

PN-ACD-998

# RPM

**RATIONAL PHARMACEUTICAL MANAGEMENT PROJECT**



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PNACD-998

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

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C A No HRN-0004-A-5002-00  
Washington, DC  
December, 1995

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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 Pskov Oblast from December 4 - December 8, 1995. The indicator portion of the assessment was conducted just prior to and during this time period by locally trained pharmaceutical sector data collectors.

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 Pskov 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 Pskov Oblast using NIS Add-on funds
- Utilize the assessment report as a basis for a Pskov 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 Pskov

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.

For a list of acronyms used in this report see Appendix 6. The assessment methodology used in the survey of Pskov Oblast can be seen in Appendix 7.

**SECTION ONE**  
**SUMMARY OF FINDINGS OF THE PSKOV ASSESSMENT**



## I EXECUTIVE SUMMARY

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

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

On-site training with counterparts selected by Oblast Health Committee will be provided. If computer related equipment is necessary, this will be provided with appropriate training. During the joint Pskov/Novgorod Policy Options Workshop in March, 1996, RPM will discuss survey findings with local, national, and international specialists, and local policy makers. Specific RPM assistance will be determined at that time. The following suggested activities 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

- Pskov does not have a locally developed formulary list that is used as a basis for drug procurement and use
- With an increasing number of private and public sector wholesale drug companies in Pskov Oblast, the introduction of many new drug products has occurred
- The introduction of many new drug products has not been accompanied with information about the drugs, leaving prescribers and dispensers without proper training and current information

#### 2 Proposed Activities

- Familiarize local decision makers with formulary system management concepts
- Work with Oblast Health Administration to identify appropriate personnel to serve on formulary system committees, and specific hospitals where the systems will be put in place

- Assist formulary system committees to establish a locally appropriate drug formulary list
- Work with the formulary system committees to
  - Modify the drug formulary list for specific hospitals
  - Implement drug formularies in selected hospitals
  - Expand access to, and use of, current unbiased drug information
  - Identify priority therapeutic needs through examination of local morbidity/mortality statistics
  - Identify drugs now in use which are not suitable for inclusion in a drug formulary, based on world-wide experience
  - Provide computer equipment at selected hospitals, if necessary, and provide software and training for use in developing and maintaining formulary lists
  - Promote official adaptation of the formulary lists
  - Establish standard procedure for requesting and procuring non-formulary drugs needed for specific patients
  - Launch programs for monitoring of adverse drug reactions and drug side effects  
Utilize information from this program to establish DUR studies 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 Procurement and Tender Management**

In Russia prior to 1991, drug procurement was a centralized function in which drugs were acquired largely from domestic and NIS manufacturers. Current managers of pharmacies have limited management 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 are not familiar with options for national or international procurement.

## 1 Findings

- ▶ Pharmacia purchases drugs through negotiation with drug distributors and manufacturers Other than one attempt in 1995, tendering procedures have not been utilized
- ▶ With pharmacies and hospitals ordering drugs from other wholesalers, establishment of a routine procurement cycle by Pharmacia is not possible
- ▶ The computer system available at Pharmacia doesn't monitor orders placed for drugs from suppliers or supplier performance
- ▶ Markup policies limiting profit by Pharmacia and pharmacies may not generate sufficient funds for procurement and operating expenses

## 2 Proposed Activities

- ▶ Work with Oblast Health Committee to identify personnel and facilities where procurement techniques will be implemented
- ▶ Assist selected personnel with the following
  - Identify options to promote rational and competitive domestic and international procurement practices for drugs, given funding constraints at this time
  - Establish a selection and quantification system which employs ABC analysis, VEN analysis, international price lists, and quantification methodologies based on consumption and morbidity data
  - Train personnel on use of the MSH-developed *Estimed* software Modify the software based on local needs, and perform a quantification of Oblast drug needs
  - Modify the MSH-developed formulary database system to meet Pskov Oblast health needs, and utilize database to assist in formulary development
  - Assist in developing forms and documents necessary to conduct a tender and to monitor domestic and international procurement
  - Assist with oblast tenders for drugs in public sector facilities
  - Assist with pooled procurement for municipal pharmacies if the Oblast elects this policy
  - Assist with computerized inventory management such as INVEC (procurement and inventory management software) at the State Enterprise Pharmacia Provide computers, if necessary, and install and train personnel on the use of INVEC

## **C 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**

- DUR activities are not being used in healthcare facilities in the Oblast

### **2 Proposed Activities**

- Identify appropriate medical specialists with the assistance of the Oblast Health Committee
- Assist in forming DUR committees and train members in DUR program techniques
- Assist committees in developing DUR programs using the USP DI drug utilization review framework
- Assist committees in incorporating the DUR programs in the formulary management system
- Launch a DUR program at the Veterans hospital, Central Oblast hospital and one rayon hospital, to study if selected drugs are prescribed, dispensed, and administered properly

## **D Drug Information Development**

During the transition from a central to an oblast controlled health system, the provision of quality drug information services has been difficult to maintain. Several officials were interviewed during the assessment in order to determine the status of current drug information activities and the need to upgrade existing drug information services.

### **1 Findings**

- Pharmaceutical manufacturing representatives are the primary providers of current drug information
- No drug information network exists in the Oblast at this time, nor are there any drug information centers

### **2 Proposed Activities**

- Collaborate with the Oblast Health Committee in creating a drug information network, and establishing two drug information centers in Pskov and Velikie Luki

- Provide a computerized drug information database, and train those personnel identified by the Oblast Health Committee
- Provide study tours, workshops and conferences for appropriate Oblast personnel
- Assist with the selection of appropriate reference materials for the drug information centers
- Assist in developing the capability of creating drug information materials, and of providing the materials readily to the community

## **E 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**

- DUR programs for studying the rational use of prescribed drugs were not found to exist in oblast hospitals or outpatient clinics
- Currently STGs are present in the oblast, but are based on federal general guidelines, the STGs need to be updated and combined with DUR programs for promoting rational drug use

### **2 Proposed Activities**

- Work with Oblast Health Committee to establish a Rational Drug Use Committee
- Work with the Rational Drug Use committee to modify existing STGs, utilize international recommendations for establishing the STGs
- Include STG development and revision programs in those facilities where formulary systems are being developed

## **F Community Pharmacy Management**

In the transition from central drug management to local management the pharmacy distribution system in Pskov Oblast is still very much in a state of flux. Many pharmacists have limited management skills, which has contributed to the difficulties in maintaining economically viable enterprises

### **1 Findings**

- Prior to 1991 most pharmacies did not participate in the decision-making process, and currently lack experience in one or more areas of pharmacy management

- Delays in reimbursement for exempt prescriptions, as well as a punitive tax structure, contribute heavily to financial difficulties of pharmacies
- The large number of personnel working in a typical pharmacy, compared to western standards, exacerbates the struggle pharmacies have in remaining profitable

## 2 Proposed Activities

- Conduct basic pharmacy management workshop(s) to orient managers in sound managerial skills in the following areas operations, human resources, procurement strategies, price structures, and marketing strategies
- Conduct advanced pharmacy management workshop(s) to build on the skills learned in the basic skills workshop, including development of a business plan
- Provide technical assistance in the implementation phase of the business plans
- Work with pharmacy managers to explore vendor relationships and possible group activities as a means of increasing procurement efficiencies
- Assist in development of relationships with other health related organizations for the purpose of increasing exchange of information and expertise

## II PHARMACEUTICAL INDICATORS

Indicator results from the Pskov assessment are presented 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 types 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  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	Oblast Public Health Pharmacy Department, and Licensing and Accreditation Commission
Drug Procurement and Distribution	Oblast Decree “On Bidding Process for Drug and Medical Supplies Procurement for Public Health Facilities” February 24, 1995	Oblast Public Health Committee

Drug Quality Control	Federal Order #149 "On Quality Assurance of Pharmaceuticals, Medical Supplies, and Medical Equipment," June 28, 1993  Federal Order #53 "On Drug Quality Control Labs" March 25, 1994	Oblast Public Health Drug Quality Control Laboratory
Sales Practices	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  Oblast Decree "On Pricing Policies for Pharmaceuticals and Medical Supplies" November 2, 1994	Oblast Public Health Pharmacy Department, and Licensing and Accreditation Commission
Medical Insurance	Oblast Decree for carrying out of Federal Decree on Medical Insurance	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

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. Also a manual information system exists in the form of a bound book, "Register of Drugs in Russia, 1994" which is available at Pskov Public Health Committee offices

5 *Number of drugs registered*

Currently there are approximately 9,000 drugs registered in Russia, a substantial increase since 1991

6 *Law permitting generic substitution by pharmacists*

There is no law in Russia at this time, however, the MOH and the Pskov Oblast Health Committee allow it. Substitution is done at pharmacists own discretion

7 *Practice of generic substitution*

Of the 5 pharmacies reporting, 9 of 21 pharmacists or 81.8% practiced generic substitution

**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 which restricts drugs that can be legally dispensed. However, there is a national list of "Vitaly Important Drugs" for dispensing to exempt patients. There are 164 drug products which should be stocked at all times.

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

Pskov Oblast does not currently have drug information centers. 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. Drug information centers are required in order to promote rational selection, procurement, and use of drugs.

### **C Budget and Finance for the Pskov Oblast Public Health Sector**

Financial data reported during the survey covers the fiscal year October 1, 1994 through September 30, 1995 unless otherwise stated. Ruble to US\$ conversions were done using the following average rates calculated from the 1994 and 1995 rates list 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 *Pskov Oblast budget or expenditures on pharmaceuticals, US\$ per capita*

The per capita drug expenditure in the public sector was 3.70 US\$ (15,000 Rubles).

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

Drug costs are not recovered from hospital patients. Hospitals receive funds to purchase drugs from either the Oblast Health Committee or mandatory medical insurance. A wage tax is levied on the working population to fund the insurance.

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

Information was not collected during the assessment.

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

Oblast Administration devoted 12.6% of its total budget to Public Health.

5 *Percentage of total Oblast Administration budget allocated to pharmaceuticals*

Oblast Administration allocated 10.8% of its budget to pharmaceuticals

**D Pskov Oblast Pharmaceutical Procurement in the Public 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*

Pskov Oblast uses centralized procurement only for drugs requiring special licenses, for example narcotics, spirits, poisons

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

The % average international price paid for the last regular procurement of the indicator drugs in 5 pharmacies was 261%, while for Pharmacia was 89%

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

A competitive tender was done one time in Pskov Oblast, it was estimated to be 1.1% of the drug budget. The tender was considered successful.

**E Pskov Oblast Public Health Sector Pharmaceutical Logistics**

1 *Weighted average percentage of inventory variation for a set of indicator drugs in MOH storage and health facilities*

This information was not collected during the assessment. 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*

This indicator reveals the magnitude of discrepancy between records and the real stock levels of individual drug products, no variation was found for this indicator.

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

This indicator was reported as 100%

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

In Pskov Pharmacia this was 100% In 4 health facilities surveyed the indicator was 77% with a range of 68% to 88%

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

In Pskov Pharmacia for the first 9 months of 1995, the indicator drugs were out of stock an average of 12.5% of the time In 4 health facilities surveyed during the same period of time, the stock out average was 13.1%

## **F Patient Access and Drug Utilization**

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

The population per health facility that dispenses drugs is 1230 persons

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

With 154 pharmacists and 561 pharmacy technicians the population per dispenser is 1174 persons

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

The population per authorized prescriber is 172.5 persons

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

In 3 health facilities reporting this indicator, patients were prescribed an average of 2 drugs per curative encounter The range among facilities was 0.8 to 3 drugs per curative encounter

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

Of 4 health facilities reporting this indicator an average of 34% of drugs was prescribed by generic name, with the range among facilities from 21% to 46%

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

Since Oblast does not have a Drug Formulary this data was not collected

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

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

Of the 3 facilities reporting, injectable drugs were prescribed 17% of the time, with a range of 16% to 27%. Of the 3 facilities reporting antibiotics were prescribed 22% of the time, with a range of 16% to 27%.

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

Of 5 pharmacies reporting, an average of 61% of prescribed drugs presented for dispensing were actually dispensed, with a range of 43% to 88%.

## **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 10,200 individual quality tests were performed in fiscal year 1994.

2 *Use of WHO Certification Scheme*

The WHO Certification Scheme is not used in Pskov 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, and reporting is done on an individual basis, depending on the circumstances. 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**

1 *Population per licensed private sector drug retail outlet*

With only 9 private sector drug retail outlets the population per outlet is 93,277 persons.

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

With 5 inspectors and 173 registered retail pharmacies there are 35 pharmacies per inspector.

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

These data were not collected in the Oblast since 1992, since the Pharmaceutical Committee was disbanded at that time

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

The total value of the total private sector retail pharmaceutical sales is 208,333 US\$ (850 million Rubles), therefore the per capita amount is 0.28 US\$

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

The combined value of public and private sector pharmaceutical expenditures is 1.8 million US\$ (7.5 billion Rubles), therefore the per capita is 2.40 US\$

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

This information could not be collected since a formulary list does not exist in the oblast

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

This information was not collected during the survey

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

The oblast has set a limit of 40% mark-up on drugs at each stage in the distribution process. This applies to both the public and private sectors. Competition has kept the actual mark-up below the maximum allowable, for example in most pharmacies, the mark-up is less than 22%

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

In the facilities reporting for this indicator 38% of the time antibiotics were sold without a physician's prescription

**III ACTIVITIES OF OTHER DONORS AND INTERNATIONAL AGENCIES IN PSKOV**

The oblast administration spoke with a member of the United States Congress about constructing an oncology center in the oblast, to date there have been no results from these conversations

The oblast is working with the World Health Organization on diphtheria control, a \$300,000 project, since the oblast has the highest diphtheria rate in northwest Russia. The project will improve the cold chain, provide training, and set up immunization schedules. The vaccine will be produced by Russian manufacturers

There is a project funded by the Swedish government that is working on training of dentists to prevent tooth decay. The project provides fluoride tablets to schools

**SECTION TWO**  
**FINDINGS OF THE PSKOV ASSESSMENT**

#### IV PUBLIC SECTOR DRUG SUPPLY SYSTEM

##### A Structure and Organization of the Pskov Drug Supply System

Pskov Oblast is divided into 26 administrative units as follows

- 24 Rayons -- analogous to counties in the United States
- 2 Cities -- Pskov and Vilikie Luki

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

- Oblast Administration
- Oblast Health Committee
- Pharmaceutical Department
- State Enterprise Quality Control Laboratory
- 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 Committee, to which the Pharmacy Department reports. 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 Committee

The main goal of the Oblast Health Committee is to coordinate public health activities through its various departments and agencies. These activities include facility inspection, quality control, planning and finance, drug procurement, immunization schemes, and medical insurance.

##### Pharmaceutical Department

This department was established on July 1, 1995 and is responsible for monitoring pharmacy practice in the Oblast. The department reports administratively to the Oblast Health Committee. There are 5 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.

##### State Enterprise Quality Control Laboratory

The main purpose of the lab 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 on an ad hoc basis. There are 5 pharmacists on staff who conducted 10,200 tests either in the Quality Control Department laboratory or on site in the respective pharmacies during 1994. The main constraint identified by the Quality Control Lab in carrying out its functions is that funds are very limited for equipment replacement or purchase.

#### State Enterprise Pharmacia

Pharmacia is the state-owned enterprise responsible for the procurement, storage and distribution of drugs, vaccines, and medical supplies for the public health system in Pskov. Although state-owned, Pharmacia is responsible for making a profit and supporting its own operations. The Pharmacia warehouse is located in Pskov city, and employs 116 people. The role of Pharmacia in the procurement and distribution of drugs is described in detail in other sections of the report.

#### Hospitals/Health Facilities

Medical care in Pskov Oblast is provided for the population through a network of facilities with different levels of care. There are larger hospitals in Pskov city serving the entire Oblast such as Central Oblast Hospital for adults, War Veterans Hospital, and Childrens Hospital. In each rayon there is one general hospital, and one or more district hospitals distributed throughout the rayon. There are several specialty hospitals located in Pskov city and in rayons (see Appendix 5). Polyclinics and ambulatories (smaller clinics) located throughout the Oblast provide outpatient services. Dispensaries which offer inpatient and outpatient specialty services are usually found in the larger towns. There are five sanatoria which serve to rehabilitate patients through special treatment and diets. The most prevalent type of health facility is the Feldsher/Nurse station (first aid stations), there are 600 of these, which are found mostly in rural areas. The following data was collected from the three hospitals visited during the interview portion of the survey.

	Veterans Hospital	Municipal Hospital No.1	Central Rayon Hospital (Palkino)
Annual Admissions	980	9600	3,000
Number Beds	80	555	85
Number Physicians	35	80	15
Number Nurses	56	317	43
Has Pharmacy	NO	NO	YES
Number Pharmacists	NA	NA	1
Number Information Pharmacists	NA	NA	1
Number Technicians	NA	NA	4

Does Compounding	NA	NA	YES
------------------	----	----	-----

In summary, there are approximately 656 public health facilities in the network, with many of them capable of dispensing drugs

### **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

<b>Position</b>	<b>Number</b>	<b>Pskov Population per Health Professional</b>
Physician	2301	365
Pharmacist/Pharmacy Technician	806	1042
Feldsher/Nurse/Midwife	6631	127

Pharmacist to population ratios are low because Russian hospitals often do not have formal pharmacy departments. On the other hand Russia has a large number of physicians in that population per physician world-wide is 3,980, in the United States is 420 and in Russia is 210

## V FINANCE

### A Funding Public Sector Drug Purchases in Pskov 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 1994 and 1995 Ruble to US\$ conversion rates. Because of the economic difficulties Pskov Oblast receives 60% of its budget from the federal government.

#### 1 Sources of the funds

In 1995 medical expenses including drug purchases are funded from two sources

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

#### 2 Disbursement of monies to health facilities

Reimbursement to health facilities is done according to a system of tariffs. Outpatient facilities are paid per patient encounter. Hospitals are paid by one of 5 different tariffs according to the level of hospital. Hospitals compete for working patients since reimbursement from the fund is more reliable than from the oblast budget. Twenty two Rayons are now paying the hospital fees of the non-working population.

**B Pskov Oblast Consolidated Public Health Budget and Expenditures**

## 1 Amount spent in 1994

<u>Budget Category</u>	<u>US\$(millions)</u>	<u>Rubles (billions)</u>
Capital investments (construction of new facilities)	0 04	0 17
Salaries	5 2	21 3
Benefits (medical insurance, pension fund, etc)	1 9	7 9
Operational costs (utilities)	2 9	12 0
Travel expenses	0 03	0 14
Food for patients	1 0	4 2
Pharmaceuticals	1 6	6 6
Medical equipment	0 37	1 5
“Soft” inventory (pillows, blankets, etc)	0 03	0 14
Capital repairs	1 3	5 5
Other	0 54	2 2
Totals	14 9	61 7

## 2 Total budget and amount spent in 1995

<u>Budget Category</u>	<u>US\$(millions)</u>	<u>Rubles (billions)</u>
Oblast Health Budget	7 6	31 2
Non-working population insurance payments	9 8	40 0
Local budgets	11 5	47 0
Total actual expenditures	35 7	145 7

## 3 Amount Allocated for 1996

For the first time since 1991, the health budget is going to increase as a % of the Oblast budget, as noted in the following table

<u>Year</u>	<u>Health Budget as % of Oblast Budget</u>
1991	20 %
1994	12 %
1995	4 %
1996	16 %

**C Pharmacia Financial Information**

The following figures are reported for the period January 1, 1995 to November 1, 1995. As was mentioned earlier in the report, Pharmacia is providing a much smaller percentage of drugs to the public health sector, since many hospitals and pharmacies are free to order from any source

<u>Category</u>	<u>US\$ (millions)</u>	<u>Rubles (billions)</u>
Drug inventory value 11-1-95	0 49	2 0
Drug purchases	2 5	10 2
Value from drugs sold	3 0	12 4
Operating expenses	0 39	1 6

#### D Hospital Financial Information

The following table shows financial information for the 3 hospitals visited during the interview portion of the survey, and covers the period October 1, 1994 to September 30, 1995. Data were not always available since budgets and funds were variable during the period.

Numbers are in: Thousands US\$ (Billions Rubles)	Veterans Hospital	Municipal Hospital No. 1	Central Rayon Hospital (Palkino)
Total Budget Requested	0 270 (1 1)	0 637 (2 6)	0 115 (0 590)
Total Budget Approved	0 211 (0 864)	1 57 (6 4)	0 070 (0 287)
Drug Budget Requested	0 118 (0 481)	0 127 (0 52)	0 018 (0 075)
Drug Budget Approved	0 083 (0 340)	0 294 (1 2)	0 004 (0 016)
Total Drug Purchases	0 083 (0 340)	0 294 (1 2)	0 040 (0 165)
Drug Purchases from Pharmacia	0 004 (0 016)	Not Reported	0 022 (0 091)
Drugs from Donations	0	Not Reported	0
Current Debt to Pharmacia	0 004 (0 016)	Not Reported	0 007 (0 030)
Total Debt to Drug Suppliers	0 009 (0 037)	0 063 (0 256)	0 011 (0 043)

## E Financial Debt in the Pharmaceutical System

The Oblast Health Committee reported that with difficult economic circumstances at present, drug prices are very high. Those drugs needed are usually available to purchase, but often there are not enough funds in the budget to purchase them. The following information summarizes the pharmaceutical debt problems at this time.

- 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 the 3 hospitals surveyed, current debt to Pharmacia is 11,000 US\$ (46 million Rubles).
- For the 3 hospitals surveyed current debt to all suppliers is 80,000 US\$ (416 million Rubles).
- Normally the public health budget provides 290,000 Rubles/person/year from all sources of funding. The Oblast only achieved 120,000 Rubles/person/year in some rayons, with the overall Oblast average being 174,000 Rubles.
- According to the insurance fund, the 3.6% wage tax from the working population is not sufficient to fund the health care system, approximately 8% to 9% is needed. This is mainly because Pskov Oblast has one of the highest unemployment rates in Russia (ranking six from the bottom). In 1995, 64% of the Oblast budget was provided by the federal government.

## F Pricing Policy

Drug pricing policy is determined by the Oblast Administration. Currently, the markup is 40% of the purchase price at each stage in the distribution process, for both public and private sector facilities. Competition has caused many facilities to mark-up much less than the maximum allowable. For example, the average mark-up for pharmacies is 22%, in Viliكية Lukı Rayon the average mark-up is 17%. Due to these drug pricing policies several pharmacies have experienced extreme financial difficulties, since 1993.

There is no problem accessing foreign exchange for use in purchasing pharmaceuticals when Ruble funds are available. Pharmacia purchases drugs directly from two international pharmaceutical companies, Schering-Plough and Merck, Sharp and Dohme, and pays for the drugs in US\$.

## G User Fees

In hospitals most inpatients receive drugs and services at no cost to them. Payments to the hospitals for these services are made from Oblast Medical Insurance Fund and/or Oblast Health budget depending on type of service and type of patient. There is some fee for service health care in the public sector,

such as for false teeth, some gynecological services, and cosmetic surgery. In addition some hospitals have private rooms payable by the patient.

Effective November 1, 1995 reimbursement tariffs for medical services were established by Oblast Health Committee, and the Mandatory Medical Insurance Trust. For hospitals five tariffs were established per patient day, level of hospital services and other criteria. Composition of the tariffs for level 1 (full service hospital) is < 30% personnel, > 14% meals, and > 10% drugs. The following table illustrates some of these fees.

	Top Level	Middle Level	Lowest Level
Treatment	Daily Cost US\$ (Thousand Rubles)	Daily Cost US\$ (Thousand Rubles)	Daily Cost US\$ (Thousand Rubles)
Infectious Disease	11.64 (47.5)	8.28 (33.8)	8.28 (33.8)
General Surgery	17.70 (72.2)	10.93 (44.6)	7.21 (29.4)
Gynecology	13.73 (56.0)	7.94 (32.4)	8.28 (33.8)
Traumatology	15.86 (64.7)	12.62 (51.5)	7.21 (29.4)
Neurology	12.25 (50.0)	7.94 (32.4)	7.57 (30.9)

In order to receive reimbursement for services rendered, hospitals must submit a monthly invoice to the Insurance Trust with appropriate information, the following being examples: number of inpatient admissions, polyclinic outpatient visits, and average length of stay per type of treatment.

## H Exempt Patients

Federal decree #890 dictates that certain categories of the population have the right to receive drugs totally free or at a discount. Examples of patients receiving drugs totally discounted are war veterans, children 0-3 years old, diabetics, and those with AIDS. In addition, a discount of 50% is given to patients who are retirees receiving the minimum pension.

Because of the federal decree and the large number of veterans in Pskov city, Oblast Health Committee estimates that 40% of the patients in the city are exempt patients. All public and private sector pharmacies can sell drugs to exempt patients, but most private pharmacies prefer not to do so because of long reimbursement times. Reimbursement times are normally 10-45 days, but due to lack of funds it is sometimes months.

## I Insurance Medicine

### Mandatory Medical Insurance

In 1995 Pskov Oblast began to develop 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". Basically, all citizens are to be provided with complete medical coverage, including drugs, which is funded by Oblast Administration and municipal budgets, or through the wage tax paid by employers. Pskov Oblast Medical Insurance Fund has been established to oversee the medical insurance program with the function of accumulating and balancing finances for the Pskov Oblast program. The fund's finances are the property of the Russian Federation and are not included in the budget or any other funds for the Oblast.

The program started with mandatory insurance programs in 3 rayons, this has expanded to 17 to date. Oblast Administration expects to include all 24 rayons in the program by January 1, 1996. Funds for the insurance program consist of two parts:

- 3.6% wage tax paid by firms for each employee. 3.4% of the tax stays in the Oblast, 0.2% goes to the federal fund. Reimbursement to health facilities is done according to a system of tariffs. Outpatient facilities are paid per patient encounter. Hospitals are paid according to the five established tariffs. Hospitals prefer treating working patients since reimbursement from the fund is more reliable than from the oblast budget.
- Oblast and municipal budgets provide funds to health facilities for non-working population, and for target programs (special health programs which vary annually).

The medical insurance fund covers about 35.2% of the overall health budget. Most of the remainder comes from the oblast and municipal budgets (61%), and a small amount from fees for service (4%).

The fund is buying software for its offices and health facilities. The software will be used to keep statistics, and track payments from firms and to facilities. The fund has average length of stay figures for each disease. If the length of stay for a patient is less than 15% of the average, the hospital is given a per diem, rather than full reimbursement. The fund does inspections to see if monies are used correctly.

The insurance fund signed an agreement with Vilkie Lukie hospital, giving the hospital 400 million Rubles to buy diagnostic medical equipment (ultrasound, respirometer, dialysis). The equipment resulted in 221,000 US\$ (900 million Ruble) savings to the hospital. A decrease in length of stay of one day was attributed to the equipment. As a result of the decreased length of stay, the hospital received less reimbursement from the fund, but made this money up through increased admissions. In other words, more patients were treated with the same expenditures. City hospital #1 plans to purchase endoscopy equipment in a similar agreement.



**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 are increasing as drug budgets are decreasing since 1991
- 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 See Appendix 8 for exchange rates
- About 40% of outpatients and inpatients receive prescriptions either free of charge or at a discount, reimbursement to pharmacies and health facilities for exempt patient prescriptions takes up to 6 months and reimbursement funds are not indexed to inflation
- Normally the public health budget provides 290,000 Rubles/person/year from all sources of funding, due to financial constraints the Oblast only provided a total of 174,000 Rubles/person in 1995

## VI DRUG PROCUREMENT IN THE PUBLIC SECTOR

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

### A Procurement Decisions and Responsibilities

Drug procurement for the public sector has been the responsibility of Pskov Pharmacia, which orders from both domestic and international suppliers, however, as the market economy develops, fewer drugs are being supplied through Pharmacia.

#### 1 Drug procurement by Pharmacia

##### Staffing

The Pharmacia staff is composed of 16 pharmacists, 9 accountants, and 46 technicians with a total of 116 personnel, plus 4 computer specialists employed by a limited partnership company within Pharmacia. The Procurement Department employs 2 pharmacists and 3 technicians, and conducts marketing surveys to study drug prices, do quantification exercises, and decide what products to buy. The director may become involved in procurement decisions when funds are scarce.

##### Purchases

Pharmacia decides what to buy based on information obtained from health care facilities and pharmacies, as well as morbidity information from the Bureau of Medical Statistics at the Oblast Hospital. Quantification has become more difficult now that there are many local wholesalers. Contracts with suppliers are usually for one year, but shipments are received monthly in order to keep inventory low. Purchase orders are tracked with a card system, and supplier performance is gauged mainly by staff knowledge and experience. Pharmacia purchases mostly from suppliers that accept delayed payment, usually 15-30 days.

##### Purchases from Non-Domestic Sources

Direct purchases are made from Lithuania, Belarus, Latvia, and Estonia, and are payable in Rubles. Direct international hard currency purchases are made from two manufacturers, Schering-Plough and Merck, Sharpe and Dohme. Drugs purchased from international sources are antihistamines, corticosteroids, hormones, and antibiotics, with payment in US\$.

##### Vaccines

Responsibility for purchasing diphtheria and other vaccines for Oblast health facilities has been given to Pharmacia. Purchases are based on quantification done by health facilities, and prepayment is required. In addition, the firm has the responsibility for storage and distribution of vaccines received from federal programs, although compensation is not received for these services. Vaccines for federal programs are received in insulated containers, all others are received by mail in non-insulated containers.

##### Breakdown of Purchases

Pharmacia estimates a breakdown of 25% international versus 75% domestic purchases. Pharmacia orders about 65% from manufacturers and 35% from distributors like Pharmimex in Moscow. There is

one small manufacturing firm in the Oblast which produces extracts and tinctures, and sells products outside the Oblast as well

#### Management Information System

Pharmacia has two large domestic made computers (like IBM600) One is used to enter incoming and outgoing products, and to print waybills The second is used for accounting, and client information The director of Pharmacia considers the current MIS very outdated, and would like to purchase a new computer and software

#### Procurement by Tender

The first drug tender was conducted in the oblast in 1995, the tender committee consisted of chief specialists of the oblast, head of the pharmaceutical department, supervisor of the oblast financial department, deputy chief physician of the oblast hospital, and head of Pharmacia Oblast head physicians decided to conduct the tender for 5-7 of the most expensive antibiotics, anti-allergic, and cardiovascular drugs Insulin was not included in the tender Hospitals did a quantification exercise to assist in the tender The procedures of the tender were

- List of drugs was defined by generic name
- Health facilities quantified needs
- All wholesale companies in oblast received tender announcement with details and requirements
- Wholesale companies responded to the tender -- 5 days
- Proposals were analyzed and awarded -- 30 days
- All wholesale companies received a letter explaining the award and drug prices

Pharmacia and two other wholesalers won the tender The tender was deemed successful by the Oblast Administration Another tender is planned for 1996, and will be larger in scope

## 2 Drug procurement by health facilities

#### Ordering from Pharmacia

Drug orders are placed daily to monthly by health facilities, depending on the particular drug Order quantities are usually determined by review of past consumption Orders placed with Pharmacia provide the following information name, quantity ordered, and bank account number Daily orders are placed by telephone, with payment being made through bank transfers after receiving the drugs The major problems in getting drugs from Pharmacia are unavailability of certain drugs, cost of some drugs compared to other sources, and availability of hospital funds Until 1991, 95% of drugs were ordered from Pharmacia

#### Ordering from sources other than Pharmacia

City Hospital No 1 orders drugs only from Municipal Apteka #3, Veterans Hospital purchases drugs from various sources The Central Rayon Hospital at Palkino receives drugs from the limited partnership pharmacy located in the hospital Orders are placed by telephone, or in person, and payment is made through bank transfer There was little drug procurement from the private sector at the hospitals visited due mainly to unavailability of funds

**B Areas of Concern Related to Drug Procurement**

The following concerns were noted during the survey

- Since there are over 1200 drug wholesale and manufacturing firms in Russia alone, not counting the vast number of international firms, it is more difficult to determine the most cost effective prices
- Tendering procedures were utilized only one time in the Oblast (1995)
- Pharmacia is receiving fewer drug orders from health facilities, making it difficult to determine the proper mix of drugs to stock
- The computer system at Pharmacia needs to be upgraded in order to monitor drugs from various suppliers placed by tender, as well as to perform procurement analyses such as ABC and VEN analyses
- Unbiased drug information necessary to make rational procurement decisions, is limited at Pharmacia and health facilities

## VII DRUG DISTRIBUTION IN THE PUBLIC SECTOR

Drugs enter the Pskov Oblast drug distribution system from both domestic wholesalers and manufacturers, as well as foreign manufacturers. Within the oblast Pharmacia has been the major wholesaler of pharmaceuticals prior to 1991, but this is changing as the market economy takes effect, and subsidies to health facilities diminish. For example, in Pskov city there are now 16 private sector wholesalers, one State Enterprise wholesaler and 4 public sector municipal pharmacies also serving as wholesalers. Hospitals and pharmacies can purchase drugs from any of 1200 firms in Russia at this time.

### A State Enterprise Pharmacia

#### Stock and Inventory Levels

In October 1995, Pharmacia had 680 drugs and medical supplies in stock. An attempt is made to keep the 164 products on the Federal Essential Drugs List in stock at all times, normally 1.5 months supply. Pharmacia has ten retail outlets, all opened since 1991. These pharmacies are responsible for 25% of Pharmacia's turnover, and do not serve exempt patients. Certain medications can only be purchased and distributed by Pharmacia, as mandated by decree: insulins, narcotics, psychotropics, anesthetics, vaccines, serum, and blood. For that reason they are considered priority items by the firm. Inventory is taken yearly with the most recent count taken on November 1, 1995, total value was 490,196 US\$ (2 billion Rubles), including the stock at the ten Pharmacia retail outlets.

#### Receiving

Drugs are arranged by therapeutic groups, according to Federal regulation #520. The computer system tracks expiration dates, which allows Pharmacia to sell drugs FEFO (first expiration, first out).

#### Transportation

Most clients provide their own transportation for drugs, although Pharmacia has eight delivery trucks. The closest client is 500 meters from Pharmacia, the farthest is 400 km away.

#### Supply to Clients

Pharmacia has approximately 164 clients in the Oblast, including its own retail outlets. Drugs are ordered by telephone or telefax, and turn around time can be up to several days, although many orders are processed immediately. Since clients usually pick up their orders, therapeutic substitution for drugs not in stock can be discussed at that time.

#### Returned Goods

There have been some problems with receipt of damaged goods, or receipt of the wrong product, but they are rare. Most problems are resolved by negotiations between Pharmacia and the supplier.

### B Other Health Facilities

#### Compounding

Only one of the three hospitals visited has a pharmacy. The hospital pharmacy does compounding of prescriptions. Once the drug has been compounded and checked by a second pharmacist, a quality test

is performed by the analyst on staff. Records are kept of each batch compounded, and quality tests performed. The Oblast Quality Control Department does random testing of compounded prescriptions to verify accuracy. Physical and chemical tests, such as a titrated colorimetric method, are done for both qualitative and quantitative analysis. It was reported that reagent solutions for quality tests were not always available for purchase.

#### Transportation

Drug orders are picked up by the facility placing the order, delivered by Pharmacia, or delivered by the supplier.

#### Receiving and Storage Procedures

The head nurse receives, checks and stores the drugs on the appropriate ward. Storage is usually in cabinets, and there are refrigerators available when needed. The number of drug stock units kept in the hospitals varied from 25 to 200, and ledgers are being used to manually record receipts and disbursements.

#### Product Quality Assurance

Reports on product quality ranged from "never had a problem" in the case of one hospital, to expired drugs in others. The head physician decides what course of action to take when quality problems are discovered.

### **C Areas of Concern Related to Drug Distribution**

- With health facilities being able to order from any drug supplier, it is difficult to control public sector drug distribution.
- Many hospitals do not have pharmacies, nor pharmacist involvement in monitoring inpatient drug distribution and use.
- Mostly biased drug information in the form of package inserts is available for prescribers and dispensers to use for new drugs coming into the Oblast.

## VIII COMMUNITY PHARMACY

Outpatients receive drugs from the network of community pharmacies located throughout the Oblast. Before 1991 the government did not require pharmacies to be profitable, and would provide financial assistance when needed. Today public sector pharmacies are needing to achieve profitability, since health budgets are unable to provide the same level of assistance. Private pharmacies have evolved during the same period of time, and the number of private pharmacies will likely continue to increase.

### A Structure of the Pharmacy Network

#### Number of Retailers

Pharmacies supplied by municipal warehouse pharmacies -- 109 (40 in cities, 69 in rural areas) \*

Pharmacies in health facilities -- 8

Pharmacies in Pskov city -- 29

Pharmacies in Vilkie Luki -- 8

Private retail pharmacies -- 9

Pharmacies operated by Pharmacia -- 10

*Total number of retail pharmacies -- 173*

\* (total number includes municipal warehouse pharmacies)

### B Regulation and Inspection

The following federal and oblast departments monitor pharmacies, health facilities, and manufacturers for compliance with federal and oblast regulations: Pharmaceutical, Quality Control Lab, Pricing, Narcotics, Tax, Finance, Sanitation and Epidemiological Control. Because the Pharmacy Department was disbanded from 1992 to 1995, results of inspections for pharmaceutical services were not recorded. Currently with the 5 persons assigned to the Pharmaceutical Department, inspections are done as needed and to establish licensing for a new facility. The Pharmaceutical Department inspectors monitor for sanitary conditions, storage conditions, expiration dating, and control of narcotics, poisons, and spirits.

### C Community Pharmacy Interviews During the Assessment

Three pharmacies were visited during the interview portion of the survey: two in Pskov city, one in Palkino rayon. The number of outpatients that receive drugs at these pharmacies range from 12,000 to 100,000 patients, depending on the population they serve. Since pharmacies only keep records of prescriptions dispensed to exempt patients, and for narcotic, poisons and spirits, the exact number of patients visiting the pharmacies on a given day is unknown, however, using cash register and exempt patient records as a guide, the average daily outpatient visits were estimated to be 100 in the case of Palkino pharmacy to 1400 for one of the Pskov city pharmacies.

#### Pharmaceutical Services

Items usually available in the three pharmacies visited are: prescription, OTC, and compounded drugs,

as well as, various sundries such as shampoo, band aids, and sphygmomanometers. Some pharmacists indicated they counsel patients on the proper use of medicine, and provide information to prescribers when requested. The pharmacist at Palkino pharmacy was appointed to serve on the recently established formulary committee of Palkino Central Rayon Hospital.

### 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.

	<u>Municipal Enterprise Pharmacy # 3</u>	<u>Municipal Enterprise Pharmacy # 100</u>	<u>Central Rayon Hospital Pharmacy (Palkino)</u>
Number Pharmacists	9	8	1
Number Technicians	24	8	5
Number Clerks	2	2	0
Number Cashiers	3	2	0
Number Drivers	0	1	1
Number Clean/Wash	1	3	1
Number Assistants	5	1	1
Avg. Number Hours Worked per Week	38	38	41

### Dispensing

The dispensing operation is shared by pharmacist and technician, both interpret, fill or compound prescriptions. For prescriptions that have been compounded, a second pharmacist checks for accuracy and an analytical pharmacist performs qualitative and quantitative testing. Commercially prepared products are dispensed in the containers in which they were purchased from the supplier. For prescriptions compounded in the pharmacy the following information is placed on the label: patient name, pharmacy name, date compounded, pharmacist's initials, name of drug, number of units, quality test number, expiration date, storage conditions, external use only (if appropriate), and sterile (if appropriate).



Sales Category Percentages by Value	<u>Municipal Enterprise Pharmacy # 3</u>	<u>Municipal Enterprise Pharmacy # 100</u>	<u>Central Rayon Hospital Pharmacy (Palkino)</u>
Compounded Rx's	3 2	1 0	3
Commercial Drugs	51 1	79 0	40
OTC Drugs	44 3	18 3	17
Other	1 4	1 7	40

Generic substitution is done by the pharmacist for out of stock drugs, however, the physician is contacted if no generic substitute exists

#### Pharmaceutical Monitoring

For all pharmacies the last pharmacy inspection was by the Oblast Financial Department in November and December, 1995, respectively. The purpose of the inspection was to determine if local taxes had been paid and to check prescription prices. Palkino pharmacy indicated that the Central Analytical Lab in Pskov had inspected the compounding area in February, 1995.

#### Drug Information

When dispensing prescriptions to outpatients the pharmacist discusses potential patient allergies and drug reactions, if appropriate. Commercially prepared products are dispensed with the package insert intact. Drug references available in the pharmacy are *Mashkovsky, Vidal, and the Russian Pharmacopoeia*. These and other references are updated as they become available.

#### Drug procurement and Inventory Management

The head pharmacist determines which drugs to order based on usage, but the quantity ordered is usually determined by availability of funds. If unavailable from other sources, the drugs are ordered from Pharmacia. Normally orders are received within 1 to 2 days, except for the Rayon pharmacy which ranges from 1 to 7 days. Orders are placed by telephone (sometimes Pharmacy No 100 uses telefax), and payment is made by bank transfer. The major problem experienced in getting drugs from suppliers is availability, cost, and lack of funds.

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

Thousands of US\$ (Millions of Rubles)	<u>Municipal Enterprise Pharmacy #3</u>	<u>Municipal Enterprise Pharmacy # 100</u>	<u>Central Rayon Hospital Pharmacy (Palkino)</u>
Inventory Jan 1, 1995	82 4 (336 045)	15 7 (64 1)	Not Reported
Inventory Jan 1, 1994	18 7 (76 214)	5 6 (22 7)	Not Reported
From Pharmacia Aug-Oct, 1995	20 0 (81 578)	6 2 (25 4)	Not Reported
From Other Suppliers Aug-Oct, 1995	123 1 (502 351)	56 5 (230 4)	Not Reported
Direct from Manufact. Aug-Oct, 1995	140 1 (571 545)	Included with "From Other Suppliers" data	Not Reported

Common practice is to conduct physical inventories twice a year, and the most recent inventories were done in October and November, 1995. The Rayon pharmacy stocks 115 different drug items, the Pskov city pharmacies, 2500 items. Most pharmacies use stock cards and ledgers to control drug inventories, Pharmacy No 3 uses a computer. In all pharmacies visited commercially prepared drugs constitute the majority of drugs dispensed.

#### Financial Data

The three pharmacies visited during the interview portion of the survey provided the following information relative to percentage of sales of different drug categories:

Categories as Percentage of Sales	<u>Municipal Enterprise Pharmacy #3</u>	<u>Municipal Enterprise Pharmacy # 100</u>	<u>Central Rayon Hospital (Palkino)</u>
Private pay @ 100% retail price	19 1	44 2	25
Exempt pay up to 100% of retail price	22 4	37 7	30
Wholesale pay	58 5	18 1	5

During the survey, seven pharmacy directors were issued spreadsheets and asked to provide financial information for their pharmacies. The following is a synopsis of those results.

	Source or Category	Average %	Average Number
Revenue	Cash transaction	50.0	NA
	Exempt prescription	35.8	NA
	Wholesale transaction	14.2	NA
Expenses	Wages	* 51.0	NA
	Taxes and Licenses	11.6	NA
Staffing	Personnel	NA	** 19.3
Profitability	Net Profit Before Taxes as % of Sales	7.8	NA

\* (US average is 57.5% from NARD Lilly Digest 1995)

\*\* (approximately four times western standard)

For the seven community pharmacies providing financial data, six financial ratios were calculated, which relate to solvency, managerial efficiency, and profitability of the pharmacy. The ratios showed that all seven pharmacies posted a profit, but in only two pharmacies were all six ratios in the normal range of acceptable performance.

### Drug Pricing

Oblast Administration has set a mark-up limit of 40% at each stage in the distribution process, for both public and private sector facilities. All three pharmacies indicated that they normally use the 40% markup for prices to patients. For procurement from Pharmacia, Palkino hospital indicated they pay cost plus 25% markup.

### Physical Facility

The pharmacy space was reported to be adequate in most cases, but all needed one or more upgrades to equipment such as the distilled water system, or the sewage system of the facility. 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. Palkino Hospital Pharmacy indicated that in addition there is technical training provided once weekly.

**D Areas of Concern Related to Community Pharmacy**

- Prior to 1991 most pharmacies did not participate in the decision-making process, and currently lack experience in one or more areas of pharmacy management
- Delays in reimbursement for exempt prescriptions, as well as a punitive tax structure, contribute heavily to financial difficulties of pharmacies
- The large number of personnel working in a typical pharmacy, compared to western standards, exacerbates the struggle pharmacies are having in remaining profitable

## **IX 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**

Drug registration laws in Russia require that all marketed drugs be registered. The federal agency established for this purpose is the MOH Bureau for Drug Registration. At the Oblast level registration is verified by referring to the *Register of Russian Drugs* published by the federal agency. Drugs that are registered after the reference book is published for both foreign and domestic products, are communicated to the various Oblasts through the newspaper, *Pharmaceutical Review*, which is prepared by a pharmaceutical company in association with PharmedInfo, Federal quality control agency, and Federal drug registration bureau. A computer database of all registered products is also available.

### **B Drug Imports**

In order to import drugs into the oblast, importers must contact the federal licensing bureau each time an order is placed. Insulins are imported duty free, other drugs have a 10% duty charge.

### **C Pharmacy Practice Act**

Both pharmacists and pharmacy technicians are allowed to dispense medications in the oblast. Pharmacies may be State owned, individually owned, or owned by State societies. Private pharmacies, however cannot dispense controlled substances, spirits and poisons. Pharmacists and Physicians working in the public sector can own private pharmacies if they wish. All Pharmacies must have a pharmacist on the premises, and there are no restrictions on selling sundries.

### **D Medical Practice Act**

The following health care providers are allowed to prescribe medications in the public sector: Physician, Feldsher, and Feldsher Midwife. In the private sector only physicians are licensed to prescribe at this time. Physician licenses must be renewed after the 1st year and then every 5 years for public sector, every 3 years for private sector physicians.

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## X DRUG UTILIZATION AND DISEASE PATTERNS IN THE OBLAST

### A Morbidity

The most frequent causes of illness in Pskov Oblast in 1995 for adults and children 0-14 years of age by percentage were

<u>Adults</u>		<u>Children</u>	
<u>Disease</u>	<u>Number</u>	<u>Disease</u>	<u>Number</u>
Respiratory	38.4	Respiratory	65.3
Trauma	19.8	Infection	10.6
Central Nervous System	9.0	Trauma	8.6
Skin	8.8	Central Nervous System	6.6
Skeleto-muscular	5.4	Skin	6.0
Genito-urinary	5.3	Digestive Tract	3.9
Infection	5.2	Genito-urinary	0.9
Digestive Tract	3.4	Musculo-skeletal	0.7
Blood/Circulatory	2.7		
Cancer	1.9		

The following birth/ death rates and population growth were reported for the Oblast

Year	Birth Rate	Mortality	Child Mortality	Population Growth
1992	9.3	16.6	18.3	-7.3
1993	8.1	20.3	19.5	-12.2
1994	7.9	22.6	20.3	-14.7

### B Treatment Protocols

Standard treatment guidelines of varying types are available in the public sector and the Oblast Health Committee indicated an interest in RPM assistance with revising and updating them. None of the hospitals visited reported a program in place to perform drug usage review studies.

### C Areas of Concern Related To Drug Utilization and Disease Patterns in the Oblast

- DUR programs for studying the rational use of prescribed drugs were not found to exist in oblast hospitals or outpatient clinics
- Currently STGs are present in the oblast, but are based on federal general guidelines, they need to be updated and combined with DUR and formulary programs for promoting rational drug use

## **XI QUALITY CONTROL TESTING AND INSPECTIONS**

Drug products in Pskov Oblast are tested for quality at the Oblast Quality Control lab in Pskov city, and individual pharmacies where drugs are compounded. The Oblast Quality Control lab conducted a total of 10,200 tests in 1994. Quality tests include identity and strength (colorimetric method or chemical analysis method used), and stability (includes tests for strength on spirits). Distilled water is tested on a daily basis by each pharmacy where the water is distilled. Equipment used for testing includes spectrophotometer, photocolormeter, pH meter, polarimeter, refractometer, and analytical balances. No gas or high pressure liquid chromatography is available for testing.

Samples for commercial drugs are pulled when received at Pharmacia. The Quality Control lab estimates that 70% of commercial drugs received in Oblast are tested, the rest are accepted on a certificate of analysis. A certificate of analysis usually comes with imported drugs. Samples for compounded prescription are pulled in the pharmacy where compounded, by the analytical pharmacists of the oblast lab. It is estimated that 1.5% of all tests conducted reveal defective products, including tests of raw materials, commercial drugs, and distilled water. When problems are discovered, contact is made same day of discovery by telephone to all pharmacies and the Oblast Health Committee. The Oblast lab is monitored by the Quality Inspection Department of the MOH in Moscow, usually by sending products to Moscow, although on-site inspections are done on a random basis.

Current reported problems with quality testing include 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. There is no established system for reporting problems with drugs, they are handled on an individual basis.

## **XII DRUG INFORMATION**

During the transition from a central to an oblast controlled health system, the provision of quality drug information services has been difficult to maintain. Several officials were interviewed during the assessment in order to determine the status of current drug information activities and the need to upgrade existing drug information services. According to those interviewed, the most popular and often the only reference book encountered in health facilities is Mashkovski, existing periodicals are few, and pharmaceutical manufacturing representatives are the primary providers of current drug information. For a list of the persons met and the facilities visited see Appendix 3.

### **A Oblast Health Committee**

In a meeting with the heads of the Oblast Health and Pharmaceutical Committees, interest was expressed in establishing two drug information centers in the Oblast: one in Pskov, the other in Velikie Luki, the two largest cities in the Oblast, which are located approximately 160 miles apart. Before 1953 Pskov and Velikie Luki were separate oblasts, and even today continue to serve their respective geographic regions. The two drug centers would be located in the Pskov Oblast Hospital and the Velikie Luki City Hospital.

### **B Pskov Oblast Hospital**

The Central Oblast Hospital has a library which provides medical information to prescribers. However, current medical reference materials are limited due to lack of funds, with the majority of information being provided by pharmaceutical manufacturing representatives. Hospital officials expressed interest in establishing a drug information center at the hospital, and have already identified space to locate it.

### **C Velikie Luki Central City Hospital**

Officials of the City Health Committee and the hospital expressed an interest in establishing a drug information center at Velikie Luki Central City Hospital. There was currently no space available to place the center, but arrangements could be made in the future with little difficulty.

### **D Areas of Concern Related to Drug Information**

- There is no drug information network, nor drug information centers in the Oblast at this time.
- Current drug information is very limited. In most health facilities, medical reference books are not readily available except for Mashkovski. Pharmaceutical manufacturing representatives provide the bulk of current information to pharmacies, health facilities and hospitals in the Oblast.



**APPENDICES**

**APPENDIX 1**  
**TRACER DRUG LIST FOR HOSPITALS**

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

	<b>ПРЕПАРАТ</b>	<b>DRUG</b>	<b>ДОЗА</b>	<b>ФОР МА</b>
1	преднизолон	prednizolone	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	acetylsalycilic acid	500mg	таб.
22	доксциклин	doxicycline	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.**

	<b>ПРЕПАРАТ</b>	<b>DRUG</b>	<b>ДОЗА</b>	<b>ФОРМА</b>
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	doxicycline	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**

**PSKOV OBLAST  
FACILITIES VISITED AND PERSONS MET**

Dr Sergei A Shlygin	Head of Oblast Health Committee
Dr Anatoli Bogatin	Deputy Head of Oblast Health Committee
Alexei Kluchanski	Chief of Oblast Pharmaceutical Department
Dr Victor D Konovalov	Head of Velikie Luki City Health Committee
<u>Municipal Hospital No 1</u>	
Dr Alexei Korotkevich	Chief Physician
Tatiana Valaksina	Pharmacist
<u>Veterans Hospital</u>	
Dr Margarita Lukachova	Chief Physician
Dr Ludmila Nuchina	Deputy Chief Physician
<u>Central Oblast Hospital</u>	
Dr Victor V Antonov	Chief Physician
Dr Uriy V Matveev	Deputy Chief Physician
Irina U Shetinina	Director of Library
<u>Velikie Luki Central City Hospital</u>	
Dr Tatiana A Avdoseeva	Deputy Chief Physician
<u>Central Rayon Hospital (Palkino)</u>	
Dr Victor Kazmin	Chief Physician
Dr Antonina Prusakova	Deputy Chief Physician
Latyfova Gulnara Mubarovna	Head of Pharmacy
<u>Municipal Enterprise Pharmacy #100</u>	
Valentina Gavrishchuk	Head of Pharmacy
<u>Municipal Pharmacy # 3</u>	
Nina Nentzova	Head of Pharmacy
Lidia Pankratieva	Chief Accountant
<u>Pskov State Enterprise Pharmacia</u>	
Elena Kamenskaya	Head of Facility
Kira Stankevich	Chief of Trading Department
<u>Pskov Central Quality Control Laboratory</u>	
Galina Kostina	Head of Facility

**APPENDIX 4**  
**PHARMACIES PROVIDING DATA FOR THE INDICATOR STUDY**



**PHARMACIES PROVIDING DATA FOR THE INDICATOR STUDY**

<u>Name</u>	<u>Type</u>	<u>Location</u>
Pharmacia Apteka #1	Public	Pskov
Pharmacia Apteka #2	Public	Pskov
Apteka #3	Public	Pskov
Apteka #4	Public	Pskov
Apteka #5	Public	Pskov
Apteka #71	Public	Pskov
Apteka #100	Public	Pskov
Apteka #103	Public	Pskov
Apteka #106	Public	Pskov
Apteka #107	Public	Pskov
Apteka #42	Public	Velikie Luki
Apteka #43	Public	Velikie Luki
Apteka #105	Public	Velikie Luki

**APPENDIX 5**  
**OBLAST HEALTH FACILITIES BY TYPE AND LOCATION**

## HOSPITALS AND HEALTH FACILITIES PSKOV OBLAST

The network of medical and prophylactic establishments in Pskov Oblast exists at various levels and is based on location of population (urban or rural), who provides the funding, and the types of services provided. Following is a listing of these facilities.

### Funded by Pskov Oblast budget

- Central Oblast hospital
- Veterans hospital
- various specialty hospitals and facilities eg tuberculosis, cutaneous disease, oncology, mental disease, neurology, and infectious disease
- blood transfusion stations
- sanatoria
- stomatologic polyclinic
- orphanages for 0-3 years old
- autopsy center
- drug information center
- medical schools for nurses

### Funded by Municipal Budgets

- various municipal health facilities
- rayon and city hospitals
- district hospitals
- polyclinics and ambulatories for outpatient services
- dispensaries for inpatient and outpatient specialty services usually in larger towns
- feldscher first aid stations all in rural areas

### Funded by MOH Budgets

- railroad, military and border guard facilities
- industrial enterprise facilities

### Funded by Federal Budgets

- sanitary-epidemiological centers
- federal MOH warehouse for drugs

**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 Susutamability Contract
INRUD	International Network for the Rational Use of Drugs
LAC	Latin American and Carribbean 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 Pharmaceopeia
WHO	World Health Organization

**APPENDIX 7**  
**RPM ASSESSMENT METHODOLOGY**

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## 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 Committee

### 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 Committee 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 Committee
- Pharmaceutical Department of the Oblast Health Committee
- State Enterprise Pharmacia
- Municipal and Rayon Hospitals
- Insurance Funding Company
- Municipal and Rayon, Public and Private Enterprise Pharmacies

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)