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**RUSSIA
RATIONAL PHARMACEUTICAL
MANAGEMENT PROJECT
NOVGOROD OBLAST
PHARMACEUTICAL SECTOR
ASSESSMENT**

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INTRODUCTION

The Rational Pharmaceutical Management (RPM) Project is being carried out in Russia under the MSH Cooperative Agreement NIS Add-on (New Independent States). This pharmaceutical sector assessment was conducted in Novgorod Oblast from November 27 - December 1, 1995. The indicator portion of the assessment was conducted just prior to and during this time period by local data collectors trained by Oblast specialists who attended an RPM Assessment Workshop.

Objectives of the assessment are to

- Provide data that will allow the USAID mission to compare pharmaceutical sector problems identified in this oblast with those encountered in the Ryazan Oblast assessment
- Provide Novgorod officials with a comprehensive report of the status of the local pharmaceutical sector, and an options analysis to address problems identified in the assessment
- Identify opportunities for future technical activities in formulary management, product selection, procurement and tender management, community pharmacy management, drug utilization review programs, rational drug use, and drug information development in Novgorod Oblast using NIS Add-on funds
- Utilize the assessment report as a basis for a Novgorod Policy Options Workshop to be held in March, 1996 in which RPM, USAID, and local and national health officials and specialists will develop an implementation plan for addressing pharmaceutical system problems in Novgorod

We wish to express our appreciation to all those individuals who helped plan and conduct the assessment, allowed themselves to be interviewed and supplied the required data.

See Appendix 7 for the assessment methodology used in the Novgorod survey, and Appendix 6 for a list of acronyms used in this report.

**SECTION ONE:
SUMMARY OF FINDINGS OF THE NOVGOROD ASSESSMENT**

I EXECUTIVE SUMMARY

RPM assistance could be provided in the following areas in Novgorod Oblast

- formulary management
- drug use review (DUR)
- procurement and tender management
- community pharmacy management
- drug information development
- rational drug use

This assistance will include on-site training to local counterparts, as well as provision of equipment and training as appropriate. The exact program of activities will be determined during the joint Novgorod/Pskov Policy Options Workshop, during which RPM will discuss survey findings with local, national, and international specialists, and local policy makers.

The following suggested activities of these areas of assistance are provided as a basis for discussions at the workshop.

A Formulary Management

A critical first step to reducing drug costs and maximizing the therapeutic benefit of public sector expenditures on drugs is rational selection of drug products through formulary management. Formulary systems focus on use of the most cost effective products for common diseases. The formulary maintenance process should include drug use review, adverse drug reaction monitoring, and the establishment of therapeutic substitution guidelines. In addition, in order to be effective and sustainable, the process must involve practitioners at all levels of the medical and pharmaceutical sectors.

1 Findings

- Novgorod does not utilize locally developed formulary lists or manuals that restrict drug procurement and use.
- Funds are limited, and termination of centralized system of procurement and distribution has led to increased expenditures at the Oblast level.
- MOH has altered its policies, allowing a dramatic increase in the number of drug products entering Russia, which has resulted in the introduction of many previously unknown products into Novgorod.
- The rapid introduction of new drug products has created a gap between the need for drug information by prescribers, and the availability of unbiased sources of information. The formulary process helps to ensure that the introduction of new drugs is accompanied by the provision of necessary information, training and education.

2 Proposed Activities

The Head of the Public Health Administration has suggested that *rational use of the health care budget* and *a formulary for exempt patients* become RPM priorities. With this as a guideline the following activities are proposed:

- Familiarize the “Working Group on Improving Drug Supply” with formulary management concepts, this group was formed in September, 1995 by the Public Health Administration to study how to improve the oblast drug supply
- Work with the formulary committees recently selected by the “Working Group” as they begin to implement formulary development and management procedures to
 - Expand access to, and use of, current unbiased drug information
 - Identify priority therapeutic needs through examination of local morbidity statistics as well as past utilization patterns
 - Establish a locally appropriate formulary list at the following hospitals: Veterans, Oblast Adults, Oblast Children, Municipal No 1, Maternity, Oblast Tuberculosis, Oblast Neurological, Oblast Skin and Venereal Disease, and Central Rayon Hospitals of Novgorod, Borovichi and Staraya Russa
 - If appropriate, provide computers, software and training for use in developing and maintaining Oblast and hospital formulary lists
 - Assist as necessary in promoting official adoption of the formulary lists
 - Establish mechanisms for requesting and obtaining non-formulary drugs needed for specific patients
 - Launch a program of adverse drug monitoring and side effects of drugs for inclusion in the formulary maintenance process
 - Establish, and regularly review and revise approved therapeutic substitutions, based on drug availability and cost
 - Establish mechanisms to ensure that health professionals are updated on formulary changes, including the provision of information, or education needed to properly utilize new drugs

B Drug Use Review (DUR)

Drug use review is a tool used to examine quality of drug use in hospitals and other healthcare facilities. It is a systematic, ongoing activity that collects data based on objective criteria, as established by facility specialists, with the goal of promoting rational drug use.

1 Findings

- No DUR programs were found to be in place in hospitals, polyclinics, and other healthcare facilities in the Oblast
- From the assessment forms the average number of drugs prescribed per outpatient encounter was 2.4. However, according to the Oblast Health Administration, excessive amounts are often prescribed in certain outpatient clinics (eg Polyclinic No 3-- six to seven drugs per patient, and Veterans Hospital -- more than 10 per patient)

2 Proposed Activities

- In cooperation with the Oblast Health Administration, identify appropriate specialists, and train them in DUR and rational prescribing techniques
- Form appropriate DUR committees and develop DUR programs using the USP DI drug utilization review framework
- Assist in incorporating the DUR programs in formulary management systems

C Procurement and Tender Management

In the former Soviet system, planning and carrying out drug procurement was a centralized function in which drugs were acquired largely from domestic or East European manufacturers. However, current pharmacy managers have limited experience in such critical tasks as accurately estimating order quantities, using competitive procurement techniques such as tendering, and monitoring supplier performance. Additionally, many of these managers may not be familiar with options for national or international procurement.

1 Findings

- ▶ Drug purchases by State Enterprise Pharmacia are made through negotiation with drug distributors and manufacturers. Other than one tender in 1995 for insulin, tendering procedures have not been utilized.
- ▶ The computer system at Pharmacia doesn't monitor orders placed for drugs from suppliers, or supplier performance.
- ▶ Even though some drugs are received with quality certificates, they are still subject to testing by the Oblast quality control laboratory, for which Pharmacia must pay.

- ▶ With high inflation and sale of drugs by Pharmacia and pharmacies based on limited markup, pharmaceutical facilities may not generate sufficient funds for procurement and operating expenses
- ▶ Oblast Administration, community pharmacies, and hospitals owe Pharmacia 289,800 US\$ (1 182 billion Rubles)

2 Proposed Activities

RPM can collaborate with the "Working Group on Improving Drug Supply" to transfer the following basic procurement skills through training and technical assistance to appropriate individuals

- Identify options to promote rational and competitive domestic and international procurement practices for drugs, given existing financial constraints Domestic options may include procurement within Novgorod Oblast, and other parts of Russia
- Assist in establishing techniques for Oblast Health Administration and Insurance Companies to centrally procure and distribute vital drugs as mandated by the federal law "On Medical Insurance for Citizens of Russian Federation "
- For the public health sector, establish a selection and quantification system which employs ABC analysis, VEN analysis, international price lists, and quantification methodologies based on consumption and morbidity data
- In cooperation with local counterparts, conduct a quantification of Oblast drug needs, using the MSH-developed *Estmed* software, after modification based on local needs Conduct training in the use of the software
- Utilize the MSH-developed formulary database system with modifications to the Novgorod Oblast situation to assist in formulary development
- Establish a system for tendering and screening for quality control of products, using an optimal mix of manual and computerized tracking systems Assist in developing forms and documents necessary to monitor domestic and international procurement These documents may include tender announcements, vendor registration forms, supplier evaluation and monitoring forms, tender lists (with instructions for tenderers), adjudication forms, and procurement contracts
- In selected public sector sites provide computers and install suitable microcomputer based software such as INVEC (procurement and inventory management)
- Assuming that local officials decide to introduce competitive procurement techniques, RPM can assist as follows
 - ▶ Help to publish notification of impending tenders, to begin the process of supplier selection Provide detailed instructions for providing vendor registration forms in response to inquiries

- ▶ Assist with qualifying domestic producers, and identifying and qualifying international pharmaceutical vendors, based on documented performance and proper completion of vendor registration forms, and based on ability to work within financial mechanisms available
- ▶ Assist with completing tender documents, and mailing the documents to qualified vendors. Assure system is in place to receive and manage tender submissions from vendors
- ▶ After tenders are received help evaluate and adjudicate the tender, and place orders for pharmaceuticals. Put systems in place to monitor order status and follow-up with problems encountered
- ▶ Provide a summary report describing results of the procurement effort, along with recommendations for follow-up technical assistance which may be needed to sustain improved procurement management systems

D Community Pharmacy Management

Many pharmacists have limited management skills due to the fact that in centrally controlled drug systems, the skills were not required. In the transition from central drug management to local management, community pharmacies have encountered difficulties in remaining economically viable.

1 Findings

- According to Public Health Administration, 29 pharmacies experienced financial difficulties in 1993, and were downsized through personnel layoffs and other efficiencies
- According to the Oblast Administration, 8 or 9 of the municipal enterprise pharmacies were not profitable in 1995

2 Proposed Activities

- Identify appropriate pharmacy managers and conduct a basic pharmacy management workshop with emphasis on operating costs, staffing levels, product acquisition costs, procurement strategies, price structures, and marketing strategies
- Conduct an advanced pharmacy management workshop including the development of a business plan for community pharmacies
- Conduct train the trainer workshops in pharmacy management techniques, so that local pharmacy managers will be able to pass these concepts on to all pharmacies in the Oblast
- Provide technical assistance to pharmacy managers as they implement their business plans

- Assist pharmacy managers in exploring the possibility of group buying activities, and in establishing relationships with other health facilities in order to improve procurement activities and promote an exchange of information and expertise

E Drug Information Development

Drug information resources and services in the Oblast are very limited at this time, due to lack of funds for staffing and reference materials. The most active information providers are drug manufacturing representatives, who visit medical societies, hospitals, pharmacies, and other health care facilities.

1 Findings

- The only drug information center in the Oblast was formed in November, 1995 at the State Center of Prophylactic Medicine and Rehabilitation in Novgorod city, but is not fully staffed, nor funded at this time
- Drug information at the Medical College in Novgorod consists of a library of 60,000 titles, which are mostly English language medical journals that were donated by an American university
- In most health facilities visited the only medical reference book available was Mashkovski
- The Oblast public health budget does not provide funds for the specific purchase of medical reference materials in Oblast health facilities
- Drug information is so limited that health professionals and citizens of the Oblast continue to call Novgorod Pharmacia for drug information, even though Pharmacia's drug information center has not officially existed since 1992

2 Proposed Activities

- Work with the Oblast Health Administration to create a drug information network, and establish one or more drug information centers in the Oblast
- Provide a computerized drug information database, and training of appropriate personnel
- Provide study tours, workshops and conferences for Oblast personnel, who will establish and operate the drug information centers
- Assist with the selection of appropriate reference materials for the drug centers
- Facilitate capability to create drug information materials and proactive outreach programs
- Work with the faculty of Novgorod Medical College to develop and incorporate rational drug use courses in the existing curricula

F Rational Drug Use

In order to contain drug costs and assure that prescribers are using the most effective treatment modalities, rational drug use can be monitored through the establishment of standard treatment guidelines (STGs), and drug use review studies for inpatients and outpatients of health facilities

1 Findings

- Oblast Health Administration indicated that STGs do exist in the public sector, but need revisions to include diagnoses and financial considerations
- Two of the 3 hospitals visited indicated that the STGs at their facilities were very general and based on 1991 federal healthcare standards
- None of the hospitals visited reported a program in place to perform drug usage review studies

2 Proposed Activities

- Work with Oblast Health Administration to establish a Rational Drug Use Committee
- Work with the ASKO Insurance Company to develop STGs according to international recommendations
- Work with Oblast Health Administration to select facilities where formulary systems are being developed and include STG revision
- Work with facilities which are implementing formulary systems and include DUR programs

II PHARMACEUTICAL INDICATORS

Indicator results from the Novgorod assessment are presented in in this section of the report, using the format of the manual “*Rapid Pharmaceutical Management Assessment An Indicator-Based Approach*”

A Policy, Legislation, and Regulation

1 Existence of a national drug policy approved by government

Russia does not have a National Drug Policy per se, but there are separate decrees, laws, and regulations written at the Federal and Oblast levels, pertaining to various aspects of drugs

2 Existence of comprehensive drug control legislation, regulations and enforcement agencies

Comprehensive federal legislation and regulations exist governing drug control in Russia, including the 1993 *Law Concerning Basics of Legislation of Public Health Protection of the Population* Examples of regulations for specific areas of pharmacy follow

Subject	Description of Regulation	Enforcement Agency
Drug Manufacturing	Federal Decree #890 “On Government Support of Medical Industry and Improvement of Provision of Population and Medical Facilities with Drugs and Medical Supplies” July 30, 1994 Regulation “On Licensing Drug Manufacturing and Sales” March 17, 1994	Federal Ministry of Health and Medical Industry (MOH)
Drug Registration	Several Federal regulations cover this area, the most important one is Federal Order #177 “On Licensing Regulations of Export and Import of Pharmaceuticals, Medical Equipment and Medical Supplies” July 23, 1993	Federal Pharmacy Committee of MOH
Licensing of Pharmaceutical Activities	Federal Decree #890 “On Government Support of Medical Industry and Improvement of Provision of Population and Medical Facilities with Drugs and Medical Supplies” July 30, 1994 Decree “On Licensing and Accreditation of Pharmaceutical Activities in Oblast” December 24, 1993	Oblast Public Health Pharmacy Department, and Licensing and Accreditation Commission

Drug Procurement and Distribution	<p>Oblast Decree "On Bidding Process for Drug and Medical Supplies Procurement for Public Health Facilities" February 24, 1995</p> <p>Oblast Decree "On Measures for Improvement of Population and Health Facilities Provision with Drugs and Medical Supplies" July 7, 1995</p>	Oblast Public Health Committee
Drug Quality Control	<p>Federal Order #149 "On Quality Assurance of Pharmaceuticals, Medical Supplies, and Medical Equipment," June 28, 1993</p> <p>Federal Order #53 "On Drug Quality Control Labs" March 25, 1994</p>	Oblast Public Health Drug Quality Control Laboratory
Sales Practices	<p>Federal Decree #890 "On Government Support of Medical Industry and Improvement of Provision of Population and Medical Facilities with Drugs and Medical Supplies" July 30, 1994</p> <p>Oblast Decree "On Measures for Improvement of Population and Health Facilities Provision with Drugs and Medical Supplies" July 7, 1995</p> <p>Oblast Decree "On Pricing Policies for Pharmaceuticals and Medical Supplies" November 2, 1994</p>	Oblast Public Health Pharmacy Department, and Licensing and Accreditation Commission
Medical Insurance	Oblast Decree "On Medical Insurance for the Citizens of Russian Federation in Novgorod Oblast for 1996" (Carrying out Federal Decree)	Novgorod oblast Medical Insurance Trust

3 *Percentage of unregistered drug products in a sample of private sector drug retail outlets*

There were no unregistered drugs reported on the survey data forms, which indicates that the federal drug policy is being followed

4 *Type of drug registration information system*

At the federal level there is a computerized drug registration database at the Bureau for Drug Registration at the Ministry of Health and Medical Industry (MOH). Also a manual information system exists in the form of a bound book, "Register of Drugs in Russia, 1994" ed Y F Krylov, which is available at the Pharmacy Department of the Public Health Administration, Novgorod Oblast

5 *Number of drugs registered*

Currently there are approximately 9,000 drug products registered in Russia, this is a substantial increase over the number of drug products available in Soviet times

6 *Law permitting generic substitution by pharmacists*

There is no law in Russia at this time. However, the MOH and the Novgorod Oblast Health Administration allow it and unofficially demand it. Bioequivalent substitution is done by pharmacists at their own discretion. Therapeutic substitution can be made only through consultation with a prescriber.

7 *Practice of generic substitution*

Although pharmacists realize that generic substitution is allowed, of 20 pharmacies surveyed 65% actually practice substitution, an important principle of cost reduction.

B Formulary/Essential Drugs List and Drug Information

1 *Number of unique drug products on Drug Formulary List*

2 *Existence of an official manual, based on the Drug Formulary List, providing basic drug information to prescribers, revised and published within the last five years*

3 *Percentage of public health facilities visited with the most current edition of an official manual based on the Drug Formulary List*

There is neither a National nor Oblast formulary restricting drugs that can be legally dispensed, which indicates that rational resource allocation is not being practiced. However, there is a national list of "Vitaly Important Drugs" that should be stocked at all times for use in exempt patients. This list was revised on March 17, 1995 by MOH Order #63, and contains 164 drug products. Novgorod modified the list for its population of exempt patients, and it contains 129 drugs.

4 *Existence of drug information centers that provide unbiased and current information to public health decision makers, health care providers and consumers*

There is a Central Resource Bureau in the Oblast, which provides drug availability to health providers and consumers, however, health providers at all levels mostly use biased information such as package inserts, information from drug company representatives, and the French reference book "Vidal," which is similar to the "Physicians Desk Reference" in the United States.

C Budget and Finance for the Novgorod Oblast Public Health Sector

Financial data reported during the survey covers fiscal year October 1, 1994 through September 30, 1995 unless otherwise stated. Ruble to dollar conversions were made using the following rates, which were averaged from those in Appendix 8

4500 RR = 1 US\$ for calculating indicator data on drug prices (rate for calendar year)

4080 RR = 1 US\$ to make calculations using the Oblast Health budget (rate for fiscal year)

1 *Novgorod Oblast budget or expenditures on pharmaceuticals US\$ per capita*

With a population of 742,000, the per capita drug expenditure in the public sector was 4.70 US\$ (19,176 Rubles)

2 *Existence of a system for recovering the cost of drugs dispensed in Public Health facilities*

Drugs patients receive in hospitals are paid for, either by Oblast Health Administration or the ASKO Medical Insurance Company with proceeds from the wage tax. See wage tax discussion in Medical Insurance section of this report. From drug budgetary constraints at this time it is evident that the Oblast Administration needs additional means to recover the costs of drugs dispensed.

3 *Percentage of patients who pay a charge for drugs they receive in Public Health facilities*

Normally the cost of inpatient drugs prescribed is covered by mandatory medical insurance, however, in cases where the hospital pharmacy does not have a prescribed drug, or the patient insists on a certain brand, the patient pays for the drug himself. Therefore, in the 18 hospitals surveyed 60 of the 540 patients observed or 11% paid for the prescribed drugs. Outpatients of public health clinics must pay for their drugs, with the exception of exempt patients, who obtain drugs free or at a discount.

4 *Percentage of total Oblast Administration budget used for Public Health*

The percentage of the total budget devoted to public health in Novgorod Oblast for the past 5 years was

1991	17%
1992	15.8%
1993	13.2%
1994	12%
1995	12%

The public health budget in 1995 was 29 million US\$ (118.662 billion Rubles). As can be seen over the last 5 years, the budget has decreased steadily.

5 *Percentage of total Oblast Public Health budget allocated to pharmaceuticals*

Novgorod Oblast allocated 12% (3.5 million US\$, or 14.239 billion Rubles) of its budget to pharmaceuticals. This has not been enough to provide the level of care outlined in the federal decree on mandatory medical insurance.

D Novgorod Oblast Pharmaceutical Procurement in the Public Health Sector*1 Existence of a policy limiting pharmaceutical procurement of drugs on the Drug Formulary List*

As noted there is no Oblast formulary and therefore no policy exists

2 Percentage by value of drugs purchased through a central procurement system

In Novgorod Oblast centralized procurement is managed by the Oblast Public Health Administration only for vital drugs, such as antibiotics, psychotropics, oncologicals, tuberculostatics, and insulins. The percentage by value of these drugs purchased versus the Oblast drug budget was 6% (210,000 US\$ or 857 million Rubles). The other drugs are purchased by the respective health facilities using Oblast budget funds, bypassing the economies of scale possible with centralized procurement.

3 Percentage of average international price paid for last regular procurement of a set of indicator drugs

Percentage of average international price paid for last regular procurement of indicator drugs is 90%

4 Percentage by value of Public Health drugs purchased through competitive tender

A competitive tender was done by Oblast Administration for insulins in 1995, which amounted to 5% by value of the drug budget (175,000 US\$ or 714 million Rubles). It was unsuccessful in that Pharmacia purchased the insulins with its own funds, and the Oblast could not readily provide reimbursement. Competitive tendering for all drugs used in the Oblast would result in more economic purchases, if financing can be assured.

E Novgorod Oblast Public Health Sector Pharmaceutical Logistics*1 Weighted average percentage of inventory variation for a set of indicator drugs in public sector storage and health facilities*

Using data from 15 public health facilities the weighted average percentage of inventory variation for the indicator drugs was 2.75%. In hospitals and community pharmacies the range was from 0-4%. This indicator measures the degree to which stock record keeping systems reflect the real status of drugs in stock.

2 Average percentage of individual variation for a set of indicator drugs in public sector storage and health facilities

Only 2 of 16 public sector facilities reported this indicator, the average percentage of individual variation for the indicator drugs was 15.5%. This indicator reveals the magnitude of discrepancy between records and the real stock levels of individual drug products.

- 3 *Average percentage of stock records that correspond with physical counts for a set of indicator drugs in public sector storage and health facilities*

Of the 16 public sector facilities reporting, it was determined that the average percentage of stock records that correspond exactly with physical count for the indicator drugs was 98.0%, indicating that the numbers obtained in C 1 and C 2 were somewhat skewed by a small number of items

- 4 *Average percentage of a set of unexpired indicator drugs available in public sector storage and health facilities*

Only 7 of 16 public sector facilities reported, the average percentage of available unexpired indicator drugs was 65.7%. The facility specific averages were: City hospitals - 86%, Rayon hospitals - 78%, Oblast and City warehouses - 58%, public sector pharmacies - 58%

- 5 *Average percentage of time out of stock for a set of indicator drugs in public sector storage and health facilities*

Data collectors were unable to collect this information during the survey

F Patient Access and Drug Utilization

- 1 *Population per functional public health facility that dispenses drugs*

With 561 health facilities and a population of 742,000 in Novgorod Oblast the population per health facility is 1322 persons

- 2 *Population per licensed pharmacist or pharmacy technician in the public sector*

With 176 pharmacists and 398 pharmacy technicians the population per dispenser is 1293

- 3 *Population per authorized prescriber in the public sector*

With a total of 4,351 prescribers in the Oblast the population per prescriber is 171 persons. Prescribers include physicians and feldshers

- 4 *Average number of drugs prescribed per curative outpatient encounter in public health facilities*

Of the 12 health facilities surveyed the average number of drugs prescribed per patient encounter was 2.4 with a range of 1.5 to 5.6 drugs per patient encounter

- 5 *Percentage of drugs prescribed by generic name in public health facilities*

Of 12 health facilities surveyed the percentage of drugs prescribed by generic name was 74%. It is easier to control drug costs when drugs are prescribed by generic name

6 *Percentage of drugs prescribed from the Oblast Drug Formulary List in public health facilities*

As noted previously, since Oblast does not have a Drug Formulary this data could not be collected

7 *Percentage of outpatients who received prescribed injections at public health facilities*

8 *Percentage of outpatients who received prescribed antibiotics at public health facilities*

With a range of 7% to 67%, the average percentage of outpatients prescribed injections was 22%

With a range of 13% to 83%, the average percentage of outpatients prescribed antibiotics was 28%

Injections and antibiotics are often expensive and it is important to assure these are properly prescribed

9 *Percentage of prescribed drugs presented for dispensing that are actually dispensed in public health facilities*

For the 7 facilities reporting data, 78% of outpatient prescriptions presented for dispensing were actually dispensed. The range was 59% to 100%. This indicator reveals the availability of the public health system to supply drugs when needed.

G Product Quality Assurance

1 *Public Health drug product quality laboratory tests during the past year, (a) number of drug products tested and (b) total number of drug product quality tests performed*

The number of drug products tested was not available, however, for the time period Oct 15, 1994 to Oct 15, 1995 the number of tests conducted were 9771 (some drugs have multiple tests performed). This indicator illustrates Oblast attention to drugs being purchased outside the Oblast. With the use of imported drugs increasing, this area needs special attention.

2 *Use of WHO Certification Scheme*

The WHO Certification Scheme is not used in Novgorod Oblast.

3 *Existence of formal systems for reporting (a) product quality complaints, and (b) adverse drug reactions (ADRs)*

No formal policies and procedures exist for these problems, adverse drug reactions and drug quality complaints are reported informally within the Oblast. A well developed program of drug complaints is needed to assure safety of the drugs arriving from varied sources as they do today.

H Private Sector Pharmaceutical Activity

Financial data reported during the survey covers the period October 1, 1994 through September 30, 1995 unless otherwise stated.

1 *Population per licensed private sector drug retail outlet*

Population per licensed private sector drug retail outlet is 20,054 persons, there were a total of 37 individual pharmacies and outlets in business during the assessment year

2 *Number of licensed or registered drug retail outlets per government drug inspector*

The number of licensed drug retail outlets per government inspector is 150

3 *Percentages of drug manufacturers, distributors, and drug retail outlets inspected during a one-year period*

During the period Sept, 1994 to Oct, 1995, 100% of drug manufacturers, distributors and drug retail outlets were inspected. Pharmacies were inspected 1.6 times, the one manufacturing firm was inspected one time, and the 30 drug warehouse/distributors in the Oblast were inspected an average of 2.0 times

4 *Total value of total private sector retail pharmaceutical sales US\$ per capita*

According to the Oblast Health Administration, the value of total private sector retail pharmaceutical sales is 938,000 US\$ (3.827 billion Rubles). With a population of 742,000, the value per capita is 1.26 US\$ (5,157 Rubles)

5 *Combined value of public sector pharmaceutical expenditures and private sector retail sales, US\$ per capita*

With the public sector pharmaceutical expenditures at 3.5 million US\$ (14.2 billion Rubles), and the private sector retail sales at 938,000 US\$ (3.8 billion Rubles) the combined value is \$5.98 (24,300 Rubles) per capita

6 *Percentage of products on Drug Formulary List that are currently manufactured or co-manufactured within the Oblast*

Since there is only one drug product manufactured in the oblast most drugs must be ordered from other oblasts or internationally

7 *Average of median private sector drug retail prices as a percentage of Public Health acquisition prices for a set of indicator drugs*

In 13 retail pharmacies reporting (2 of these are public), drug retail prices in 22 of 25 indicator drugs averaged 177% of Novgorod Pharmacia acquisition prices

8 *Existence of price controls for drugs in the private sector*

Drug pricing policy is determined by the Public Health Committee of the Oblast Administration. The current law was established on November 24, 1995 and limits total markup to 50% above the manufacturing price. There is no special pricing policy for staff or for any patient who cannot afford to pay for medication.

9 *Percentage of licensed drug retail outlets where an antibiotic was available without a prescription*

Antibiotics were available without a prescription in 92% of the pharmacies surveyed

24

**SECTION TWO:
FINDINGS OF THE NOVGOROD ASSESSMENT**

III PUBLIC SECTOR DRUG SUPPLY SYSTEM

A Structure and Organization of the Novgorod Drug Supply System

Novgorod Oblast is divided into 24 administrative units as follows

- 21 Rayons -- analogous to counties in the United States
- 2 City Rayons -- cities of Borovichı and Staraya Russa
- 1 City -- Novgorod

The public health system including the pharmaceutical sector, is organized into these administrative units. Funds for municipal and rayon budgets are provided by the Oblast Administration and ASKO Medical Insurance Company. In Novgorod Oblast public sector departments and organizations most involved in the administration and delivery of pharmaceutical services are

- Oblast Administration
- Oblast Health Administration
- Pharmacy Department
- Quality Control Department
- State Enterprise Pharmacia
- Hospitals/Health Facilities
- Community Pharmacies

Oblast Administration

The primary role of the Oblast Administration in the pharmaceutical sector is to finance and supervise the activities of the Oblast Health Administration, to which the Pharmacy and Quality Control Departments report. The Head of Oblast Administration (analogous to a United States governor) has the authority, as determined by federal law, to issue regulations affecting the pharmaceutical sector.

Oblast Health Administration

The main goal of the Oblast Health Administration is to coordinate public health activities through its various departments and committees. These activities include facility inspection, quality control, planning and finance, drug procurement, immunization schemes, and medical insurance. The Head of the Public Health Committee recently formed a working group to study how to improve the oblast drug supply during the year. During their work the group will deal with a gamut of issues like tax exemptions for medical centers, Pharmacia, and policies for insurance companies. Currently, the group is focusing on

- Centralized procurement
- Rational pharmaceutical management through implementation of formularies
- Opening drug information centers

The group has met 6 times, and their proposals are due by the end of 1996. Eventually, a decree on public health will be drafted by the group, to be made into an oblast law. The working group consists of

- Head of Oblast Public Health Administration
- Member of Novgorod Pharmacia Marketing Department
- Representative of Novgorod Pharmaceutical Association
- Director of Municipal Pharmacies which also function as warehouses
- Chief Specialists of the Public Health Committee
- Chief Physician of Veterans Hospital
- General Director of ASKO Medical Insurance Company
- Executive Director of the Mandatory Medical Insurance Trust
- Chairman of Novgorod City Public Health Committee

Work on standard treatment guidelines (STGs) is not part of this plan, since a group within the Commission for Medical Insurance is responsible for STGs

Pharmaceutical Department

The Pharmaceutical Committee was reorganized on October 16, 1995 establishing the Pharmaceutical Department and the Quality Control Department, which share responsibility for monitoring pharmacy practice. These departments report administratively to the Oblast Health Administration. There are two pharmacists in the Pharmaceutical Department whose responsibilities are

- to ensure compliance of pharmacies with all governmental standards in the areas of sanitary conditions, rules of drug dispensing, pricing, and special restrictions as outlined by individual pharmacy licences
- to ensure that proper procedures are followed in health facilities regarding use and dispensing of narcotics, spirits, poisons and other controlled drugs

During the assessment year, according to regulations, the Pharmaceutical Department inspected all pharmacies, warehouses, and the one manufacturing facility at least one time. The pharmacies serving as warehouses were inspected twice.

The main constraints identified by the Pharmaceutical Department in carrying out its functions are the following: too few personnel, lack of methodology from MOH on how Oblasts should license facilities, and transportation.

Quality Control Department

The main purpose of this department is to perform drug quality tests and inspect quality control labs located in various compounding pharmacies throughout the Oblast. Drug testing is done on random samples of commercially prepared medications which are pulled at Pharmacia. In addition, testing is done on drugs compounded by pharmacists in the Oblast, distilled water used in compounding IV solutions, and other drugs by special request. There are 9 pharmacists on staff who conducted 9,771 tests either in the Quality Control Department laboratory or on site in the respective pharmacies, during the period Oct 15, 1994 - Oct 15, 1995.

The main constraints identified by the Quality Control Department in carrying out its functions are the following too few personnel, material base is low such as equipment, testing reagents and standards, and lack of current information on drug quality testing

Pharmacia

Pharmacia is the state-owned agency responsible for the procurement, storage and distribution of vital drugs, vaccines, and medical supplies for the public health system in Novgorod. Although state-owned, Pharmacia is responsible for making a profit and supporting its own operations. The Pharmacia warehouse and offices are located within 2 kilometers of the Oblast health Administration offices, and employ 110 people, 48 being pharmacists or pharmacy technicians. The role of Pharmacia in the procurement and distribution of drugs is described in detail in other sections of the report.

Hospitals/Health Facilities

The network of medical and prophylactic establishments in Novgorod Oblast exists at various levels and is based on location of population (urban or rural), and the types of services provided. There are three tertiary care hospitals in Novgorod serving the entire Oblast, they are Central Oblast, Veterans, and Childrens Hospitals. At the rayon (county) level most have one general hospital, and one or more district hospitals distributed throughout the rayon. There are several specialty hospitals either in Novgorod city or in other rayons. Polyclinics and ambulatories (small clinics) located throughout the Oblast provide outpatient services. Dispensaries which offer inpatient and outpatient specialty services are usually found in the larger towns. Four sanatoria which serve to rehabilitate patients through physiotherapy, water treatment, and special diets are located in more pleasant areas of the Oblast. The most prevalent type of health facility is the Feldsher/Nurse station (first aid stations), which are found mostly in rural areas, there are 418 of these stations. The following data was collected from the four hospitals visited during the interview portion of the assessment.

	Oblast Hospital	Veterans Hospital	Children's Oblast Hospital	Central Rayon Hospital (Staraya Russa)
Annual Admissions	14,000	2,000	10,000	12,000
Number of Beds	925	100	540	520
Number of Physicians	180	53	80	131
Number of Nurses	Not reported	170	317	377
Has Pharmacy	YES	NO	YES	NO
Number of Pharmacists	2	NA	1	NA
Number of Drug Information Pharmacists	1	NA	1	NA
Number of Pharmacy Technicians	6	NA	4	NA
Does Compounding	YES	NA	YES	NA

There are 607 public health facilities in the network, with 505 of them capable of dispensing drugs. For a comprehensive summary of the health facilities and their locations see Appendix 5.

Community Pharmacies

Drug needs for the majority of the ambulatory population are met through a system of community pharmacies, which number 550 retail pharmacies at this time. Pharmacies may be State owned, or privately owned. Private pharmacies, however, normally only sell commercially prepared products and do not dispense to exempt patients, since this would slow repayment. Private pharmacies are not allowed to dispense controlled substances, spirits, and poisons. The Oblast Health Administration is studying the possibility of combining Pharmacia and several larger pharmacies to form a cooperative buying group, or possibly a single enterprise in order to take advantage of economies of scale.

B Public Health Facility Staffing

Actual Oblast staffing in all Public Health facilities at the time of the survey is presented in the table below.

Position	Number	Novgorod Population per Health Professional
Physician/Feldsher/Feldsher Midwife	4351	171 (physician only = 314)
Pharmacist/Pharmacy Technician	574	1293
Nurse/Midwife	4391	169
Dental Surgeon/Dentist/Dental Technician	181	1543

The lower number of pharmacists and pharmacy technicians per population in hospitals is notable. This is because Russian hospitals often do not have formal pharmacy departments, and facilities with pharmacies operate on a ward stock distribution system, rather than dispensing drugs to individual patients. In the case of physicians the opposite is true in that the population per physician world-wide is 3,980, in the United States is 420 and in Russia is 210.

IV FINANCE

A Funding Public Sector Drug Purchases in Novgorod Oblast

Russia has experienced a significant problem with the devaluation of the ruble in recent years, however, since the summer of 1995 the government is making an attempt to stabilize the currency. See Appendix 8 for a listing of the 1994 and 1995 Ruble to US\$ conversion rates

1 Sources of the funds

Funds were provided totally by the Oblast Administration, until the 2nd quarter of 1995 when funding was established from two sources

- Oblast budget-- monies come from several federal and local taxes
- Novgorod Oblast Medical Insurance Trust fund -- monies come from two sources
 - ▶ the wage tax levied on firms employing workers in the Oblast
 - ▶ oblast and local level administration budgets to cover medical expenses for the non-working public and target medical programs

2 Disbursement of monies to health facilities

A contract was awarded to ASKO Company, a private insurance company in Novgorod for disbursement of the Oblast and Insurance Trust funds. These monies are generally sufficient to cover salaries, food, and drugs of health facilities. Reserve funds to cover debts of hospitals to pharmacies and to cover needs such as repairs to facilities are also available from ASKO, however, they do not have to be repaid, since this is stipulated in the mandatory medical insurance regulations. Pharmacia and community pharmacies are self supporting and do not receive funds from ASKO. ASKO employs 38 people, 21 of them working in rayons with local tax inspection departments to collect wage taxes from firms.

B Novgorod Oblast Consolidated Public Health Budget and Expenditures

1 Amount Allocated for 1995 (Shows figures updated in September, 1995)

<u>Budget Category</u>	<u>US\$(millions)</u>	<u>Rubles (billions)</u>
Oblast Budget (Target Health Programs and Special Oblast Level Health Facilities)	6 45	26 3
Non-working population insurance payments	9 73	39 7
Rayon and municipal budgets	6 08	24 8
Receipt of wage tax from firms	7 35	30 0
Totals	29 61	120 8

2 Amount Spent in 1995

The total expenditures were 34 8 million US\$ (142 billion Rubles)

3 Amount Allocated for 1996

<u>Budget Category</u>	<u>US\$(millions)</u>	<u>Rubles (billions)</u>
Oblast Budget (Target Health Programs and Special Oblast Level Health Facilities) *	12 3	50 3
Non-working population insurance payments	11 1	45 3
Rayon and municipal budgets	20 6	84 0
Receipt of wage tax from firms	15 1	61 7
Totals	59 1	241 3

* The target programs for 1996 are scientific research, continuing education, mother and child programs, and immunoprophylaxis

C Pharmacia Financial Information

The following figures are reported for the period January 1, 1995 to November 1, 1995. As is mentioned elsewhere in the report, Pharmacia is providing a decreasing percentage of drugs to the public health sector, since many hospitals and pharmacies are free to order from any source (manufacturers, wholesalers, pharmacies)

<u>Category</u>	<u>US\$ (thousands)</u>	<u>Rubles (millions)</u>
Drug inventory value 11-1-95	461 1	1881 4
Recurrent funds as of 1-1-94	31 6	128 9
Recurrent funds as of 1-1-95	110 3	450 0
Recurrent funds as of 11-1-95	308 1	1257 2
Revenues from drug sales	608 7	2483 3
Drug purchases	2400 0	9792 0
Hard currency drug purchases	288 7	1177 9
Operating expenses		
Salaries	68 7	280 4
Interest on bank loans	50 8	207 4
Facility maintenance	59 1	241 2
Other	141 8	578 6
Debts to suppliers	485 8	1982 0
Pharmacia Accounts Receivable		
Community pharmacies	130 0	530 2
Hospitals	128 0	522 3
For Exempt Patients	31 8	129 9
Humanitarian aid for 1995	0	0

The following table shows the breakdown for Pharmacia purchases from major suppliers for the period 1-1-95 to 11-1-95. Pharmacia purchased drugs from 110 suppliers during this period.

	<u>US\$</u> <u>(thousands)</u>	<u>Rubles</u> <u>(millions)</u>
Manufacturer, located in		
Mercurii, Saransk	57 1	233
JS Rospharmacia, Moscow	51 5	210
Pharmindustria, Moscow	49 0	200
October, St Petersburg	45 6	186
Rosmedbasa, Moscow/Reutov	30 4	124
Semasko, Moscow	29 4	120
Biomed, Moscow	13 0	53
Wholesaler, located in		
Transpharma, Berlin	171 6	700
Protech, Moscow	78 9	322
Biotech, Moscow	25 7	105

Pharmacia has managed one tender, which occurred in 1995 for insulins in the amount of 250,000 US \$ (1 02 billion Rubles) Drugs purchased through direct negotiations totaled 10% of all purchases

D Hospital Financial Information

The following table shows financial information for the 4 hospitals visited during the interview portion of the survey, and covers the period October 1, 1994 to September 30, 1995 Data was not always available since budgets and funds were variable during the period

Numbers are in: Thousands US\$ (Billions Rubles)	Central Oblast Hospital	Veterans Hospital	Children's Hospital	Central Rayon Hospital (Staraya Russa)
Total Budget Requested	265 7 (1 084)	331 6 (1 353)	1960 8 (8 0)	887 5 (3 621)
Total Budget Approved	420 3 (1 715)	207 8 (0 848)	1062 3 (4 334)	730 0 (2 978)
Drug Budget Requested	147 1 (0 6)	50 5 (0 206)	Not reported	691 9 (2 823)
Drug Budget Approved	146 8 (0 599)	33 8 (0 138)	297 8 (1 215)	133 6 (0 545)
Total Drug Purchases	Not reported	2 9 (012)	249 8 (1 019)	76 5 (0 312)
Drug Purchases from Pharmacia	Not reported	Not reported	16 2 (0 066)	76 5 (0 312)
Drugs from Donations	Not reported	0	Not reported	Not reported

Current Debt to Pharmacia	27 0 (0 110)	8 8 (0 036)	Not reported	20 1 (0 082)
Total Debt to Drug Suppliers	39 2 (0 160)	28 2 (0 115)	42 9 (0 175)	20 1 (0 082)

E Financial Debt in the Pharmaceutical System

The Oblast Health Administration reported that with difficult economic circumstances at this time, drug prices are very high. Those drugs needed in hospitals and pharmacies are usually available, but often there are not enough funds in the budget to provide them. Current priorities are to provide funds for the purchase of drugs for exempt patients. The following information summarizes the pharmaceutical debt situation at this time.

- Director of Pharmacia goes to the Oblast Administration to try and secure funds for hospitals when they do not have money to pay for drugs
- Hospitals must prepay Pharmacia for short supply or low volume drugs
- Reimbursements to pharmacies for exempt patient drugs can take up to 6 months. During this period the balance due is not indexed to inflation
- For 3 of the 4 hospitals surveyed, current debt to Pharmacia is 55,900 US\$ (228 million Rubles). See table in previous section for breakdown by hospital
- For the 4 hospitals surveyed current debt to all suppliers is 130,400 US\$ (532 million Rubles). See table in previous section for breakdown by hospital
- Total unpaid debts to Pharmacia from hospitals, community pharmacies and reimbursement by Oblast Health Administration for exempt patient drugs at the time of the survey was 289,800 US\$ (1 182 billion Rubles)
- ASKO still owes Pharmacia 95,000 US\$ (387 6 million Rubles) from the tender conducted in 1995 where Pharmacia used its own funds to purchase the drugs

F Pricing Policy

Drug pricing policy is delegated to the Public Health Committee of the Oblast by Decree # 890, November 24, 1995 setting 50% as the maximum markup. Drug pricing markups in the Oblast currently range from

Wholesalers to hospitals and pharmacies	5-25%
Pharmacies to hospitals or the public	25-45%

According to the Oblast Health Administration, 29 pharmacies experienced financial difficulties in 1993

all in rural areas. Fourteen of the 24 municipal pharmacy enterprises serving also as wholesalers to hospitals were all making a profit, however, 10 of the municipal pharmacies located in rural areas were not profitable according to data obtained in October, 1995.

There is no problem accessing foreign exchange for use in purchasing pharmaceuticals when Ruble funds are available. The Mandatory Medical Insurance Fund has a Deutschmark account, and the Oblast Financial Committee has a US\$ account. The Commission on Economics has a special bank account for emergency purchases. Access is controlled by the Oblast Public Health Committee.

G User Fees

In hospitals most inpatients receive drugs and services free of charge. Payments to the hospitals for these services are made from ASKO Insurance Company, and/or Oblast Health Administration budget depending on type of service and type of patient. Since 1993 health facilities have had the option of establishing a fee-for-service unit in the facility. The fees must be approved by either the oblast or rayon committee on pricing. There are two private clinics in the oblast, one for cosmetic surgery, the other for public sector vehicle operators. Generally physical therapy services are provided on a fee for service basis.

Effective November 1, 1995 fees for medical services were established by Oblast Health Administration, Novgorod Medical Insurance Trust, and ASKO Insurance Co. The fees were established per patient day for three levels of health facilities: Oblast, Inter-Rayon, and Rayon. The breakdown of the fees is as follows: 60% salary and benefits, 14% meals, 10% drugs, and 16% incidentals. The following table illustrates some of these fees.

Treatment	Daily Cost	Oblast Level		Inter-Rayon Level		Rayon Level	
		Avg # Days Stay	Total Cost	Avg # Days Stay	Total Cost	Avg # Days Stay	Total Cost
Cardiology	5.43 (22.15)	23	124.9 (509)	21	113.4 (465)	20	100.0 (443)
General Surgery	7.4 (30.40)	16	119.2 (486)	15	111.7 (456)	13	96.8 (395)
Urology	11.2 (45.7)	17.5	196.00 (799)	12	134.4 (548)	na	na
Orthopedic	10.9 (44.7)	25	274.0 (1118)	20	219.2 (894)	20	219.2 (894)
General Therapy	4.2 (17.1)	22	92.2 (376)	16.5	69.1 (282)	16.5	69.1 (282)

In order to receive reimbursement for services rendered, hospitals must submit a monthly invoice to ASKO with the following information

- a list of hospital departments
- average length of stay for each type of treatment
- cost for one patient day
- number of admissions
- number of polyclinic (outpatient) visits

H Exempt Patients

Federal decrees #890 and #710 dictate that certain categories of the population whether inpatient or outpatient, have the right to receive drugs totally free or at a discount. Examples of those patients receiving drugs free of charge are war veterans, children 0-3 years old, diabetics, and those with AIDS. Retirees who receive the minimum pension qualify for a 50% reduction in the cost of their prescriptions.

In the three community pharmacies visited during the survey it was estimated that 30% of patients were allowed exemptions from the cost of prescriptions, the range was 3% to 60%. This compares to the overall estimate of 30 to 50% exempt patients in the Oblast.

In July, 1995 the Oblast Administration recommended that each of the 21 rayons designate 1 or more pharmacies to fill all exempt prescriptions. On the day of the survey this activity had not been completed, except for Novgorod City Administration where 3 pharmacies have been selected for filling all exempt prescriptions. Central Pharmacy, pharmacy at Veterans Hospital, and another pharmacy in the most populated area of the city.

I Insurance Medicine

1 Mandatory Medical Insurance

Novgorod Oblast has developed an oblast-wide medical insurance program for all citizens of the Oblast in order to carry out the federal law, "On Medical Insurance for the Citizens of the Russian Federation." In principal, all citizens are to be provided with complete medical coverage, including drugs, which is funded by Oblast Administration and municipal budgets, and by the 3.6% wage tax collected from employers in the Oblast. A fund for preventive measures receives 0.2% of the wage tax.

Novgorod Oblast Medical Insurance Trust (the Trust) has been established to oversee the medical insurance program. The Trust has been defined as an independent, non-commercial, financial-crediting state organization, which accumulates and balances finances for the Novgorod Oblast program. Its finances are the property of the Russian Federation and are not included in the budget or any other funds for the Oblast.

The Trust has hired the ASKO Insurance Company to disburse the funds to health facilities in Novgorod. Pharmacia and community pharmacies are self funded and do not receive subsidies as

hospitals and health facilities do. In addition ASKO is responsible for ensuring compliance by the hospital or health facility with its own standard treatment guidelines, as well as those provided by the MOH.

Of funds collected by the Trust, Oblast Administration retains 1%, ASKO retains 3% to cover operating expenses. In 1995 Novgorod Oblast contributed 1.78 billion rubles to the insurance fund, and received 6.0 billion rubles from the federal government. The funds were used as follows:

- 1st quarter -- covered debts of all health facilities
- 2nd quarter -- purchased equipment for the veterans hospital
- 3rd quarter -- paid hospital expenses
- 4th quarter -- raised salaries of medical workers

In 1996 ASKO is budgeted to receive 50 billion Rubles from the oblast wage tax, and 90 billion Rubles from the oblast health budget for the non-working population, for a total of 140 billion Rubles. This should provide about 12 billion rubles per month, but the director expects that 9 to 10 billion rubles is a more realistic figure of monthly receipts.

2 Private (Voluntary) Insurance

ASKO is a general insurance company offering health, property, and life insurance. Its voluntary insurance department was established four years ago. ASKO indicated that the biggest obstacle to growth by the department is lack of ability by the population to pay premiums.

With the family policy, medical, maternity and dental services are completely covered. ASKO states that patients with policies will be guaranteed a comfortable environment for medical care delivery, for example, maternity patients with insurance must go to a designated hospital for delivery. Patients without insurance can go to these facilities and pay for the same services. The medical insurance policy also includes life insurance for both mother and child.

J Areas of Concern Related to Finance

- Availability of funds for drug procurement was frequently cited as a problem for oblast health facilities.
- Drug prices have increased since 1991 and drug budgets have decreased.
- Debts owed by health facilities to Pharmacia and other drug suppliers preempts them from ordering from those suppliers until the debts are resolved.
- Devaluation of the ruble has averaged 6% a month since January, 1994, and will continue to strain the economy, public health budgets, and drug procurement.
- Approximately 30-50% of outpatients receive prescriptions either free of charge or at a discount under the current system, and reimbursement to pharmacies are problematic given the current rate of inflation.

V DRUG PROCUREMENT IN THE PUBLIC SECTOR

This section of the report details drug procurement procedures at various stages of the drug distribution cycle. Data was obtained through interviews at the Oblast Health Administration, Pharmacia, and several hospitals and pharmacies.

A Procurement Decisions and Responsibilities

Until 1991 all drug procurement for the public sector was done by Novgorod Pharmacia, which orders from both domestic and international suppliers. However, as the market economy develops, market share has decreased. Based on procurement price, Pharmacia currently supplies 40 % of drugs for the public sector in municipal facilities and 60% in rural settings.

1 Drug procurement by Pharmacia

Pharmacia is made up of the following departments:

- Commercial department -- determines which drugs and quantities to purchase, and where to buy them. The department has eight employees, all pharmacists or pharmacy technicians. Quantities are calculated based on discussions with the Sales and Warehouse departments. Each pharmacist in the Commercial Department is responsible for a particular class of drugs. Given limited resources for procurement, Pharmacia has a goal of keeping some drugs in stock in each class.
- Marketing Department -- performs market research for monitoring prices of drugs used in the oblast.
- Sales Department -- responsible for sales to all clients.
- Storage Department -- responsible for warehouse management and price adjustment. The department may lower prices to increase turnover, this is based on markups of every drug received. The average mark-up is up to 15%, however, this is adjusted upward to cover drugs with lower margins. As noted previously, the maximum mark-up is 50%.

Certain medications can only be purchased and distributed by Pharmacia, as mandated by Federal and Oblast decree. They are insulins, narcotics, vaccines, and serum (vitaly important drugs). For that reason they are considered priority items by the firm.

Previously determined minimum stock levels are used to trigger purchases. However, to determine order quantities of endocrine drugs, records of registered diabetics are used, for vaccines, the Oblast Chief Epidemiologist is consulted, for other drugs, order quantities are determined mainly by availability of funds.

Typically yearly contracts are signed for drug procurement, with monthly receipts of drugs. The initial price agreement is really for the first month, and prices are negotiated monthly thereafter. If delays in delivery are predicted, prices can be negotiated downward. Pharmacia purchases only from suppliers.

that accept delayed payment, with the delay range being about 10-90 days. The lowest possible price for purchases is sometimes not chosen because of the payment terms.

Information Center

An information center is being designed to collect information from suppliers in the oblast. The center will function primarily to provide information on availability and price, and secondarily for medical information. The center will be funded by those suppliers that are providing information.

Management Information System

A computer based system is used by the firm which has the capability of producing invoices, automatically calculating late payment fines, and maintaining stock counts. However, it cannot be used to manage tenders, nor does it have a field for entering expiration dates.

Procurement from Non-Domestic Sources

- Former Soviet Suppliers -- narcotics are purchased from Kazakstan, Gyurza snake antivenom from Uzbekistan. Payment to Kazak, and Uzbek companies are in US\$.
- International Suppliers -- purchases are generally done through local representatives with the exception of Pfizer, and Japanese companies. For example, Eli Lilly has a local representative. Pharmacia tries to do business only with international firms that provide educational programs, and those that accept delayed payment, as all companies mentioned here do.

Breakdown of purchases

Pharmacia estimates that up until now, 60% of the drugs it purchased were produced by international manufacturers, although direct purchases from international producers, including former Soviet republic producers amounted to < 10%. The trend is changing and Pharmacia estimates purchases for drugs produced domestically is approaching 50%. It is notable that many drug manufacturers in Russia own wholesale companies.

Procurement by Tender

The oblast managed one tender in 1995. The tender was announced in the press, and requested that interested suppliers send selling prices for antibiotics and endocrine drugs. The announcement stated that one supplier would receive all funds for the procurement, although the amount to be provided was not specified. It was later decided that the tender would be for 175,000 US\$ (714 million Rubles). Novgorod Pharmacia won the tender, and the oblast requested that a quantification exercise for insulin be conducted. Pharmacia did the quantification, negotiated prices with suppliers, and purchased the insulin using its own funds from Eli Lilly Co. To date 95,000 US\$ (387.6 million Rubles) of the tender fund is still owed to Pharmacia by ASKO Insurance Co. Pharmacia won this tender partly because it had the only cold-chain capabilities in the oblast at the time, but now other suppliers have cold-chain capabilities as well. Since that time, Novgorod Pharmacia and Eli Lilly have opened two diabetes education centers, which they hope will enhance their chances of winning future tenders.

At Oblast Health Administration request, Pharmacia will conduct a tender in January, 1996 for the following drug categories, anti-diabetic, psychotropic, tuberculostatic, oncological, cardiologic, antiarrhythmic, asthma, antihypertensive, and connective tissue disorder. Before the tender, Oblast Health Administration will decide which drugs within the categories will be included. The tender will total 3.1 million US\$ (12.5 billion Rubles), and is calculated to save 40% (1.2 million US\$ or 5 billion Rubles) if tendered directly from drug manufacturers. Commission to be involved in the tender is comprised of the following Oblast Health Department Chiefs: Economics, Finance, Surgery, Pediatrics, Therapeutics, Physician Association, Deputy Head of Oblast Administration, Chairman of Oblast Health Committee, Chairman of Pharmaceutical Department. They are considering the inclusion of a representative from the Insurance Foundation on the commission, as well. If Oblast budget will not allow the total tender amount, then a tender only for insulin will be made.

2 Drug procurement by health facilities

Ordering from Pharmacia

Hospitals provide a yearly drug estimate to Pharmacia, drug orders are placed daily to monthly depending on the particular drug. Order quantities are usually determined at a joint meeting with all hospital department heads and the pharmacy director, during which a review of past consumption and disease patterns is considered. Ultimate authority for drug purchases rests with a combination of Chief Physician, Deputy Chief Physician, and Pharmacy Director (unless there is no hospital pharmacy). Monthly orders are placed to Pharmacia on forms containing the following information: name, strength, and dosage form, date order submitted, date order received, quantity ordered, and quantity received. Daily orders are placed by telephone, and are often in the form of inquiries to ascertain if Pharmacia has received a needed drug yet. Payment is made through bank transfers after receiving the orders, which takes approximately 3 days. Orders are received almost on a daily basis. The major problems in getting drugs from Pharmacia are unavailability of various drugs, excessive cost of some drugs compared to other sources, and availability of hospital funds.

Drugs are not dispensed at Polyclinics with the exception of eye drops for diagnostic purposes and vaccines. These drugs are purchased and delivered by Pharmacia to clinics and pharmacies, pharmacies in turn deliver to Polyclinics, Feldsher and Midwife stations.

Ordering from sources other than Pharmacia

Hospitals purchase drugs from any source they wish, and owe lots of money to many firms, rather than paying these debts, most are taking budgeted money and buying from companies they don't owe, according to the Oblast Health Pharmaceutical Department. Currently, purchases are being made from several private sector suppliers, through negotiated procurement on an as-needed basis. The chief physician usually approves all such orders, but one hospital indicated that the pharmacy director also has authority. Orders are placed by telephone, received within 1 to 7 days, and payment is made through bank transfer within 3 days after the order is received. The main problem with drug procurement from the private sector is availability of hospital funds.

B Areas of Concern Related to Drug Procurement

The following concerns were noted during the survey

- Competitive tendering procedures have only been utilized 1 time, which was for one drug only. Prices continue to be high and this puts a strain on the drug procurement budget.
- There is a lack of consolidated information at all levels of the oblast concerning reliability, product quality and comparative prices of drugs. There are over 1200 drug wholesale and manufacturing firms in Russia alone, plus a vast number of international firms.
- The computer system at Pharmacia is not adequate to monitor orders placed by tender or from a diverse set of suppliers. It also does not track expiration dating of drugs. Likewise it cannot perform standard procurement analyses such as ABC and VEN analyses. These tools will become critical as increasing prices and decreasing state subsidies force all purchases to be limited to the most essential pharmaceuticals.
- Under current regulations, receipt of drugs by Pharmacia without invoice causes unnecessary delays in distribution, because a selling price cannot be fixed by Pharmacia without the invoice.
- Some drugs received with quality certificates are nonetheless subject to testing by the Oblast Quality Control Lab, resulting in financial loss for Pharmacia, since Pharmacia must pay for the tests.
- Unbiased drug information necessary to make rational procurement decisions, is limited at Pharmacia and health facilities.

VI DRUG DISTRIBUTION IN THE PUBLIC SECTOR

Drugs enter the Novgorod Oblast drug distribution system from supply points that include both domestic wholesalers and manufacturers, as well as foreign manufacturers. Within the oblast Pharmacia has been the major wholesaler of pharmaceuticals, but this is changing as the market economy takes effect, and subsidies to health facilities diminish. For example, there are now 5 private sector wholesale drug companies, and 24 public sector pharmacies that serve as wholesalers in the oblast, in addition to Pharmacia. Hospitals and pharmacies can purchase drugs from any of 1200 firms in Russia that sell drugs.

A Novgorod Pharmacia

Inventory Levels

Usually about 100 drug products and 25 medical supplies are in stock at one time. Pharmacia tries to achieve an inventory turnover rate of 30 days, but during the last reporting, turnover averaged 45 days. Inventory levels are kept as low as possible because of lack of funds, and due to the fact that interest rates for loans to purchase drugs can be from 14% to 180%. Turnovers can be lengthened by delays with the Oblast Quality Control (QC) Lab, since drugs cannot be sold until they have passed QC Lab testing.

Storage

Reserves are kept for certain critical drugs, including medical gases, alcohol, vaccines and selected narcotics in special storage areas. These drugs are regularly rotated to prevent expiration, and other drugs are arranged in the warehouse by therapeutic category. Physical stock counts are done twice a year.

Receiving

Imported drugs are kept in a quarantined area until they have cleared customs. Others are kept in the receiving department until clearance by the quality control laboratory. Narcotics and medical gases are kept in special storage.

Transportation

Pharmacia has approximately 300 clients, the closest is located within 500 meters of the warehouse, the farthest is 600 kilometers away. Clients are not on a specific supply schedule, with the exception of oxygen supply. Pharmacia has 25 trucks, its own garage and a contingent of mechanics to maintain the vehicles. Delivery is usually done immediately, in order to be competitive with other suppliers. Delivery charges are based on mileage and the type of truck used, but deliveries are made free of charge for drugs that need quick turnover. Delivery charges are sufficient to pay for the expenses of the garage.

Supply to Clients

Clients must have required licenses, including narcotics licenses, before Pharmacia will enter into contracts with them. Contracts with regular clients are for one year. If a particular drug is out of stock, therapeutic substitution of drugs is done only by agreement with clients.

Returned Goods

Drugs have been returned by Pharmacia to suppliers for the following reasons incorrect labeling where product label differed from outer package, presence of impurities, and products found to be radioactive Sale of drugs is sometimes delayed due to improper shipping documents These problems are negotiated with the supplier

B Other Health facilitiesCompounding

Three of the 4 hospitals visited have pharmacies and do compounding of prescriptions and repackaging of drugs for distribution within the hospital Compounding is done by the pharmacist using reference books for instructions on a particular formula Batch records are kept and quality tests are performed on each batch compounded The Oblast Quality Control Department does random testing of these formulae to verify accuracy Quality tests include physical and chemical tests such as a titrated colorimetric method, which are used for both qualitative and quantitative reports Unavailability of reagent solutions for quality tests was mentioned as an occasional problem The following table shows drugs that are compounded at the Children's Hospital Note that several of them are large volume parenteral solutions The distilled water used to manufacture these is manufactured and tested daily at each pharmacy

Compound Name	Units Compounded per Month
Glucose Inj 5% 1000 ml	500
Potassium Chloride 4% 1000 ml	60
Sodium Chloride 0.9% 1000 ml	400
Vaseline Oil	8
Glutamic Acid	10
Hydrogen Peroxide	300
Potassium Permanganate	5
Magnesium Sulfate	12

Transportation

Other than from Pharmacia most drug orders are picked up by the purchaser, however, some private sector suppliers deliver drugs to the facility with price included in the cost

Storage of Drugs

Drugs are mostly stored in cabinets, by therapeutic groups, using a first in- first out- rotation method,

however, larger quantities are stored on pallets. Cold chain refrigerator and freezer temperatures are checked on a daily to weekly basis, but are not recorded.

Receiving Procedures

Drugs for the pharmacies are received and checked by the director of the pharmacy with assistance from technicians as necessary. Copy of the invoice is then forwarded to the accounting department. For hospitals without pharmacies, the head nurse receives, checks and stores the drugs on the appropriate ward. In one case drugs were returned to Pharmacia because of unexpected price changes.

Product Quality Assurance

Poor packaging was reported as the major problem, in one case some vials were received without labels. When problems occur the director of pharmacy and head physician decide whether the problem warrants sending drugs back to supplier.

Inventory Management

The number of drug items kept in the pharmacies varied from 200 to 700. Ledgers are generally used to manually record inventory levels, but at Children's Hospital, a computer is used for this purpose. In one pharmacy using the manual method it was reported that a monthly physical stock count is done, while counts are done annually in the hospital having a computer.

C Areas of Concern Related to Drug Distribution

- As the number of local distributors increases, it will become increasingly difficult to monitor the public sector drug distribution system. The impact on large distributors like Pharmacia will likely be significant.
- Floor stock drug distribution systems are used in hospitals in the oblast, and pharmacy departments do not exist in others, resulting in little or no pharmacist involvement in monitoring inpatient drug distribution and use. Floor stock systems generally require a greater amount of drugs in the distribution pipeline.
- There is not an indicator based, systematic program for monitoring pharmaceutical distribution in oblast health facilities, coupled with the fact that the Oblast Health Administration Pharmaceutical Department has fewer resources than in former times.

VII COMMUNITY PHARMACY

Drug needs for the majority of the ambulatory population are met through the system of community pharmacies. Until 1995 pharmacies were partially subsidized by Oblast Administration to cover their losses. At present the 14 of the 24 public sector pharmacy enterprises that also serve as wholesalers are profitable. Pharmacies may be State owned, or privately owned. Private pharmacies prefer to sell commercially prepared products, they do not compound prescriptions nor fill exempt patient prescriptions for economic reasons.

A Structure of the Pharmacy Network

Number of Retail Pharmacies

Municipal and rayon pharmacies -- 70 (47 in cities, 23 in rural areas)

Pharmacy outlets in feldsher/ambulatory stations supplied by municipal and rayon pharmacies -- 418

Kiosks that belong to larger pharmacies -- 19

Private pharmacies -- 37 (pharmacies and kiosks)

Pharmacies operated by Novgorod City Pharmacia -- 6

Total number of retail pharmacies and outlets-- 550

Reforming the Pharmacy Network

To order to make the network more efficient and economically viable, the Oblast Health Administration is considering the following options:

- Detailed assessment of individual rayons to evaluate the possibility of turning some municipal pharmacies into pharmacies budgeted by hospitals. This may not improve efficiencies in some rayons, since municipal pharmacies sometimes only supply one retail pharmacy each.
- Turn Novgorod Pharmacia and the 24 municipal pharmacies into joint stock companies belonging to the same "Association."
- Turn Novgorod Pharmacia and the 24 municipal pharmacies into one joint stock company only.

In all cases the Oblast Administration would retain at least 50% of the joint stock shares.

B Regulation and Inspection

Pharmaceutical services provided by public and private sector pharmacies, hospitals, and manufacturing facilities are monitored by the Pharmaceutical and Drug Quality Control Departments of

the Oblast Health Administration. However, many other Federal and Oblast agencies also inspect pharmacies including the following: Pricing, Narcotics, Tax, Finance, Sanitation and Epidemiological Control. All pharmacies are inspected regardless of size. According to law, pharmacies, manufacturing companies, and wholesalers must be inspected once a year, and according to records all were inspected at least once during the last fiscal year (Oct 1, 1994 - Sept 30, 1995). Results of inspection visits are recorded and a copy sent to the respective pharmacies with deadlines for corrections. An example of pharmaceutical services monitored are

- Records of prescriptions for narcotics, poisons, and exempt patients only. All records of financial transactions, must be kept at a pharmacy or clinic for inspection purposes
- Generic substitution is demanded at the Oblast level
- Therapeutic substitution is allowed by prescriber authority only

Pharmacy services no longer monitored are

- number of pharmacies in a geographic location or for a given population
- number of employees in a pharmacy

C Community Pharmacy Interviews During the Assessment

Three pharmacies were visited, two in Novgorod city, one in Staraya Russa rayon where the Central Rayon Hospital is also located. Clients utilizing these pharmacies ranged from 80,000 to 100,000 patients. The average number of patients visiting the pharmacies on a given day varied from 200 in the case of Staraya Russa to 5000 for Apteka #54 in Novgorod city. The average number of daily visits were determined from cash register and exempt prescription records, since a record of all prescriptions dispensed by a pharmacy are not kept.

Pharmaceutical Services

Types of products provided to outpatients are: commercially prepared drugs, compounded drugs, non-prescription drugs such as aspirin and cough syrup, herbal preparations, controlled substances, narcotics, syringes, shampoo, blood pressure cuff and stethoscope, testing kits for pregnancy and some crutches, walkers and wheel chairs. In the pharmacies surveyed, insulin is not provided unless to inpatients of a hospital. Other specialty products such as gynecological products, oral contraceptives, IV solutions, dressings and bandages, feminine hygiene products, and incontinence products are often available for outpatients.

Pharmacists provide the following services: counselling patients on the proper use of medicine, providing information to prescribers on new medications, and training of pharmacy students prior to graduation. In most cases pharmacists do not serve on public health committees unless the pharmacy is the primary supplier for a larger hospital (eg Staraya Russa pharmacy).

Staffing

The following staffing was reported for each of the three pharmacies visited during the interview portion of the survey. This information was also viewed for previous years, and indicated a fairly stable staffing pattern.

Number of Employees	<u>Pharmacia State Enterprise Pharmacy # 1</u>	<u>State Enterprise Pharmacy # 54</u>	<u>Central Rayon Pharmacy # 93 (Staraya Russa)</u>
Pharmacists	0	11	4
Technicians	2	19	5
Clerks	0	2	2
Cashiers	0	2	0
Drivers	1	0	0
Clean/Wash	1	4	3
Assistants	0	0	2
Avg. Number Hours Worked per week	35	35	35

Dispensing

In every community pharmacy, pharmacists discuss potential patient allergies, drug-drug reactions, and other problems, both pharmacist and pharmacy technician interpret, fill, or compound prescriptions (if compounding is done at that pharmacy), and the analytical pharmacist checks drugs that have been compounded. Usually the pharmacy technician will hand the medication to the patient. For compounded prescriptions the following information appears on the label: patient name, pharmacy name, date compounded, name of drug, number of units, number of analysis, expiration date, storage conditions, external use only (if appropriate), and sterile (if appropriate). The table below compares the percent by value of different drug categories.

Sales Category Percentages by Value	<u>Pharmacia State Enterprise Pharmacy #1</u>	<u>State Enterprise Pharmacy # 54</u>	<u>Central Rayon Pharmacy # 93 (Staraya Russa)</u>
Compounded Rx's	0	14	8
Prescription Drugs	60	48.6	44
OTC Drugs	35	35	43
Sundries	5	15	5

47

Contact with physicians occurs frequently and is done on an as-needed basis

Pharmaceutical Monitoring

For all pharmacies visited, the last inspection was by the Oblast tax agency in November, 1995, with the purpose of determining if local taxes had been paid and to check prescription prices. No problems were reported with the inspections.

Drug Information

The patient receives the following information orally by the pharmacist or pharmacy technician each time a new prescription is dispensed: name and strength of drug and verbal dosage instructions, however, special instructions (eg suppository, ophthalmic, etc), and in some cases potential adverse reactions are communicated by the pharmacist only. Written information is provided on request, unless the pharmacist thinks the situation warrants it, like for elderly patients. Package inserts are given to the patients who receive commercially prepared medications. Drug references available in the pharmacy are *Mashkovsky, Vidal, and the Russian Pharmacopoeia*. These and other references are updated as they become available.

Inventory Management

The number of drug items varied from 360 in the Staraya Russa Central Rayon pharmacy to 1619 in one of the Novgorod City pharmacies, with commercially prepared drugs constituting the majority of the products. Inventory records are kept in a variety of ways but primarily using stock cards and ledgers. Physical inventories are done twice a year consistently, with the most recent inventories being conducted the latter part of November, 1995.

The mix of drugs in stock, as well as the quantity to order at any time is determined by the head pharmacist, who usually uses a pre-determined minimum level to stimulate re-ordering. However, lack of funds for procurement is a frequent problem. A tracking system for drug orders is done manually and contains the following information: date order placed, quantity ordered, quantity received, estimated cost, and date order received.

Drug procurement

Drugs are ordered from Pharmacia from one to four times monthly. Normally orders are received within one to two days, except for the rayon pharmacy which ranges from two to seven days. Orders are placed by telephone (one pharmacy sometimes uses telefax), with bank transfer being the primary payment method. The major problem experienced in getting drugs from Pharmacia is excessive mark-up for some groups of drugs, consequently, pharmacies are ordering from different suppliers.

Value of inventory as well as drug purchases were recorded for the pharmacies as follows:

Thousands of US\$ (Millions of Rubles)	<u>Pharmacia State Enterprise Pharmacy #1</u>	<u>State Enterprise Pharmacy # 54</u>	<u>Central Rayon Hospital Enterprise Pharmacy # 93</u>
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Inventory Jan 1, 1995	17 0 (69 49)	50 5 (206 15)	5 6 (22 862)
Inventory Jan 1, 1994	7 4 (30 0)	8 2 (33 53)	3 9 (16 064)
From Pharmacia Aug-Oct, 1995	56 5 (230 635)	102 5 (418 0)	70 1 (286 0)
From Other Suppliers	Not reported	196 3 (801 0)	34 7 (141 5)
Direct from Manufacturer	Not reported	48 6 (198 2)	19 4 (79 0)
Carried on consignment	Not reported	82 2 (335 2)	8 4 (34 178)

Financial Data

Two pharmacies reported they do not pay rent for pharmacy occupied space, however, one pharmacy does pay rent. Financial data is collected either by the chief pharmacist or bookkeeper if one is on staff. For exempt patients pharmacies receive reimbursement directly from the Oblast Health budget or through an insurance company, which can take from 1 to 6 months. During this waiting period the balance due is not indexed to inflation. Records of billings are kept and reconciled with payments on a monthly basis. An estimated percentage of sales was recorded for the following categories:

Categories as Percentage of Sales	<u>Pharmacia State Enterprise Pharmacy #1</u>	<u>State Enterprise Pharmacy # 54</u>	<u>Central Rayon Pharmacy # 93 (Staraya Russa)</u>
Private pay at 100% retail price	40	65	7
Exempt pay	60	25	3
Wholesale pay	0	10	90

Gross sales for public versus private pharmaceutical sectors

Private pharmacies (1995)	938,000 US\$ (3 827 billion Rubles)
Public sector pharmacies (10-1-1994 to 9-30-1995)	4 7 million US\$ (19 313 billion Rubles)

Drug Pricing

See pricing policy in the Finance section of this report

Physical Facility

The pharmacy space was reported to be adequate in most cases, but practically all pharmacy directors

indicated the need for computers, one or more upgrades to equipment such as the distilled water system, and minor repairs to the facility itself. Medication storage is mostly done in cabinets, although some are stored on pallets. Special categories of drugs like narcotics, and flammable products are stored in secured cabinets.

Training

Continuing education consists of postgraduate training once every 5 years for both pharmacists and pharmacy technicians.

D Areas of Concern Related to Community Pharmacy

- Historically, financial management skills have not been important requirements for community pharmacy directors. As subsidies to pharmacies decrease or are eliminated, these skills will become increasingly important.
- Drug markups are often not sufficient to cover replacement costs of drugs as well as operating expenses.
- Community pharmacies are having difficulty maintaining profitability in the transition from central to local pharmacy management.
- Reimbursement to pharmacies for exempt patient prescriptions can take up to 6 months, which is a likely contributor to financial failure.

VIII DRUG CONTROL LEGISLATION

In order to understand drug control legislation in a country the logical approach is to review the National Drug Policy, Medical Practice Act, Pharmacy Practice Act, and relevant drug registration laws. These areas were addressed thoroughly in the Ryazan Oblast Assessment report, and therefore will only be briefly mentioned here.

A Drug Registration

All drugs marketed in Russia are required to be registered by the Federal MOH Bureau for Drug Registration as outlined in Federal order #177. Once registered, drugs are given a unique identification number by manufacturer and product strength and size. Registration may be verified in the reference book *Register of Drugs in Russia*, which contains both foreign and domestic registered products, and is updated periodically through the newspaper, *Pharmaceutical Review*. The Pharmacy department of the Oblast Health Administration disseminates this information within the oblast. The newspaper is prepared by a pharmaceutical company in association with PharmedInfo, Federal quality control lab, and Federal drug registration bureau. A computer database exists containing information on all registered drug products. The database can be purchased from the MOH.

B Drug Imports

Those wholesalers or pharmacies that import drugs into Novgorod Oblast must have a federal license for each order according to Federal Decree #177. Public sector drugs are imported duty free, as well as insulins, oral anti-diabetics, and biologicals.

C Pharmacy Practice Act

The main points of Oblast decree "Licensing and Accreditation of Pharmaceutical activities in Oblast" are:

- Pharmacists and Pharmacy Technicians may dispense medications
- Pharmacies may be State owned or privately owned. Private pharmacies, however cannot dispense controlled substances, spirits or poisons
- Pharmacists and Physicians working in the public sector can have private pharmacies
- All Pharmacies are required to have a pharmacist on the premises
- Pharmacies can sell non-drug items, including anything that doesn't have negative impact on drugs and sanitation laws

D Medical Practice Act

The following are the main points of the Federal and Oblast Decrees on medical practice:

- Physician, Feldsher, and Feldsher Midwife, may prescribe medications in the public sector

- Private sector requirements are less strict for physicians where attention is paid primarily to medical qualification, but not necessarily to meet all the federal requirements of the Sanitation and Epidemiology Bureau
- Physician licenses must be renewed every 5 years for public sector, every 3 years for private sector

IX DRUG UTILIZATION AND DISEASE PATTERNS IN THE OBLAST

A Morbidity

The most frequent causes of illness in Novgorod Oblast for 1994 for adults and children 0-14 years of age were

Adults per 1000 population

Children per 1000 population

<u>Disease</u>	<u>Number</u>	<u>Disease</u>	<u>Number</u>
Respiratory	239 2	Respiratory	837 15
Cardiovascular	135 68	Nervous system	148 17
Nervous system	118 51	Infectious and parasitic	121 96
Traumas and poisoning	99 44	Dermatological	85 81
Muscular and bone	72 76	Traumas and poisoning	76 95
Gastro-intestinal	72 03	Gastro-intestinal	51 15
Infections and parasitic	55 01	Muscular and bone	41 35
Urinary tract	52 77	Urinary tract	28 78
Mental disorders	50 17	Endocrine system	21 69
Dermatological	48 04	Congenital anomalies	20 72

The following data was reported relative to outpatient visits per 1000 population, and average inpatient hospital stays in 1994

- number of visits to physicians, stomatologists and dentists -- 7810 1
- number of physician visits to patients home for adults -- 6852 7
- number of physician visits to patients home for children 0-14 years of age -- 6625 8
- average length of stay in hospital for adults -- 17 93 days
- average length of stay in hospital for children 0-14 years of age -- 14 days

B Treatment Protocols

Standard treatment guidelines are available in the public sector and the Oblast Health Administration indicated an interest in getting help from RPM with revising and updating them to include diagnostics and economics. Two of the 3 hospitals visited, however, indicated that the ones in existence were very general and based on 1991 federal healthcare standards. None of the hospitals visited reported a program in place to perform drug usage review studies.

C Areas of Concern Related To Drug Utilization

- DUR programs were not found to exist in oblast health facilities, for example, Oblast Health Administration reported excessive numbers of drugs are being prescribed per patient in the Veterans hospital
- Standard treatment protocols are very general, request was made by Oblast Health Administration to assist in modifying the STGs

X QUALITY CONTROL TESTING AND INSPECTIONS

Drug products in Novgorod Oblast are tested for quality at the federal MOH quality control lab, Oblast quality control lab, and individual pharmacies where drugs are compounded

The following tests were conducted by the Oblast Health Administration Quality Control lab in 1994

- 3,989 on commercially prepared products--89 did not meet tests
- 4,400 on compounded products--65 did not meet tests
- 30 on the single drug produced by the only manufacturing company, in the Oblast
- 40 on herb products
- 45 repeat tests on some of the above tests
- 12 tests at the request of private citizens

Quality tests include identity and strength (colorimetric method often used), stability (includes tests for strength on spirits), and dissolution, however, distilled water is tested on a daily basis at each pharmacy where the water is distilled. Equipment used for testing includes spectrophotometer (needs replacement), photocolormeter, pH meter, analytical balances. No gas or high pressure liquid chromatographs are available for testing.

Problems reported with quality testing is the unavailability of standards and reagents, as well as outdated equipment in the oblast quality control lab. In addition, more quality problems have appeared with imports since more drugs are imported than are manufactured in Russia. Costs to perform analytical tests range from 8.60 to 19.60 US \$ (35,000 to 80,000 Rubles).

XI DRUG INFORMATION

Several health facilities and institutions were visited during the assessment to determine the level of drug information services being provided in the transition from a centrally controlled health care system to one at the local level. As could be expected, drug information services are in a state of flux at this time. The most popular and often the only reference book encountered in health facilities is Mashkovski. Some medical journals from Moscow are available. Currently, the most active information providers are pharmaceutical manufacturers, who send their representatives to medical societies, hospitals, pharmacies, and other health care facilities. Periodically, TV and radio medical programs provide an opportunity for patients to call and ask about their medications, including indications, price and availability. For a list of the persons met and the facilities visited see Appendix 3.

A State Center of Prophylactic Medicine and Rehabilitation

A drug information center (the Center) was established in November, 1995 at the State Center of Prophylactic Medicine and Rehabilitation in Novgorod city. Staff is only partly in place and at the time of writing this report, the director is no longer with the Center. The Center signed an agreement with PHARMEDINFO and purchased several databases, but has not yet paid for them. A situation paper describes the Center's activities as, providing drug information on availability, prices, new drugs, and marketing issues, to health professionals and the population of Novgorod Oblast. The facility consists of 2 small rooms with 1 telephone line and one personal computer (386 chip). According to plans every medical facility in Novgorod Oblast is supposed to pay a monthly fee to the Center in exchange for any drug information requested from the Center.

B Novgorod Medical College

The Novgorod Medical College was established two years ago to train second level prescribers (nurses and feldshers). It has a library of 60,000 titles, which are mostly medical journals in English that were donated by Rochester University. The Assistant Dean expressed an interest in establishing a drug information center at the college, but was unable to indicate where space could be provided at that time.

C Novgorod Pharmacia

Prior to 1992, Pharmacia was a division of the Pharmaceutical Committee, and had an established drug information center in its structure. When the Pharmaceutical Committee was disbanded, Pharmacia became a regional state enterprise, and its drug center was terminated. Even at that, many health professionals and citizens continue calling Pharmacia for drug information where they receive information on drug availability, prices, side effects, and dosage. The management information system utilized by Pharmacia in its procurement activities include one pentium chip, three 486 chip, seven 386 chip, and eight 286 chip personal computers, and various software. Pharmacia expressed great interest in having a drug center again, and indicated that space is available.

D Central Oblast Hospital

The library of the hospital has a part time physician on staff and approximately 100,000 titles. In addition there are branches of the library in eight different hospitals throughout the Oblast. Drug information services provided by the library are as follows:

- On a monthly basis "specialist" day is held for a particular disease (eg. cardiology) where new drug information is presented to physicians.
- Every other month the library staff visits different health facilities in Novgorod Oblast, discusses new drugs, and provides current drug literature.
- Every six months the staff chooses a particular disease (eg. diabetes), and utilizing current literature, publishes a report in the Oblast newspapers.
- When requested by higher level physicians and PhD candidates, the library staff will search and evaluate literature on a particular subject.

Funds for drug information services have steadily decreased over the last few years, and the hospital would not be able to establish a drug information center without financial aid.

E Central Oblast Childrens Hospital

The directors of the hospital are very interested in establishing a drug information center at the hospital, however, it would be very difficult at this time due to lack of staff and available space. Several of the staff are English speakers, and existing computers are used to search medical literature on the internet.

F Oblast Public Health Committee

The chief economist of the Oblast Health Administration indicated that no separate line item exists in the health budget for obtaining drug information. However, in 1995, there was a special reserve fund of 200,00 US\$ for workshops and business trips, which could be spent on reference materials.

G Areas of Concern Related to Drug Information

- There is no well-defined drug information network in the Oblast at this time. Currently, Novgorod's only drug information center, established in November, 1995, is not fully operational due to lack of staff and funding.
- Current drug information is very limited, at Novgorod Medical College the library consists of 60,000 titles, all in English, which are donated medical journals. In most health facilities, medical reference books are not readily available except for Mashkovski.
- Funds for medical reference materials have decreased over the last four years, and current public health budgets do not contain a line item for purchase of these materials.

APPENDICES

APPENDIX 1
TRACER DRUG LIST FOR HOSPITALS

**СПИСОК ЛЕКАРСТВ КОНТРОЛЬНОЙ ГРУППЫ. НОВГОРОД.
ЛПУ/АПТЕЧНЫЕ СКЛАДЫ HOSPITALS/WAREHOUSES**

	ПРЕПАРАТ	DRUG	ДОЗА	ФОР МА
1	преднизолон	prednisolone	30mg	д\и
2	гентамицин	gentamicin	40mg	д\и
3	ампициллин	ampicillin	1 g	д\и
4	гепарин	heparin	10000 U	д\и
5	фуросемид	furosemide	40mg	д\и
6	эуфиллин	aminophyllin	2,4%sol	д\и
7	аминазин	chlorpromazin	25mg	д\и
8	пилокарпин	pylocarpin	1% sol	гл.кап.
9	диазепам	diazepam	5mg\ml	д\и
10	димедрол	diphenhydramine	10mg	д\и
11	папаверин	papaverine	2% sol	д\и
12	викасол	vit. K	10mg	д\и
13	диклофенак натрия	diclofenac sodium	25mg	таб.
14	фенобарбитал	phenobarbital	50mg	таб.
15	пирацетам	pyracetam	400mg	таб.
16	дигоксин	digoxin	0,25mg	таб.
17	нифедипин	nifedipin	10mg	драже
18	клонидин (клофелин)	clonidin	0,01% sol	д\и
19	ранитидин	ranitidin	150mg	таб.
20	сальбутамол	salbutamol	0,1mg\ d	аэроз.
21	ацетилсалициловая к-та	acetylsalicylic acid	500mg	таб.
22	доксциклин	doxycycline	100mg	таб.
23	метронидазол	metronidazole	250mg	таб.
24	сульфометаксазол\три метоприм	SMX\TMP	480mg	таб.
25	натрия хлорид	sodium chloride	0,9% - 400ml	д\и

APPENDIX 2
TRACER DRUG LIST FOR COMMUNITY PHARMACIES

**СПИСОК ЛЕКАРСТВ КОНТРОЛЬНОЙ ГРУППЫ НОВГОРОД.
РОЗНИЧНЫЕ АПТЕКИ/COMMUNITY PHARMACIES.**

	ПРЕПАРАТ	DRUG	ДОЗА	ФОРМА
1	гентамицин	gentamicin	40mg\ ml	д\и
2	индометацин	indometacin	25mg	таб.
3	ампициллин	ampicillin	250mg	таб.
4	пилокарпин	pylocarpin	1% sol	гл кап.
5	парацетамол	paracetamol	500mg	таб.
6	антигеморроидальные св.	antihemorrhoidal supp.		свечи
7	нифедипин	nifedipin	10mg	драже
8	пропранолол	propranolol	40mg	таб.
9	дигоксин	digoxin	0,25mg	таб.
10	фуросемид	furosemide	40mg	таб.
11	сальбутамол	salbutamol	0,1mg\ d	аэроз.
12	гидрокортизон	hydrocortizone	1%	гл.мазь
13	этинилэстрадиол\лево ногестрел	aethynilestradiol\levonog estrel	35mkg \1mg	таб. на цикл
14	папаверин	papaverine	4mg	таб.
15	бензилбензоат	benzylbenzoate	25% sol	р-р
16	нистатин	nistatine	250000 IU	таб.
17	бензилпенициллин	benzylpenicillin	500000 IU	флако н
18	тетрациклин	tetracycline	250mg	таб.
19	пирацетам	pyracetam	400mg	таб.
20	бромгексин	bromhexin	8mg	драже
21	изосорбид динитрат	isosorbid disodium	10mg	таб.
22	сульфаметаксазол\ триметоприм	SMX\TMP	480mg	таб.
23	доксциклин	doxycycline	100mg	таб.
24	ацетилсалициловая к-та	acetylsalicylic acid	500mg	таб.
25	ал.-маг., гидроокись	Al\Mg hydroxide		гель
26	перекись водорода	hydrogen peroxide	3% sol	р-р

APPENDIX 3
PERSONS MET AND HEALTH FACILITIES VISITED

**NOVGOROD OBLAST
FACILITIES VISITED AND PERSONS MET**

Dr Valery Medic	Head of Oblast Health Administration
Dr Oleg Stukolkin	Deputy Head of Oblast Health Admin
Maya Sveridenko	Head of Oblast Pharmacy Department
Nina Kropotova	Chief of Oblast Personnel Department
Lidia Popova	Chief Economist of Oblast Planning Dept
 <u>Childrens Hospital</u>	
Dr Vladimir Soloviov	Chief Physician
Dr Vladimir Suchov	Deputy Chief Physician
Lidia Timoshina	Head of Pharmacy
 <u>Veterans Hospital</u>	
Dr Alla Horodievskaya	Chief Physician
 <u>Central Oblast Hospital</u>	
Dr Magamet Osudaliev	Chief Physician
Dr Irina Semerova	Deputy Chief Physician
Dr Sergei Novikov	Chief of Surgery for Hospital and Oblast
Natalia Stavranova	Head of Pharmacy
Ludmila Kaplanova	Librarian
 <u>Staraya Russa Central Rayon Hospital</u>	
Dr Valentina Ivanova	Chief Physician
 <u>State Enterprise Pharmacy # 1</u>	
Olga Ritzareva	Pharmacist
 <u>State Enterprise Pharmacy # 54</u>	
Nadezhda Khutoryanskaya	Pharmacist
 <u>Private Enterprise Pharmacy # 93 Staraya Russa</u>	
Natalia Ivanova	Director of Pharmacy
 <u>State Center of Prophylactic Medicine and Rehabilitation</u>	
Dr Anatoliy E Bazylev	Head of Facility
Dr Boris B Fishman	Deputy Head of Facility
 <u>Novgorod Medical College</u>	
Dr Gennadiy G Bryzshakhin	Deputy Director
Dr Viktor R Veber	Dean of Faculty for General Medicine and Chief General Physician of Novgorod Oblast

Regional State Enterprise Novgorod Pharmacia

Margarita Kim
Lyubov V Zemlyak
Tatiana Denisova

Head of Facility
Marketing Sector Manager
Marketing Specialist

ASKO Medical Insurance Company

Irina S Gremitskih

Director of Facility

APPENDIX 4
PHARMACIES PROVIDING DATA FOR THE INDICATOR STUDY

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PHARMACIES PROVIDING DATA FOR THE INDICATOR STUDY

<u>Name</u>	<u>Type</u>	<u>Location</u>
Apteka "Alex"	Private	Novgorod
Apteka TOO Pharmacom (kiosk)	Private	Novgorod
Apteka TOO Health Center (kiosk)	Private	Novgorod
Apteka TOO "Sterkh" (kiosk)	Private	Novgorod
Apteka kiosk TOO Novah	Private	Novgorod
Apteka kiosk SE Polyclinic	Private	Novgorod
Apteka TOO "Med-Diagnostic Center"	Private	Novgorod
Apteka TOO "Avicenna"	Private	Novgorod
Apteka "Stumul Plus"	Private	Novgorod
Oblast Hospital Pharmacy	Public	Novgorod
City Hospital #1 Pharmacy	Public	Novgorod
Oblast Children Hospital Pharmacy	Public	Novgorod
Veterans Hospital (Pharmacia kiosk)	Public	Novgorod
Infectious Hospital Pharmacy #72	Public	Novgorod
Novgorod Rayon Hospital Pharmacy #94	Public	Novgorod
Rayon Hospital Pharmacy #93	Public	Staraya Russa
Tesovo-Netyl Hospital Pharmacy	Public	Tesovo
Apteka 95 Pharmacia	Public	Novgorod
Apteka 54 City Pharmacia (7outlets)	Public	Novgorod
Aptekas # 58,38,23,67,29,84,82,85,83,93,51	Public	Novgorod
Aptekas # 40,87	Public	Staraya Russa
Apteka #1	Public	Borovich
Apteka #104	Public	Pankovka
Apteka #77	Public	Proletari
Apteka #90	Public	Podberezhi
Apteka #36	Public	Poddorie
Oblast S E Pharmacia pharmacia	Public	Novgorod

APPENDIX 5
OBLAST HEALTH FACILITIES BY TYPE AND LOCATION

Novgorod Oblast Health Facilities Network by Rayons

#	Rayon and Health Facilities Levels	# of HF
1	Batetski Rayon - Central Rayon Hospital	1
2	Borovichski Rayon - District Hospitals - Ambulatories	5 4
3	Valdaiski Rayon - Central Rayon Hospital - District Hospitals - Inter-Rayon Narcological Dispensary	1 3 1
4	Volotovski Rayon - Central Rayon Hospital - District Hospital	1 1
5	Demianski Rayon - Central Rayon Hospital - Rayon Hospital - District Hospitals	1 2 1
6	Krestetski Rayon - Central Rayon Hospital - Ambulatory	1 1
7	Lubytinski Rayon - Central Rayon Hospital - Rayon Hospitals	1 2
8	Malo-Visherski Rayon - Central Rayon Hospital - District Hospital - Ambulatories	1 1 2
9	Marevski Rayon - Central Rayon Hospital - Ambulatory	1 1
10	Moshenski Rayon - Central Rayon Hospital - District Hospital	1 1
11	Novgorodski Rayon - Rayon Hospitals - District Hospital - Ambulatories	2 1 13
12	Okulovski Rayon - Central Rayon Hospital - City Hospitals - District Hospital - Ambulatories - Stomatological Polyclinic - Orphanage	1 2 1 3 1 1
13	Parfinski Rayon - Central Rayon Hospital - Rayon Hospital	1 1
14	Pestovski Rayon - Central Rayon Hospital	1

15	Poddorski Rayon	- Central Rayon Hospital - District Hospital - Ambulatory	1 1 1
16	Soletski Rayon	- Central Rayon Hospital - Ambulatory - Sanatorium	1 2 1
17	StaroRusski Rayon	- Rayon Hospital - District Hospital - Ambulatory	1 1 1
18	Hvoimnski Rayon	- Central Rayon Hospital - City Hospitals - District Hospital - Ambulatories - Sanatorium	1 2 1 2 1
19	Holmski Rayon	- Central Rayon Hospital - Ambulatory	1 1
20	Chudovski Rayon	- Central Rayon Hospital - City Hospital - District Hospital - Stomatological Polyclinic - Inter-rayon Narcological Dispensary	1 1 1 1 1
21	Shumski Rayon	- Central Rayon Hospital - Rayon Hospital - Ambulatory	1 1 1
	Health Facilities in Promnent Cities		
22	Borovichu	- Central Rayon Hospital - City TB Dispensary - City Psychoneurologic Dispensary - Emergency/Ambulance Station - Orphanage - Children Sanatorium - Stomatological Polyclinic - Blood Transfusion Station	1 1 1 1 1 1 1 1
23	Staraya Russa	- Central Rayon Hospital - City Venerologic Dispensary - City TB Dispensary - City Psychoneurologic Dispensary - Stomatological Polyclinic - Emergency/Ambulance Station	1 1 1 1 1 1

24	Novgorod	<ul style="list-style-type: none"> - Central Rayon Hospital - Children Polyclinics - Physiotherapy Polyclinic - Infectious Hospital - Delivery Hospitals - City Hospitals - City Venerologic Dispensary - Medical Cosmetics Center - Stomatological Polyclinics - Commercial Polyclinic (fees) - Emergency/Ambulance Station - Children Sanatorium - City Polyclinic - Rehabilitation Center 	<ul style="list-style-type: none"> 1 3 1 1 2 2 1 1 2 1 1 1 1 1
		Oblast Level Health Facilities	
	Novgorod	<ul style="list-style-type: none"> - Oblast Hospital - War Veterans Hospital - Oblast Children Hospital - Oblast Stomatological Polyclinic - Mental Hospital - Oblast TB Dispensary - Oblast Psychoneurologic Dispensary - Psychotherapeutic Center - Anti-AIDS Center - Medicolegal Center - Medical Prevention Center - Medical Statistics Bureau - Blood Transfusion Station 	<ul style="list-style-type: none"> 1
	Borovichu	<ul style="list-style-type: none"> - Oblast Venerologic Dispensary - Oblast Oncological Dispensary 	<ul style="list-style-type: none"> 1 1
	in other towns of Novgorod Oblast	<ul style="list-style-type: none"> - TB Hospital -- Batetsk - Mental Hospital -- Valdaı - Mental Hospital -- Malaya Vishera - Rehabilitation Hospital -- Zagorie - Pulmonary Surgery Hospital -- Lubytunski Rayon - Children Sanatorium -- Tesovo 	<ul style="list-style-type: none"> 1 1 1 1 1 1

APPENDIX 6
LIST OF ACRONYMS USED IN REPORT

List of Acronyms

DAP	Drug Action Programme of World Health Organization
DMP	Drug Management Program
DUR	Drug Utilization Review
EDL	Essentials Drug List
FEFO	First Expired, First Out
GMP	Good Manufacturing Practice
HNS	Health and Nutrition Sustainability Contract
INRUD	International Network for the Rational Use of Drugs
LAC	Latin American and Caribbean Region
MOH	Ministry of Health
MSH	Management Sciences for Health
NIS	New Independent States (former Soviet Union)
RPM	Rational Pharmaceutical Management Project
STD	Standard Treatment Guidelines
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

APPENDIX 7
RPM ASSESSMENT METHODOLOGY

RPM ASSESSMENT METHODOLOGY

Assessment Team

Anthony Savelli	MSH/Washington, Project Director, RPM Russia
Thomas Moore	MSH/Washington, RPM Russia, Senior Program Associate
Harald Schwarz	MSH/Washington, RPM Russia, Senior Program Associate
Andri Zagorski	MSH/Moscow, RPM Russia, Coordinator/Advisor
Data collectors	Pharmacists provided by the Oblast Health Administration

Data Collection Tools and Tracer Drugs

The data collection tools used in Novgorod were developed by modifying questionnaires used in the RPM Ryazan Oblast assessment. The indicators and sample forms contained in the "*Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach*" were used for collection of the indicator data. The tracer drug lists were established in collaboration with Novgorod Oblast pharmaceutical sector personnel during an MSH assessment training workshop conducted in Novgorod from September 18 to September 20, 1995. The total assessment tool consists of the following components:

Oblast Administration Survey

Oblast Administration questionnaire
 Oblast Health Administration questionnaire
 Pharmaceutical Committee questionnaire

Pharmacia Survey

Pharmacia questionnaire
 Tracer Drug list
 Inventory Data Form
 International Price Comparison Data Form

Hospital Survey

Hospital questionnaire
 Tracer Drug list
 Stockout Data Form
 Drug Use Data Form
 Retail Price Comparison Data Form
 International Price Comparison Data Form

Community Pharmacy

Community Pharmacy questionnaire
Tracer Drug list
Drug Registration Data Form
Generic Substitution and Sale of Antibiotics Data Form
Inventory Data Form
Stockout Data Form
Drug Use Data Form
Retail Price Comparison Data Form
International Price Comparison Data Form

The community pharmacy and hospital/warehouse *Tracer Drug* lists used in the survey can be found in appendices 1 and 2

Description of the Assessment Process

The assessment was divided into two main parts, *interviews* using the prepared questionnaires, and *collection of indicator data* using the prepared forms, as follows

Interviews members of the study team conducted interviews with representatives of

- Oblast Administration
- Oblast Health Administration
- Pharmaceutical Department of the Oblast Health Committee
- Novgorod Pharmacia
- Municipal and Rayon Hospitals (total of 4)
- Insurance Funding Company, ASKO
- Municipal and Rayon, Public and Private Enterprise Pharmacies (total of 3)

A list of persons interviewed, as well as hospitals and pharmacies visited is in Appendix 3

Collection of Indicator Data These data were collected by the Pharmacy Directors of various pharmacies A list of the pharmacies and their locations is in Appendix 4

APPENDIX 8
RUBLE TO US DOLLAR CONVERSION RATES

Ruble to US Dollar Conversion Rates

Date	RUBLES/ 1 US\$	% CHANGE
1994		
January 5th	1247	n/a
January 28th	1542	23.7
February	1657	7.5
March	1753	6.0
April 1st	1753	0
April 29th	1820	3.8
May	1901	4.5
June	1985	4.4
July	2060	3.8
August	2153	4.5
September	2596	17.1
October	3055	17.7
November	3232	5.5
December	3550	9.8
1995		
January	3623	2.1
February	4048	11.7
March	4531	11.9
April	4920	7.9
May	5130	4.1
June	4958	-3.4
July	4553	-8.2
August	4405	-3.3
September	4447	1.0
October 4th	4490	1.0
October 27th	4504	0.3
November 1st	4504	0
November 24th	4566	1.4

The following are average rates used in Ruble to US\$ conversions for this report

4500 RR = 1 US\$ for calculating indicator data on drug prices (rate for calendar year)

4080 RR = 1 US\$ to make calculations using the Oblast Health budget (rate for fiscal year)