal Government policies or practices that are acting as major constraints to the distribution and availability of contraceptives in the Rumanian market? If so, what are these?
- What legal or regulatory requirements are involved with establishing a pharmacy, with selling contraceptives? Who is allowed to sell contraceptives?
- Are there regulations that impact on the promotion or advertising of contraceptives?
- What affect are current foreign exchange controls and realities having on foreign contraceptive commodity procurement and sales?

Commercial Realities and Opportunities

- What modern contraceptive methods (both spacing and long-term) are available and from where are they being sourced?
- Describe public and private contraceptive supply channels: What groups or entities are involved with financing/

purchase, importing, warehousing/distributing, and sales? How is payment typically handled? Who are the key players?

- What constraints do these key commercial players face in selling their products in the Rumanian market?
- Are these key commercial players actively seeking new channels for their products?
- Would any of these commercial players be receptive to a joint venture? What impact would such a joint venture have on contraceptive supply?
- Do radio and television accept paid commercials? What are the best advertising agencies? Are they affiliated to international companies?

International Donor Activities

- In Rumania, what donors are involved with family planning contraceptive supply issues? Are they supplying commodities and if so what methods and quantities, and to whom? Are there supplies being sold; if so, at what level of price or cost recovery?
- What is the status and impact of the Government's importation and sale of contraceptives using the World Bank loan?

Future Activities

- What additional analysis and technical assistance is needed to address and alleviate any impediments identified in this assessment?"

[NEW SECTIONS]

PERSONNEL AND LEVEL OF EFFORT (LOE)

Candidates for this assessment should have experience in: commercial contraceptive marketing and sales; legal and regulatory aspects of commercial sector development; and the analysis and documentation thereof. Individuals should have considerable experience working in foreign countries, as well as very good writing and verbal communication skills.

Appropriate individuals will be drawn from the staff and consultant rosters of the PROFIT Project, of the SOMARC III Project, or some combination thereof.

Two individuals are envisioned for this assessment. The maximum LOE budgeted for this assessment will be a total of seven person weeks: one week spent by one of the members prior to departure conducting preliminary research, two weeks spent in Rumania by

both team members, and one week immediately following the country visit by both team members spent completing a written report of their findings.

DEBRIEFING AND REPORT SUBMISSION

Team members will meet with interested USAID/Rumania staff at the conclusion of there two weeks in country to provide a verbal debriefing.

No later than ten working days after return to the U.S. the team will complete a draft copy of its report and forward copies of this to USAID/Rumania by commercial courier, and to G/R&D/POP/FPSD. The Mission and G/R&D/POP/FPSD will then have ten working days in which to comment on this draft report, providing their comments by fax or E-mail to team members. At the conclusion of this two week period, team members will incorporate any comments or suggestions into the report as appropriate, and submit the report in final to both USAID/Rumania and G/R&D/POP/FPSD.

Preliminary Results, Romanian Reproductive Health Survey¹

Preliminary results of 4,744 interviews of Romanian women, age 15-44, conducted by the Romanian Reproductive Health Survey, July-December 1993, reveal a Total Fertility Rate (TFR) of 1.56 for June 1990-May 1993. This is compared with a rate of 2.27, June 1987-May 1990. This dramatic decrease in fertility patterns is largely explained by the dramatic change in the abortion to live birth ratio. For 1988 and 1989, the interviewed women reported one abortion for every two live births. After legalization of abortion in December 1989, the ratio rapidly increased reaching 2.4 abortions for each live birth in 1992.

Two-thirds of the women interviewed are currently married or live in a stable consensual union. Among these 3,447 women in union, nearly 60% do not want any more children and 5% want to wait at least two years before having another child. The preferences by age reveal that family planning programs should consider spacing methods for younger women and long term or permanent contraceptive methods for older women.

Though contraceptive awareness among women in union is high, there is also a high level of misinformation and preconceptions contributing to a low prevalence rate of modern contraception. Nearly all women in union have heard of at least one contraceptive method (98%) and most recognize at least one modern method (95%). In addition, 85% of women in union know of at least one source of supply of modern contraceptive methods. However, at the time of the survey 57% of women in union reported using contraception: 43% traditional methods but only 14% modern methods.

All surveyed women were asked the primary reason for not using modern contraception. Almost half of nonusers (2,179) reported lack of sexual activity as the first reason. Nearly one-quarter maintained that they cannot become pregnant or have tried to become pregnant, unsuccessfully, for at least two years. Over 10% were pregnant, were trying to get pregnant or were postpartum/breastfeeding; 5% feared the health or fertility effects; 4% reported occasional sex only or never thought about using modern contraception. Nearly 3% report preferring abortion or opposition of partner; 1% report cost or religion as the primary reason for nonuse.

¹ Source: "Reproductive Health Survey, Romania 1993, Preliminary Report" January 1994, Institute for Mother and Child Care, Romania Ministry of Health & Division for Reproductive Health, Centers for Disease Control and Prevention, Atlanta, GA.

Women in union who were current users of traditional methods (1,449) were asked about the importance of several reasons in their decision not to use a modern contraceptive method. Three reasons were listed as very important or somewhat important for 62-72% of these women: fear of side effects, partner preference and little knowledge about modern methods. Nearly 40% cited difficulty in obtaining modern methods and over a third cited the cost as a factor. A quarter cited a doctor's recommendation to use traditional methods and only 12% cited religious beliefs. Nearly two-thirds of this group of women believed that their traditional method was more effective than or equally effective as modern contraception.

The most important sources of contraception are pharmacies, either governmental or private; they provide 39% of the women in union who are currently using a supplied method. The next important source is the governmental sector at hospitals, polyclinics, and dispensaries, supplying 23% of current users. The third most important source is the "black market" which supplies almost 19% of users. Fourteen percent of users site friends, relatives, and partners as the source of contraceptive products. The private sector supplies 5% and the principle family planning non-governmental agency supplies only 1% of users.

According to the survey, the source varies according to the specific method used. Pharmacies are the primary provider for users of condoms and pills, supplying 59% and 42% respectively. The second most common source for pills and condoms (30%) is the "black market." Governmental family planning sites provide 9% of pill users and only 2% of condoms. The private sector (excluding non-governmental organizations) supplies only 1% of pills and no condoms and the principle non-governmental organization providing family planning service supplied 3% of pill users and 1% of condom users. Sources of IUDS include the governmental family planning network (60% of users), pharmacies (16%), private sector (12%), and non-governmental organizations (2%).

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APPENDIX TWO

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APPENDIX THREE - LICENSING OF DISTRIBUTORS

I. LICENSING OF DISTRIBUTORS

A. Current Status

Regulatory barriers to the establishment of private sector drug distributorship are low. A May 1993 Ministry of Health report showed 52 private drug warehouses or distributors, thirteen in Bucharest.

The national drug distributor, UNIFARM, is scheduled to remain a parastatal corporation. It has a current turnover of 15 billion lei, 1.5 billion in delinquent accounts, and competes for business by taking a lower share of the authorized wholesale/retail markup.

Seventeen state owned regional drug distributors are owned by the State and private ownership funds (SOF and POF). Although the manager of Centrofarm, the regional distributor in Bucharest, indicated that the company and its managers were preparing for privatization, the responsible POF indicated that the distributors were well down the list for privatization. If an investor appeared and offered to buy one of the distributors, the POF would negotiate, but they have no current plans to value these businesses and actively market them. At Centrofarm, the managers are interested in a buy-out, but it is not clear that they could raise the capital to buy the company.

The government owned regional distributors have minimal marketing operations. Some, such as Centrofarm, maintain control of some retail pharmacies within their districts. Centrofarm also has national distribution rights for some small European drug importers, and there appears to be no regulatory barrier to importation of drugs by either public or private distributors.

Like UNIFARM, the regional distributors compete on price, and on credit terms. In general, they appear to provide somewhat easier credit for retail pharmacies than some of the more successful private distributors.

B. Relevant Regulations

The rules for establishing a private distributorship are minimal. The warehouse must be supervised by a licensed pharmacist and meet minimal physical standards. Distributors can even rent space in warehouses operated by other distributors. Prior approvals are required from the Ministry and the local Sanitary Commission (for the specific site).

APPENDIX FOUR - PRODUCT REGISTRATION AND TESTING

I. PHARMACEUTICAL PRODUCT REGISTRATION

A. Current Status

Licensing and registration of imported pharmaceuticals does not seem to be an important barrier to the availability of contraceptives in Romania. In all categories, some 700 to 800 additional drugs are approved each year, and the list of approved drugs now runs to over 3,000 products, up from 200 in 1989. The fee to license a new drug is approximately \$1,000. The drug registration process takes three to six months from the date of filing.

The Drugs Commission is not obligated to approve a new drug just because it is safe and effective. The Commission may refuse to register a drug if there are a "sufficient" number of approved products in its therapeutic class. The Commission is concerned about reducing side effects, but less concerned about encouraging new registrations of lower priced products. Nonetheless, we heard of no case of abuse of this discretion with contraceptives. A "morning after" pill sold by Gideon Richter has recently been approved, as has a product from Wyeth Labs. Several varieties of IUDs are approved, as is the injectable Noristerat. At the date of the interview (July 1994), Depo-Provera had not yet been approved.

B. Relevant Regulations

Filing for a drug registration requires the manufacturer to file extensive information, including basic chemical and therapeutic data. If the drug is "unknown in the literature," or has "a known chemical structure but unused in therapy" clinical trials are required in Romania before registration is approved. However, if the drug is known in the international literature, the applicant can submit evidence of clinical trials and registrations from other countries. For drugs which are registered in the country of origin, the applicant needs to file:

- pharmaceutical, pre-clinical pharmacological, pre-clinical toxicological and clinical data
- package insert
- samples for testing
- agreement to withdraw the product if required by the Ministry of Health
- copy of registration in the country of origin.

The Drugs Commission makes its recommendation to the Ministry of Health on registration within six months of filing of the application. The Commission meets once per month. The Commission recommends to the Ministry of Health how the drug should be released. In practice, this means that the Commission determines whether or not a prescription is required to obtain the drug, and whether it must be sold in a licensed pharmacy.

Once the registration is approved, it is valid for five years and may be renewed at the owner's request. Registration may be withdrawn:

- if the drug shows unacceptable side effects,
- when the drug no longer meets quality parameters, or
- when the manufacturer discontinues production.

The regulations contain normal provisions for the monitoring and reporting of drug reactions.

Beginning in September 1994, products must have package inserts in Romanian. At the present time, some of the best selling contraceptive products have package inserts written only in English.

The Drug Commission has 17 members, and a Board composed of the President, two Vice-Presidents, and a Secretary. To recommend approval for registration, two thirds of the Commission members present at a meeting must vote favorably on the application. The Secretary is drawn from the staff of the Institute for Government Control of Drugs and Pharmaceutical Research---the Government drug testing laboratory, and the Commission and the Institute work closely together. We were told that an obstetrician member of the Commission is asked to review all contraceptive products before the entire Commission acts.

II. DRUG TESTING AND IMPORTATION

A. Current Status

Batches of imported drugs are subject to testing by the Institute for Government Control of Drugs at its Bucharest labs. Imported drugs cannot be sold without a quality certificate from this testing laboratory. No manufacturer or distributor we interviewed reported that the requirement for testing of imports is a significant barrier to sales.

B. Relevant Regulations

Regulations require the quality testing of each import batch. The required sample size is the same, regardless of the size of the batch which is imported, which lowers the cost of a product imported in large quantities. The Institute (drug testing laboratory) charges a fee of 100,000 lei (US \$66) for each batch test. In order to process the tests as quickly as possible, the Institute sometimes ask the importer to provide scarce laboratory reagents along with the sample and testing fee.

APPENDIX FIVE - REGISTERED HORMONAL CONTRACEPTIVES

<i>Grupa terapeutică</i>	<i>Denumire produs</i>	<i>Forma</i>	<i>Concentrație</i>	<i>Firma</i>	<i>Tara</i>
G02 <i>Hormoni sexuali și modulatorii sistemului genital</i>					
G02A CONTRACEPTIVE HORMONALE SISTEMICE					
.. G02AA Progesteron și estrogeni combinații fixe					
• G02ANN1	Hexesvolum				
• G02ANN0	Combinatii				
• G02ANN2	Diverse				
• G02ANN1	Plante				
• G02ANN0	Combinatii				
	RO Divagel	Unguent		Colgate Palmolive	România
	RO Mastoprofen	Unguent		SC Antibiotice Iași	România
	RO Colubex	Unguent		SC Antibiotice Iași	România
	RO Miprosept	Ovule		ICPP Apicultura	România
	RO Promastop	Unguent		SC Antibiotice Iași	România
G03A CONTRACEPTIVE HORMONALE SISTEMICE					
.. G03AA Progesteron și estrogeni combinații fixe					
• G03AA03	Combinatii (Lynestrenol + Estrogeni) Yermonil	Drajeuri		Ciba	Elveția
• G03AA05	Combinatii -- (Norelisteron + Estrogeni) Trinovum	Compr.		Cilag	Elveția
• G03AA06	Combinatii (Norgestrel + Estrogeni) Ovidon	Compr.		Gedeon Richter	Ungaria
• G03AA07	Combinatii (Levonorgestrel + Estrogeni) Microgynon-21 -28 Rigevidon Triquilar-21, -28	Drajeuri Compr. Drajeuri	0,15 mg + 0,03 mg	Schering AG Gedeon Richter Schering AG	Germania Ungaria Germania
• G03AA09	Combinatii (Desogestrel + Estrogeni) Marvelon	Compr.		Organon	Olanda
• G03AA10	Combinatii (Gestogen + Estrogeni) Femoden	Drajeuri		Schering AG	Germania
• G03AA11	Combinatii (Ciproterol + Estrogeni) Diane-35	Drajeuri		Schering AG	Germania
.. G03AC Progesteron					
• G03AC01	Norelisteronum				
	Norelisteron Noristerat	Drajeuri Fole	0,5 mg, 5 mg 1 ml/200 mg	Jansapharm Schering AG	Germania Germania
• G03AC02	Lynestrenolum				
	Exlutonă Lynomin	Compr. Compr.	0,5 mg 5 mg	Organon Orion	Olanda Finlanda
G03B Androgeni					

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Source: Ministry of Health, July 1994

**APPENDIX SIX
PRICING, FOREIGN EXCHANGE, CUSTOMS DUTIES AND TAXES**

I. PHARMACEUTICAL PRICING

A. Distributor Pricing

At the distribution level, managers acknowledged that fixed prices were a problem during the period when the lei was devaluing rapidly, but did not cite the price regulations as a significant obstacle. They were much more concerned about the retail pharmacy's need for credit. Of course, the distributor does have flexibility to set his price within the allowable margin. It is the retail pharmacist who has no control over his selling price, and must settle for whatever margin is left after paying the distributor.

Drug pricing regulations control the total wholesale and retail margin. The maximum retail price is determined by adding the following amount to the domestic production or import price.

<u>Import Price</u>	<u>Combined Wholesaler/Retailer Price Markup</u>
5,000 lei or less	33 %
5,000-10,000 lei	30 %
10,000-20,000 lei	25 %
20,000-30,000 lei	20 %
30,000-40,000 lei	15 %
40,000-50,000 lei or more	12 %

The distributor has control of the amount of this margin which it retains on its products, this seems to range from five to ten percentage points out of the thirty-three percentage points available. Private sector distributors who offer better service, or a particularly desirable product, may attempt to take a larger cut of this margin.

II. RETAILER PRICING

A. Current Status

Maximum retail prices are determined based upon the combined wholesale/retail markups listed above. Interviews indicated that these price limits are generally respected, and that pharmacists are concerned about enforcement actions for violating the rules. In our limited pharmacy sample, the price of the most popular oral contraceptive, Regividon, was generally quoted at the approved level.

The government drug subsidy program is not a direct problem for most contraceptive users because contraceptives are not covered by the program for the general population. Students and the disabled are entitled to receive contraceptives free under a separate subsidy program. However, payment delays in the general government subsidy program have caused a cash

flow problem for pharmacists, who have limited access to bank loans or trade credit. The shortage of funds to purchase new stock was certainly one factor contributing to the patchy availability of contraceptives.

Recently, the payment cycle for drug subsidies has apparently improved. Further improvement in the cash flow of pharmacists could come from improved billing systems. In addition, many private pharmacists may not fully understand the cash flow benefits of increasing contraceptive sales. Since these sales are largely for cash, it can improve the pharmacists general cash position, and contraceptives should be reordered even when cash is short. In addition, automated billing and reordering systems—which are linked in pharmacies in Western Europe and the U.S. could be used to further improve pharmacist's cash flow and reduce stock outs. The level of technical sophistication and capitalization of most private pharmacists would limit their ability to purchase such systems, but they might be sold as a service—with full technical support—at a monthly fee. One aggressive private distributor is already installing computerized inventory control and reorder systems for some of his better customers.

III. FOREIGN EXCHANGE, CUSTOM DUTIES, AND TAXES

A. Current Status

Until March of 1994, shortage of foreign exchange was a major barrier to the import of contraceptives, and all other drugs. Only a small percentage of the requested foreign exchange would be made available each day, and it could take three to six months to obtain sufficient foreign exchange to pay an import invoice in full. With the lei devaluing rapidly, importers would sometimes withhold product from the market because the approved price in lei was insufficient to replace the hard currency spent to purchase the product. They would wait until a price adjustment reflected the lower value of the lei before selling the product for local currency.

Import price regulations permit a higher base price for goods ordered on consignment, but importers were afraid that rapid devaluation would still leave them with insufficient funds to pay the invoice when the product was sold. The allowable base price for imports (before addition of the distribution margin discussed above) is equal to the invoice price plus customs duty and transport costs, plus an importer's margin. We were told that the allowable import margin is 23% if paid on delivery, but 43% if the invoice is payable after thirty days, thus allowing the importer an added margin for the deterioration in the value of the lei during the extended period.

Drug importers and business people in general now report that foreign exchange is available within a week of the date that an invoice is placed for payment. There is still some paperwork with banks to certify the invoice and the foreign exchange requirement, but there were no claims that foreign exchange is now being rationed, or that "under the table" payments are required to obtain foreign exchange allocations.

B. Relevant Taxes

Value added tax: The general rate is 18%, but pharmaceutical are exempted. Condoms are not specifically exempted, and would probably pay the VAT.

Import duty:

- oral contraceptives---10%
- condoms---10%
- IUDs and injectable contraceptives are not specifically listed, but are probably subject to 10% duty (UNIFARM notes that the duty rate varies from 8% to 16% depending on the drug and country of origin).

In 1994, the Government exempted drugs purchased under the World Bank program from import duty.

Withholding tax: Basic rate for interest payments to parties outside the country is 10%, and varies up to 25% of some profits and professional service income.

Corporate income tax: Charged on all profits as defined in Romanian accounting law, regardless of ownership status of the entity. Thus, a non-profit NGO like the Marie Stopes Foundation pays tax on operating surplus. The basic rate is 30% up to 1,000,000 lei of profits, and 45% of profits above this level. There is a two-year tax holiday on profits for new companies or joint ventures, and on the profits attributable to an increase in the capitalization of an existing joint venture. Note that any expenditure on advertising, entertainment, or protocol expenses in excess of 3% of gross profits is taxable at regular rates. Thus, for a joint venture, it is more profitable to have advertising expenses paid directly by the foreign partner, with the cost incorporated in the import price of the product.

Company registration: Minimum investment is \$10,000, or 20% of the capital of a joint venture. Registration of a foreign manufacturer is not required if you import through a Romanian distributor.

**MINISTRY OF HEALTH
INSTITUTE FOR POST-GRADUATE
TRAINING AND CONSECUTIVE EDUCATION
OF PHYSICIANS AND PHARMACISTS**

**DRAFT PROGRAM
FOR SPECIFIC MEDICAL TRAINING
IN FAMILY PLANNING**

1. PRESENTATION OF THE ISSUE

Following the talks at the National Consultative Committee for the Activity of Reproductive Health and Family Planning concerning the organizing of the family planning network, in accordance with the Program of Reform of the Ministry of Health financed by the World Bank, it is incumbent on the Institute for Post-Graduate Training and Consecutive Education of Physicians and Pharmacists to adapt the existing methodology to the present situation and to improve it for the continuation of the program of training physicians specialized in general medicine and obstetrics-gynaecology, who will work in referral centers and in county local units for family planning services.

The aspects involved in the process of training for the granting of proficiency in family planning can be systematized into 4 categories:

- a) biological and medical aspects - which refer to the biological mechanisms related to human reproduction and sexuality;
- b) psychical and social aspects - involving the entire knowledge on man as an individual subject and as a member of a collectivity.
- c) organizational aspects - management in family planning.
- d) technical aspects - involving all the methods and means for the achievement of a modern contraception, with the lowest possible risks for the health of the woman and of the couple, and all the means used for the prevention, diagnosis and treatment of sterility, infertility, sexually transmitted diseases and genital-mammary cancer.

2. STRATEGY OF THE PROGRAM

The program contains a draft strategy concerning the fundamental training for a six-month period of physicians-specialists in general medicine, finalized in obtaining proficiency in family planning, and the six-week training of physicians-specialists in obstetrics-gynaecology. For the physicians employed at referral centres the program is conceived as "the training of trainers", these being designed to subsequently ensure part of the training of physicians from county local units for family planning services.

The solution of the requirements for improvement in the field of family planning aims at :

2.1. The Drawing Up of Programs for the Instruction of the Personnel will be made at intervals, programs of instruction oriented in 3 main directions being necessary :

2.1.1. the training of trainers - the basic instruction and the training of lecturers with the granting of the respective proficiency for the physicians-specialists in general medicine and obstetrics-gynaecology from the 11 referral centres (33 participants);

2.1.2. the training of physicians-specialists in general medicine and obstetrics-gynaecology from the county local units (230 local units with 690 participants), with the support of the trainers from the referral centres;

2.1.3. the information in the field of family planning of the general practitioners from the urban and rural health centres by the physicians from the local units for family planning services (about 4000 physicians per year).

2.2. The Organizing of the Program

2.2.1. The training of the future trainers (see 2.1.1.) will be carried on in university centres: foreign lecturers will participate in the modules for management, counselling, legislation, sexology and psychology.

2.2.2. The training of physicians-specialists in general medicine and obstetrics-gynaecology from the county local units will be carried on under the guidance of the trainers and of the teaching staff from the university centres, and the practical term will be carried on in a university clinic or county maternity hospital.

2.2.3. In parallel with the training of the physicians from the county local units, depending on the existing possibilities, the trainers in family planning can start

the information of the physicians from the urban and rural health care centres.

2.2.4. The Plan of Subject-Matter and the Norm of Practical Manoeuvres which are compulsory for the practical period of probation of the basic services have been drawn up by the speciality teaching staff and has been authorized by the Consultative Council for the family planning activity (see annexes I, II and III of the curriculum).

2.2.5. At the completion of the program, the participant will go in for a theoretical and practical examination before a commission approved by the Ministry of Health and will receive a characterization certifying that he or she is proficient in exercising the requested activity. On the basis of the characterization and of the marks obtained in the final examination, the participant will receive a certificate (diploma) of proficiency (competence) in family planning granted by the Institute for Post-Graduate Training and Consecutive Education for Physicians and Pharmacists which is the methodological forum of the Ministry of Health.

2.2.6. The proficiency to work in the field of family planning may equally be granted to those who attended a training program in other units in Romania or abroad. The validation of the training completed will be made after the testing of the knowledge and skills according to the conditions stipulated at point 2.2.5., the validation being made in exchange for a tax in case the participant is not included in the program of the Ministry of Health.

2.2.7. We recommend that the Ministry of Health should forbid the practice in the field of family planning to those physicians who have not obtained the proficiency in this field.

2.3. Forms of Improvement

2.3.1. Courses - through the Institute for Post-Graduate Training and Consecutive Education of the Physicians and Pharmacists;

- through the post-graduate education in the universities of medicine.

2.3.2. Stages of Probation

- in university clinics
- in district maternity hospitals

2.3.3. Courses and Stages of Probation organized with the view of obtaining proficiency.

2.4. Methods

- course ex catedra;
- practical demonstration
- clinical stages and practical activities
- group debates
- exchange of experience with specialists from Romania and other countries.

3. PRINCIPLES OF ORGANIZING THE PROGRAMS

3.1. For Physicians-Specialists in General Medicine

3.1.1. for the physicians working in family planning referral centres :

- the training of trainers through an intensive instruction during a six-month period (three months of theoretical courses and three months of probation) to obtain proficiency in family planning;

- consecutive training through participation in the existing post-graduate educational programs or in those organized by the Institute for the Post-Graduate Training and Consecutive Education of Physicians and Pharmacists, on specific issues requiring a more thorough study.

3.1.2. For the physicians working in the 230 county local units for family planning :

- Intensive training for a six-month period with the acquiring of proficiency in family planning;

- recycling of physicians through their participation in post-graduate training programs for the updating of their knowledge.

3.1.3. for the physicians who are not specialists in general medicine, short-term programs of consecutive training will be organized consisting of courses and practical probation focusing on the immediate problems of improving one's knowledge (from two weeks to two months per year) aiming at adapting the training to the specific character of the job.

3.2. For the Physicians-Specialists in Obstetrics-Gynaecology

3.2.1. in order to acquire proficiency in family planning it was decided that a minimum of six-week training in a university clinic was sufficient.

3.2.2. the organizing of recycling programs for the updating of the knowledge.

4. EVALUATION OF THE KNOWLEDGE

This will be done at the request of the Ministry of Health by the Institute for Post-Graduate Training and Consecutive Education of Physicians and Pharmacists to obtain the feed-back necessary to optimize the program in due time.

The evaluation of the knowledge, aptitudes and attitudes can be performed before the program, during the program as well as at the end of the program.

At the request of the Ministry of Health, the Institute for Post-Graduate Training and Consecutive Education of Physicians and Pharmacists can organize a post-program evaluation.

5. COST OF THE PROGRAM

It will be estimated by the Ministry of Health, in accordance with the existing taxes and tariffs, as well as the corresponding funds allotted by the joint program established with the World Bank.

The Sanitary Directions will ensure to the physicians who are training in family planning their release from the current activities and the payment of their respective salaries for the corresponding period.

**CURRICULUM
OF THE TRAINING PROGRAM
In View of Obtaining Proficiency
in Family Planning**

1. APPLICANT : The Ministry of Health.

2. BENEFICIARIES :

- physicians-specialists in obstetrics-gynaecology employed by the family planning referral centres;
- physicians-specialists in general medicine employed by the family planning referral centres;
- physicians-specialists in obstetrics-gynaecology employed in county local units for family planning services;
- physicians-specialists in general medicine employed in the county local units for family planning services;
- physicians - general practitioners from the rural and urban health centres.

3. ORGANIZERS: The Ministry of Health through the Institute for Post-Graduate Training and Consecutive Education of Physicians and Pharmacists.

4. INTERVENERS :

from Romania: - University Clinics of Obstetrics-Gynaecology
- District Maternity Hospitals.

from other countries: they will be determined by the Ministry of Health in accordance with the World Bank through the consultancy programs.

5. DURATION : 6 months (3 months for cycle I and 3 months for cycle II - see point 7).

5. STATEMENT OF MOTIVES :

the table of functions of the physicians of the local units for family planning services stipulates positions for physicians-specialists in general medicine and obstetrics-gynaecology who, depending on the volume of work and structure, will be supplemented with other speciality personnel (physicians of other specialities, biologists, psychologists) with the authorization of the Ministry of Health;

- the activity of the physician-specialist in general medicine requires services conceived for the family planning specific character (which surpasses the skill offered by the basic training of the physician);
- the identification of the general targets of this program is based on the experience conveyed by the World Health Organization concerning the activity of similar units in other countries.

7. METHODOLOGY - it comprises 2 cycles -

Cycle I: theoretical and practical education - 3 months

- it will be carried on in university clinics and it contains 7 modules:

- **module 1 - 6 weeks**

- it contains a term of obstetrics-gynaecology of 20 hours/week (3x4 hours), 120 hours in all; it is supplemented with demonstrations of 6 hours/week (3x2 hours), 36 hours in all and a course of 15 hours/week (5x3 hours) 90 hours in all on issues of contraception, contragestation, endocrinology;

- **module 2 - 1 week**

- it contains a practical term for sexually transmitted diseases in the dermato-venereological clinic of 20 hours/week (5x4 hours); it will be supplemented with practical demonstrations of 6 hours/week (3x2 hours) on infectious disease problems and dermato-venereological ones and a theoretical course of 9 hours/week (3x3 hours) on problems of infectious diseases, dermato-venereological ones and preventive medicine;

- **module 3 - 1 week - management;**

- **module 4 - 1 week - sexology;**

- **module 5 - 1 week - sociology, psychology, pedagogy and methodics (less pedagogy and methodics for the physicians from the county local units for family planning services);**

- **module 6 - 1 week - legislation, logistics, health education;**

- **module 7 - 1 week - counselling.**

For modules 3-7 the form of instruction is that of a pedagogical workshop with a duration of 7 hours/day (4 hours in the morning and 3 hours in the afternoon), 175 hours/month in all; individual study is added to that (not mentioned in the

curriculum). The workshop will be carried on as :

- courses
- practical activities
- demonstrations
- group debates
- case study.

Cycle II : practical term in obstetrics-gynaecology

- duration : 3 months - 35 hours/week (5x7 hours) 420 hours in all in county maternity hospitals and university clinics.

- the norm of manoeuvres and technics for the practical activity is presented in ANNEX I.

8. LOCATION OF THE TRAINING

- clinics of obstetrics-gynaecology from the university centres
- county maternity hospitals
- for modules 3-7, the location and length of the training performed by foreign lecturers for the trainers from referral centres will be decided by the Ministry of Health.

9. PURPOSE OF THE PROGRAM

- the basic proficiency, the structuring and adapting of the knowledge in the field of family planning, the acquirement of aptitudes and attitudes necessary to the use of the resources and the adjustment to the new techniques, ultimately leading to the acquirement of proficiency in the field of family planning.

10. OBJECTIVES OF THE PROGRAM

10.1. General Objectives of the Training

At the conclusion of the training program and on the acquirement of the proficiency the physician should be able :

- a) to assimilate the knowledge, attitudes and aptitudes in the field of family planning;
- b) to generate awareness in the community concerning the advantages of family planning;
- c) to take into account the psychic and social aspects in the various activities related to family planning;
- d) to know and put into practice correctly all the contraceptive methods;

e) to identify and to advise couples having problems of sterility and infertility;

f) to motivate the decision-making factors in the community and to determine them to participate in the activities of family planning and contraceptive and sex education;

g) to supervise the medical staff members having a medium qualification who participate in family planning activities;

h) to consolidate the fundamental aptitudes concerning anamnesis, general and gynaecological examination, the prescription of contraceptive methods, the adjustment of the psychical and social problems, counselling concerning fecundity, advice before contraception, case studies;

i) to know legislation and the system of specific interrelations;

j) the trainers from the referral centres for family planning should monitor the programs of training and consecutive education for the physicians from the primary health care network on family planning issues.

10.2. Intermediate and Specific Objectives

- These are presented in detail as a plan of subject matters (Annex II and Annex III).

11. EVALUATION OF THE KNOWLEDGE

- the final evaluation will be made through an examination to obtain proficiency in family planning;
- the proposed examination tests are : - the written test
- the practical test;
- the examination to obtain proficiency in family planning for the trainer physicians from referral centres for family planning will take place before a commission which will be appointed by the Ministry of Health and which will be composed of specialist-physicians in general medicine and in obstetrics-gynaecology and of a representative of the Institute for Post-Graduate Training and Consecutive Education for Physicians and Pharmacists.
- the graduation certificates will be delivered by the Institute for Post-Graduate Training and Consecutive Education for Physicians and Pharmacists.

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APPENDIX EIGHT - ESTABLISHING A PRIVATE MEDICAL PRACTICE

I. ESTABLISHING A PRIVATE MEDICAL PRACTICE

A. Current Status

Physicians have been slow to establish private practices (see attached list of practices established as of May 1993). In addition to the shortage of capital, many physicians have a difficult time locating suitable office space. Several observers pointed out that some doctors attempting private practice do not understand that they are, in effect, competing with the free or low cost care available through the Ministry. These physicians do not understand that they must market their services and provide a higher perceived quality of care (better ambiance, shorter waiting times, improved convenience) than the Ministry facilities in order to justify their charge.

Substantial capital is required to obtain equipment, office space, and working capital to start a practice. In general, such capital is not available in business loans from banks, and must be secured by the physician's own property if any loan is available.

The Government does anticipate passing a health insurance law which would permit further privatization of medical practice. The law which would authorize such a system was introduced in November 1993 and is currently pending in the Senate. Dr. Poenaru, Secretary of State for the MOH hopes for passage of the bill in the fall of 1994.

Realistically, implementation of a health insurance program is a year or more in the future. Initially, insurance is to be issued through a large single national insurance company, which is still to be set up. Supplemental insurance (above the government benefit package) might be privately available. Some form of credit facility or advance from the insurance company will be necessary to enable physicians to fund their private practices under this scheme.

As presently discussed, the insurance scheme has a structure which could--potentially--be used to strengthen the availability of family planning services. General practitioners are to be paid on a capitation basis, with additional fee for service revenues which would encourage "prophylactic measures of national importance." However, the government currently plans to conform the insurance payment system to the Ministry's regulations on the provision of family planning services. Fee for service reimbursement would be available for family planning consultations, but only to obstetricians, or internists who have qualified through the six month training course proposed by the Ministry (see Appendix Seven). This means that the group of practitioners authorized to bill for family planning services (on a fee for service basis) will be restricted. Many Romanian obstetricians have already shown themselves resistant to modern family planning concepts. The fee for service rate for an abortion would likely be substantially higher than for family planning consultation, thus discouraging the wide availability of counseling on family planning methods. The goals of modern family planning would be better served if:

- General practitioners are allowed to provide family planning services as part of general gynecological care.
- Family planning consultations by such practitioners are subject to the incentive reimbursement available to general practitioners for procedures of public health importance.
- Training or certification requirements for the offering of family planning services are greatly revised from the present MOH proposal in Appendix Seven. Family planning services should be available as part of comprehensive primary health care for women, as they are in America and in Western European countries.

B. Relevant Regulations

The attached regulations on establishing a private medical practice are somewhat bureaucratic, but are not per se unreasonable.

To start a private practice, a physician must obtain approval from the Ministry of health. This referral is dependent on being properly qualified to practice medicine in Romania, and an approval from the College of Physicians which certifies that the physician is in good standing. The local Sanitary Directorate must approve the site of the physicians's practice as having adequate space, lighting, sanitation, etc. In addition, the physician must incorporate and obtain the necessary documents from the Ministry of Finance.

Ministry physicians may maintain private practices which do not interfere with their Ministry obligations, and their employing institution has the right to refuse to approve a private practice. We were told that, in practice, approvals for private practice are not denied for conflict with other duties. However, the Ministry is not obligated to take back into employment or maintain the seniority of a physician who leaves for full time private practice.

Private practice physicians are required to:

- report births, deaths and listed diseases
- give emergency aid (regardless of ability to pay)
- obtain informed consent for procedures performed
- respect patient confidentiality
- maintain a daily register of patients
- give written bills
- use certain standardized forms for reporting and prescriptions.

Physicians in private practice cannot sell drugs. However, they may provide injectables (and presumably IUD's) if such items are included in the price of the procedure and not charged separately. NGO family planning clinics (Marie Stopes, SECS) reported that they did not have great difficulty obtaining special permission from the Ministry to sell contraceptive supplies to their patients.

The regulations do provide the power for the Ministry to sanction a private physician if s/he does things that are outside the approved scope of the practice. This would presumably permit the Ministry to sanction a general practitioner who performed procedures reserved for a specialist. However, the regulations for each specialty do not specifically exclude family planning services from general practice, although the regulations for the Ministry's own family planning clinics limit family planning to certain specially qualified general practitioners.

II. PRACTICE RESTRICTIONS

A. Current Status

As we read the regulations applicable to general practitioners and obstetricians, they do not appear---on their face---to limit family planning services. They do list family planning as a service to be provided by obstetricians, and the Ministry might chose to define this as a specialty requirement. As noted above, most doctors who have successfully developed _____ private practices are specialists, so the limits of what a private general practitioner could do in family planning have not been tested.

B. Relevant Regulations

The private practice OB/GYN is permitted to perform abortions during the first trimester of pregnancy, but is required to report the number of abortions performed. He is required to acquaint the women with the principles of family planning after the abortion. These regulations specify no specially required training in family planning, although they do specify a minimum course for such activities as colposcopy, electric cauterization, and echography.

Regulations governing general practitioners do not specify family planning as a service. However, they clearly anticipate that the "GP" will provide basic gynecological care, as the mandated equipment list includes a gynecological examining table and examining equipment. These gynecological items are notably lacking from the mandate equipment list for internal medicine.

MINISTRY OF HEALTH

ORDER No.657/14.05.1991
CONCERNING THE ORGANIZING AND OPERATION
OF THE MEDICAL ACTIVITIES IN THE PRIVATE SYSTEM

.....

Common Provisions

- All the medical consulting rooms operating in a private system will carry first aid drugs and the drugs and sanitary materials necessary for the performance of the usual activities in the respective speciality.

The drugs and sanitary materials used will be included in the fee or in the price for the procedure; they cannot be commercialized for home treatment.

- For the specialities where the presence of the anesthesiologist-resuscitator is necessary, medical assistance will be granted either with his own medical first-aid kit or with the kit of the respective consulting room.

- In the activity carried on in a private practice the existing standard forms are used until new ones specific to the private units and consulting rooms will be printed:

- registers for consultations, for surgery performed in an ambulatory system and check ups;
- certificates for temporary invalidity due to illness, for employment, birth, death, marriage, driving school, etc.;
- referral or hospitalization notes;
- medical prescriptions;
- cash receipts;
- medical records for consultations;
- medical records for dental treatment;
- medical certificates, etc.

OBSTETRICS - GYNAECOLOGY
The Activity of Medical Assistance (competence)

- Routine clinical examination
- Control of the pregnancy
- Consultations, counselling, treatment in family planning matters.
- Colposcopy, electric cauterization, echography - in case the respective equipment exists in the endowment of the consulting room and the physician has a proficiency certificate in these fields (an intensive course of 3 weeks).
- Uterine curettage for the termination of pregnancy on request in the following conditions:
 - the observance of the Ministry of Health regulations concerning the termination of pregnancy on request only during the first 3 months of gestation;
 - a written application from the woman for the performance of uterine curettage by the respective physician in his private consulting room; the application should also record that the patient was previously informed on the medical risks of this surgical intervention. This application will be kept for one year at the consulting room;
 - the presence of an anesthesiologist-resuscitator and of the means of resuscitation;
 - the obligatory character of the numerical reporting of the uterine curettages performed, every three months, to the Laboratory for sanitary evaluation, for statistical records purposes;
 - the acquaintance of the woman with the principles of family planning, after the surgical intervention;
- Uterine curettage with biopsy and investigation, with the observance of the conditions stipulated in paragraphs 2 and 5 above-mentioned.
- The granting of birth assistance at the pregnant woman's home, providing :
 - the correct referral of the case depending on the obstetrical risk;
 - the assuming of the responsibility for the possible complications which might appear;

- the delivery of birth, death certificates on standard forms obtained from the Sanitary Direction to which the respective consulting room is circumscribed.
- the delivery of medical prescriptions.
- the performing of specific treatments.
- the delivery of recommendations for complementary examinations in other speciality medical services from the state or private networks.
- the compulsory character of granting emergency medical assistance.
- The providing of a correct sterilization of the instruments, gloves, textile materials (tampon containers, towels, sterile sheets, etc), in accordance with the regulations in force.

Endowment

Medical equipment :

- a blood pressure apparatus with a stethoscope
- a gynaecological table
- a footed searchlight
- a balance for adults
- a taliometer
- a sterilizer or an electric boiler
- a drying closet

Medical instruments:

- speciality instruments - valves, vaginal specula, clips for tampons + button, uterine curettage kit, small surgical kit
- a pelvimeter
- a centimeter
- an obstetrical stethoscope
- various syringes
- various needles
- syringe boxes
- gloves boxes
- instrument boxes
- containers of various sizes
- a percussion hammer
- thermometers

Furniture:

- a couch for consultations
- a cabinet for instruments and/or drugs
- a small table for instruments and/or drugs

Materials :

- sheets, covers
- kidney shaped bowls
- examination gloves
- cotton
- gauze
- gauze dressings or sterile bandages
- band-aid

Supplementary Endowment:

- a colposcope
- an echographer
- an electric cautery

INTERNAL MEDICINE**Medical Activities**

- internal medicine consultations
- medical prescriptions
- minimal paraclinical investigations
- treatments, infiltrations

Equipment**Medical apparatus:**

- a blood pressure apparatus
- a biauricular stethoscope
- an oscillometer (1st grade consulting rooms)
- an electrocardiographer (1st grade consulting rooms)
- a balance for adults
- a sterilizer or an electric boiler

Medical instruments:

- various disposable syringes and needles, including those for thoracic punctures, paracentesis, etc.
- a percussion hammer
- a maximal thermometer
- various boxes for instruments or containers
- various pincers
- scalpels, various scissors

Sanitary Materials:

- examination gloves
- gauze, cotton, various bandages
- various test tubes
- various sizes of band-aid
- a plastic sheet 50/100 cm.

Furniture:

- a couch for consultations
- a cabinet for instruments and drugs
- a small table for instruments

GENERAL MEDICINE
Medical Activities

- consultations of general medicine
- medical prescriptions
- treatments

Equipment
Medical Apparatus

- a blood pressure apparatus with a stethoscope
- a gynaecological table
- a balance for adults
- a taliometer
- a sterilizer or an electric boiler

Medical Instruments

- various syringes
- various needles
- syringe boxes
- instrument boxes
- containers of various sizes
- a speculum
- a percussion hammer
- thermometers
- rectal cannulae
- urethral cannulae
- vaginal cannulae
- scissors to cut plaster casts
- vaginal valves
- small surgery kit

Furniture:

- a couch for consultations
- a cabinet for instruments and drugs
- small tables for instruments

Materials

- kidney shaped bowls
- examination gloves
- gauze
- gauze dressings or sterile bandages
- cotton
- band-aid
- Krammer splints.

Situatia unitatilor medicale privatizatein functiune la 1 mai 1993 *

Judetul	Total unit. medic.	Med. gen.	Spec. medic.	Spec. mixte	Stomat.	Tehnica dentara	Total (F+D+ +L+O)	din care:		
								Far- ma- cii	De- poz. Farm.	Opti- ca
Total	2809	346	717	183	1218	286	1,389	1,332	52	5
Alba	27	4	7	-	12	4	35	34	1	
Arad	67	6	4	2	44	11	40	38	2	
Arges		
Bacau	49	1	17	4	27	-
Bihor	44	9	11	3	16	5	25	25	-	-
Bistr.Nas.	44	5	7	2	21	9	29	27	2	-
Botosani	26	2	12	1	9	2	17	16	1	
Brasov	96	10	20	10	46	10	56	56	-	
Braila	31	-	3	1	24	3	26	24	2	
Buzau	56	6	12	6	23	9	32	30	2	
Caras Sev.	43	7	18	-	13	5	12	11	1	
Calarasi	28	8	3	1	11	5	32	33	-	1
Cluj	155	20	47	3	72	13	17	16	1	
Constanta	202	32	56	13	84	17	66	60	6	
Covasna	19	1	8	1	9	-	24	24		
Dimbovita	59						41	41		
Dolj	78	6	40	13	18	1	53	51	2	
Galati	93	8	30	3	38	14	33	32	1	
Giurgiu	
Gorj	18	2	5	-	11	-	16	16		
Harghita	40	6	8	5	15	6	24	24		
Hunedoara	38	2	11	5	19	1	46	45	1	
Ialomita	16	2	1	1	7	5	24	22	1	1
Iasi	48	3	20	3	21	1	46	35	8	
Maramures	28	2	3	-	20	3	45	43	2	
Mehedinti	32	4	8	3	13	4	13	13		
Mures	49	4	15	3	21	6	67	67		
Neamt	65	3	15	-	31	16	29	28	1	
Olt	34	1	9	2	18	4	27	27		
Prahova	182	30	50	16	59	27	68	66	-	2
Satu-Mare	29	8	5	3	13	-	19	19		
Salaj	48	1	22	4	14	7	10	10		
Sibiu	152	17	37	18	58	22	54	50	4	
Suceava	38	11	11	1	13	2	26	26		
Teleorman	26	4	10	3	6	3	32	32		
Timis	193	40	41	6	91	15	43	43		
Tulcea	23	4	7	1	6	5	13	13		
Vaslui	
Vilcea	29	3	8	-	16	2	33	32	1	
Vrancea	69	5	15	2	29	18	18	18		
Bucuresti	535	69	121	44	270	31	206	192	13	1

*Private medical practices established as of May 1, 1993 provided by the Ministry of Health.

APPENDIX NINE - ESTABLISHING A PRIVATE PHARMACY

I. LICENSURE OF PRIVATE PHARMACIES

A. Current Status

In May 1993, the Ministry of Health (MOH) reported that there were 1,332 private pharmacies, with 206 in Bucharest. The President of the Bucharest College of Pharmacy reported that there were now (July 1994) approximately 300 pharmacies in Bucharest, of which 100 were bought from the state, 100 are newly established, and 100 are still owned by state distributors. However, Centrofarm claimed that it only controls 40 pharmacies in Bucharest.

The pharmacy regulators at the MOH reported that there were 210 pharmacies in Bucharest in July 1994. At this time, they reported a total of 2,100 private pharmacies nationwide, plus 430 pharmacies still controlled by the regional distributors.

The biggest problems for private pharmacists identified by interviewees were:

- credit for drug purchases
- delays in processing and payment of drug subsidies
- uncertainty about the stability of retail store leases.

In Bucharest, the President of the College of Pharmacists worried about the potential abuse of market power by the former State distributors. He could foresee that these groups, when fully privatized, would aggressively develop a chain operation, and potentially evict those private pharmacists who currently have leases from the distributor for their retail site, or who manage a pharmacy owned by the distributor under a contract.

Price regulation per se was seen as only an indirect cause of the private pharmacists problems. The pharmacists wanted protection from unfair competition and faster payment of government subsidies, and saw such steps as compensating for the fact that retail prices are fixed. Pharmacists clearly fear to violate the priced fixing regulations, an attitude that does not extend to some other regulations, such as the requirement that they fill government subsidized prescriptions.

Although not generally cited as a problem, it is clear that the level of automation in retail pharmacies is low, and that this can contribute to both cash flow problems---due to the slow processing of subsidy claims---and to delays in ordering needed supplies. Pharmacists did report that government payments have improved recently, and some pharmacists claimed that they were getting paid within one or two weeks. However, it appears that these pharmacists have put substantial effort into better billing operations.

Some private pharmacies have clearly refused to sell "subsidized" prescriptions and operate only on a cash basis. The government did not crack down on this when payments were delayed, but may enforce the non-discrimination provisions of the regulations more strictly now that payments are more timely.

While the Certificate of need style regulations that attempt to limit the total number of private pharmacies is potentially an impediment to additional entrants, we did not hear a lot of objections. In fact, with regulated prices, the pharmacists are glad to have some limit on competition in order to keep up the volume of trade in their pharmacy.

B. Relevant Regulations

As with other health care facilities, private pharmacies need an MOH license and local Sanitary Commission approval. The physical facility regulations are not unreasonable by U.S. or Western European standards and include:

- separation and control of narcotics
- retaining a copy of the official price list
- enforcing prescription requirements and keeping a record of prescriptions
- no sale of unregistered drugs
- reporting of drug reactions
- appropriate labelling of containers

The facility must be managed by a qualified pharmacist, and the applicant for a private pharmacy license must be approved by the College of Pharmacy---which provides some opportunity to collude against more aggressive competition.

The MOH retains the right to inspect the pharmacy. The Ministry has a force of 25 pharmacy inspectors, and expects to perform two or three inspections per year of normal facilities.

The "Certificate of Need" regulations specify that only one private pharmacy will be approved for every 7,000 citizens. The catchment areas for such determinations are not precisely stated. In rural areas, a private pharmacy can be established even if the requirement for 7,000 population is not met.

APPENDIX TEN - CURRENT ABORTION STATISTICS

According to the Ministry of Health, in 1993 7% of abortions or approximately 59,000 were conducted in the private sector. (Note: Abortions conducted in the private sector are required to be reported). The number of reported abortions has been dropping steadily from a peak in 1990 of 992,265, the first year of legalization to 585,761 in 1993. This represents a three year decline of 41%.

<u>Year</u>	<u>Total Abortion Reported</u>	<u>Percent Change</u>
1990	992,265	
1991	866,934	-12.6%
1992	691,863	-20.2%
1993	585,761	-15.3%

(Source: Ministry of Health - July 1994)

The change in reported abortions varies geographically. Municipal Bucharest was down from 159,364 (1990) to 93,597 (1993), a decline of 41.2% and almost exactly the same as the country as a whole. Areas with decline higher than the national average include Bistrita (-62.6%) and Buzau (-57%). In Cluj, where smuggled Hungarian pills may have been more readily available prior to the revolution, the decline is only 28.8%. In Constanta, which is reported to have a growing problem with unwanted births, the decline was 62.5%. Statistics from May 1993 show that Constanta also has the third largest number of private pharmacies (60) outside of Bucharest. Prahova, which has the second highest number (66) of private pharmacies outside Bucharest also had a decline in reported abortions of more than 50%. The attached table provided by the Ministry of Health shows the regional breakdown for reported abortions for the years 1990-1993.

Many observers believe that the number of abortions in Romania is understated in official Ministry of Health reports. The 1993 reproductive health survey derived an estimate of 703,000 abortion and 305,000 live births in the preceding year. The data which we received from the Ministry reported 691,863 abortions in 1992--only a 2% discrepancy. The data which the Ministry apparently gave to the Reproductive Health Survey for the period in question was 617,000 abortions, a 15% discrepancy. Interestingly, the number of births reported by the Ministry in this period (260,000) was also about 15% below the number derived by the Survey.

It is impossible to get a totally accurate number of abortions performed each year. However, the Survey data show that the Ministry statistics are not totally useless for the purposes of this report. By any measures, the number of abortions in 1992 was well below the number

reported by the Ministry in 1990. The Ministry reports a further decline in 1993. The secular decline in abortions reported by the Ministry since 1990 indicates that something has changed in family planning, and that Romanian women are having fewer abortions. The reduction in abortions is not compensated by an increase in births. Based on our discussions with distributors and pharmacists, we conclude that the decline in abortion may be explained, at least in part, by the purchase of modern family planning supplies in Romanian pharmacies, and that Romanian women are beginning to use modern family planning techniques in larger numbers.

Nr. Judetul crt.	1990	1991	1992	1993	Nr. crt.
TOTAL	992265	866934	691863	585761	
din care:					
1. Alba	11651	9599	7208	5943	1.
2. Arad	14783	14804	14050	11700	2.
3. Arges	34284	29055	23174	15258	3.
4. Bacau	27725	26317	17824	16491	4.
5. Bihor	15959	12905	12223	10955	5.
6. Bistrita-N.	9364	7915	4853	3495	6.
7. Botosani	12791	12519	12967	11630	7.
8. Brasov	29545	30012	20981	16152	8.
9. Braila	20628	19029	18639	18347	9.
10. Buzau	21608	16382	12398	9245	10.
11. Caras-Sev.	15680	13375	10094	8278	11.
12. Calarasi	18250	17568	16949	15000	12.
13. Cluj	20600	19100	16583	14657	13.
14. Constanta	41685	31368	17068	15633	14.
15. Covasna	7335	7154	6644	6165	15.
16. Dimbovita	31584	26803	20317	15662	16.
17. Dolj	41058	30425	21222	18369	17.
18. Galati	32071	26391	17234	12223	18.
19. Giurgiu	15652	13412	9708	8100	19.
20. Gorj	23194	23380	23057	21180	20.
21. Harghita	8067	7890	7834	7264	21.
22. Hunedoara	22863	19628	13974	10905	22.
23. Ialomita	18889	19091	16081	14703	23.
24. Iasi	39145	35856	31770	27696	24.
25. Maramures	12738	10335	9304	9853	25.
26. Mehedinti	12719	12656	10290	7734	26.
27. Mures	16254	15859	15638	14902	27.
28. Neamt	19636	19975	18159	14667	28.
29. Olt	28132	22174	15887	12758	29.
30. Prahova	42900	34303	23219	19761	30.
31. Satu-Mare	7716	5885	3712	3015	31.
32. Salaj	5325	2918	1299	1285	32.
33. Sibiu	16877	13276	6839	5472	33.
34. Suceava	19711	16397	12996	11159	34.
35. Teleorman	18392	14539	10682	9900	35.
36. Timis	30344	27066	23225	19707	36.
37. Tulcea	11837	10908	8600	5331	37.
38. Vaslui	18291	17408	16635	14010	38.
39. Vilcea	21352	20488	22151	20996	39.
40. Vrancea	17266	16496	8989	6562	40.
41. M.Bucuresti	159364	136273	111386	93597	41.

BEST AVAILABLE DOCUMENT

APPENDIX ELEVEN - ADVERTISING AND MEDIA COSTS

I. ADVERTISING COSTS

A. Advertising Firms¹

The advertising industry is relatively well developed with six of the top ten firms having an international affiliate:

1. Grafitti/BBDO Advertising *
2. Centrade/Saatchi & Saatchi/BSB *
3. Young & Rubican/Media Pro *
4. Plus Advertising
5. Grey Advertising *
6. Clip
7. RomKu
8. DMB & B/OFC *
9. Focus Advertising
10. Primera/Ogilvy & Mather *

* Internationally affiliated agencies

The team met with the top two agencies in Romania, Grafitti/BBDO Advertising Agency and BSB/Centrade/Saatchi & Saatchi Advertising. Advertising is new to the Romanian market, given that there were no agencies in the country prior to 1990. The market for advertising services is expanding very rapidly, and consumers are gradually becoming more sophisticated in making their choices in goods and services.

B. Grafitti/BBDO Advertising Agency

The team met with Mircea Efstate, Director of Client Services. The firm began operations in Romania in 1991, and merged with BBDO International in 1992. Grafitti was the first advertising agency in Romania to be internationally affiliated, and has become a broad group, offering many services. Service departments include: Creative and Production Advertising, Media Buying, Market Research, Outdoor Media, Billboard, and Merchandising. Grafitti has ten subsidiaries throughout the country that handle local advertising and promotion.

International clients include: Phillip Morris (Marlboro), Delta, Apple, Pepsi, Tampax (local distributor). Tampax is Grafitti's only health care related product; advertising has included television, radio, print advertisements, point of purchase material and information pamphlets for pharmacies.

¹ Capital, Media Section, No. 25, June 24, 1994, p.8.

C. BSB/Centrade/Saatchi & Saatchi Advertising

The team met with Radu Florescu, Managing Director. The firm has been operational in Romania since 1990. BSB is a full service agency offering the following services: Advertising Strategy, Creative Development, Media Planning & Buying, Research Supervision, and Competitive Monitoring.

The agency has many international clients, some of which include: USAID, PHARE, Masterfood (MARS, Snickers, etc.), Brown Williamson (Kent), Oil of Olay (Proctor & Gamble), Pepsi, Air France, Digital, Home Box Office, Philips, and Honeywell. The agency is staffed by fourteen people and includes five departments: Media, Creative, Client Services, Finance, and Operations (each department is headed by an ex-patriot).

II. MEDIA AND MEDIA COSTS

A. Television:

There are two national television stations - one with international reach, and another that covers only urban markets. Advertising prices are as follows:

Primetime (weekdays): \$5,500/minute *

Primetime (weekends): \$6,600/minute

- Prices are rapidly increasing; the above primetime prices were \$3,000 and \$4,000/minute in 1993. There are two state television stations, the national RTV1 (covers 95% of the market) and RTV 2 (covers 35% of the market and is expanding). Rates for RTV 2 are about 50% lower than RTV 1.
- Television is a good medium for reaching the mass market as over 95% of Romanian households have televisions.
- While cable is becoming popular in urban markets, there is no advertising through cable. Cable companies do not have legal agreements with suppliers.

* Prices are set by the state and are expected to increase 15% in August 1994; advertising agencies expect a 30% (in dollars) increase again in January 1995.

B. Radio

There are four national radio stations and several local privately run stations. Prices are as follows:

National Public Radio Rates: \$100 - \$200 a minute

Local Bucharest Radio Rates: \$35 for a :30 spot

- There are four national state radio stations: news and music; cultural, arts, and classical music; and two youth rock stations.
- There are three private stations in Bucharest, including soft music station for early 30's crowd (owned by international ad agency, Young & Rubican); and two rock music stations for teens. Private stations are popular, but are only available in cities.

C. Print

There are three national newspapers (below) and many local papers. Newspapers are read equally by both men and women. The rates are as follows:

- Daily News (police and sensational type stories) - Advertisement charge of 7,000 - 9,000 lei per square centimeter. Very popular with a reach of over 400,000 people daily. Print is poor quality.
- Romania Libre - Ad charge \$2,000 for a full page. Circulation of 150,000; opposition paper.
- Adevarul - Circulation of 150,000; supports the government. Rates are similar to Romania Libre.

D. Regulations

Advertising of medical products is not permitted, although a social campaign with a health message would be allowed.

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