

PD-ABI-181
87

**NIS HEALTH CARE IMPROVEMENT
PROJECT 110-0004**

AMENDMENT NO. 2

Russian Humanitarian Medical Assistance

March 24, 1994



U.S. AGENCY FOR
INTERNATIONAL
DEVELOPMENT

MAR 23 1994

ACTION MEMORANDUM FOR THE ASSISTANT ADMINISTRATOR, ENI

FROM: Barbara Turner, A-DAA/ENI/PA

SUBJECT: Amendment No. 2 to Health Care Improvement Project
110-0004

Proposed Action: Your authorization of an amendment to increase the life of project funding for the Health Care Improvement Project to a total of \$194 million and extend the Project Activity Completion Date by one year to December 31, 1998. This increase of \$94 million will provide \$90 million to finance the Russian Humanitarian Medical Assistance activity and \$4 million to finance women's health activities.

Background: Prior to the break-up of the Soviet Union in 1991, the centralized Russian health system was already suffering from neglect and underfunding. Nevertheless, the Ministry of Health maintained reasonable supplies of essential drugs, and conducted an extensive immunization program with impressive achievements in child vaccination coverage. The basic infrastructure for effective service delivery and information gathering was in place, and staffed with a large health workforce, albeit one not trained to Western standards.

With the dissolution of the USSR came a disruption of supplies from other republics and Eastern European countries, as well as a disruption of local production generated by shortages of raw materials and hard currency. This disruption left Russia short of manufacturing capacity for key medical substances, materials and equipment.

Early in 1992, international donors--including the U.S.--sent a number of teams to Russia to assess the status of pharmaceutical and vaccine security. In the vaccine sub-sector they found that: (a) although immunization services and distribution systems were upset, vaccine production was being restored to adequate levels; (b) quality assurance suffers from the use of outdated equipment, low budgets and inadequate testing; (c) breakdowns in the cold chain have been experienced; and (d) the public's confidence in the immunization program has declined.

On the pharmaceutical side, the teams reported that: (a) many

essential drugs and medical supplies were not being produced in sufficient quantities such that medical facilities experience critical shortages; (b) many Russians cannot afford necessary imported medicines; (c) quality assurance is substandard; and (d) distribution systems are weak, and in part being replaced by private sector endeavors.

Although Russia has a population large enough to support local production of vaccines and pharmaceuticals, and a government which supports such production, substantial legal and policy reforms would be required in order to attract the foreign investment required to update the facilities. (A major hurdle was recently overcome when the Russian government agreed on February 16 that U.S.-manufactured drug and biological products approved by the U.S. Food and Drug Administration will have an expedited registration procedure in the Russian Federation.)

The U.S.-Russian Expanded Cooperation Package signed in Tokyo in June 1993 includes a \$75 million component for "Humanitarian Medical Assistance: Medicines and Pharmaceutical Procurement and Production." Among the objectives of the Tokyo Package is procurement of essential supplies, medicines and assistance to help Russian producers move away from dependency on foreign providers. The proposed program responds to this objective.

Description of Proposed Activities:

A. HUMANITARIAN MEDICAL ASSISTANCE. This activity would provide \$90 million over a four year period to support the development of vaccine and pharmaceutical security in Russia. The activity has two primary components:

(1) Strengthening Health Information and Response Capability. Russia's health monitoring system suffers from a history of inadequate quality controls and obsolete analytical methods. Although the epidemiology data system is nationally comprehensive, it is unreliable and not utilized effectively. The ability of the health system to respond effectively is limited by a shortage of essential drugs as well as the lack of cost-effective prevention and service delivery strategies. This component will fund approximately \$35 million (\$30 million in FY '94) in training, technical assistance and commodities to strengthen key aspects of public health information (including early warning systems), as well as strengthen the capability of the government to respond to both emergency and regular health problems. Until indigenous capacity is in place, continued inputs of certain essential commodities will be required over the short term to address fundamental humanitarian needs in specific vulnerable populations or crisis situations.

(2) Promoting Private Sector Production and Distribution of Medical Commodities. The development of private sector

ventures in medical commodities has been particularly hampered by inappropriate regulations, bureaucratic conflicts and legal ambiguities. This component will provide some \$66 million (\$30 million in FY '94) to help promote conditions favorable to private enterprise and foreign investment in the health sector, and to mobilize and leverage private sector resources in specific medical commodity production or distribution activities. It includes a number of activities:

- Approximately \$5 million of the FY '94 funds will finance TA, training and equipment upgrading to strengthen regulatory, manufacturing and management practices for pharmaceuticals and vaccines.
- Another key element of this component will be Medi-business Development, which will help foster pre-conditions to sustainable private sector investment in medical commodities, and provide financial and technical incentives to speed or attract that investment. This will include approximately \$16 million in technical assistance, training and start-up capital to help Russian small, private medical businesses launch and/or expand production and distribution activities.
- The Technology Transfer activity addresses the need for capital investment for facilities and equipment, specialized technical assistance and worker training. Approximately \$45 million is budgeted to help accelerate investments by U.S. companies predisposed towards a specific U.S.-Russian joint venture activity in the field of medical commodities. USAID awards to such firms would be competed, and funding joined with investments on the part of the joint venture partners to secure the best possible technology and encourage sustainability of the activity.

B. WOMEN'S HEALTH INITIATIVES. This amendment to the Health Care Improvement Project will include \$2 million to expand activities in Central Asia, of which \$0.5 million is budgeted for expanding the program in Tajikistan. Technical assistance and commodities will be provided through buy-ins to Global Bureau contracts. An additional \$2 million will support NIS-wide training and seminars in family planning/women's reproductive services to develop the capacity of policy makers, program managers and clinicians to improve reproductive health.

Status of Project Design: The Russian Humanitarian Medical Assistance Concept Paper, approved by USAID/Moscow, was reviewed and approved by ENI on January 28, 1994. The following issues were identified for consideration prior to implementation:

(a) Mixed Credits/Tied Aid: Given the provisions of the Helsinki

Accord which indicates program activities financed through grants or export credits are covered by tied aid credit rules and procedures, it is important that we assure the Medi-Business portion of the program meet these guidelines. USAID/Moscow is requested to send the final details of this program element to USAID/W for concurrence by PPC before obligation.

(b) Program Components: There are a significant number of management units in the concept paper, particularly components related to commodities either for procurement, distribution or local production. The Mission is asked to identify ways in the final design to reduce the number of management units and closely coordinate the commodity elements of the program.

(c) Contraceptives should be included in the pharmaceutical and investment and production capacity final design. An emphasis should also be given to generic and essential drugs.

The following is an illustrative budget for the Project by component (in \$000):

<u>COMPONENT</u>	<u>Previous Amend.</u>	<u>Amend.2</u>	<u>LOP Total</u>
I. Partnerships	23.0	0	23.0
II. Productive Capacity			
Vaccine/Pharma.	3.4	0	3.4
Russ. Hum. Med.	0	90.0	90.0
III. Expanded Health			
Trade & Invest.	3.6	0	3.6
Health Care Fin.	65.0	0	65.0
IV. Women's Health	4.5	4.0	8.5
V. Environ. Health	<u>0.5</u>	<u>0</u>	<u>0.5</u>
Total	100.0	94.0	194.0

Legislative Requirements: The Congressional Notification submitted November 22, 1993 advised Congress of AID's intent to obligate \$30 million to finance humanitarian medical assistance promised as part of the USG commitment at the Tokyo Summit. This was the amount projected to cover financing requirements for a three month period (i.e. November to February). Congress has put an informational hold on this portion of the CN pending approval by the Administration of the Concept Paper. An additional Congressional Notification will be required to fully fund this activity.

A Congressional Notification will be required in order to obligate the additional \$4 million for women's health activities.

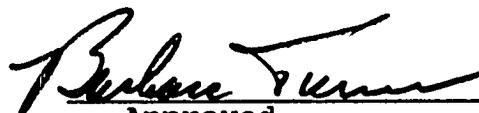
The Initial Environmental Recommendation is a positive determination, with a categorical exclusion for training activities and technical assistance. An Environmental Assessment will be carried out on all non-training/TA activities prior to their commencement in the field.

The FREEDOM Support Act and the FY 1994 Appropriations Act contain several provisions that limit assistance or require the Executive Branch to consider certain factors in providing assistance. Section 498A sets forth a number of matters to be taken into account in providing assistance to NIS countries, such as progress toward democracy and economic reform, human rights, peaceful resolution of ethnic disputes and restraining arms transfers. Section 498A also prohibits aid to any NIS country that violates any of a number of restrictions relating to human rights, arms control and nuclear proliferation. As indicated in the clearances below, State has taken these provisions into consideration in approving this memorandum.

Recommendations: That you sign: (1) below approving an amendment to the Health Care Improvement Project that provides \$90 million for Russian Humanitarian Medical Assistance, \$4 million for women's health activities, and extends the PACD to December 31, 1998; (2) the project authorization amendment increasing the life-of-project funding for Project 110-0004 to \$194 million; and (3) the Initial Environmental Examination.

Delegation of authority for implementation of a portion of the Russian Humanitarian Medical Assistance program will be conveyed separately.

No obligations for Russian Humanitarian Medical Assistance will be incurred prior to release of the Congressional hold. The initial obligation for this activity will be limited to \$30 million, and a further Congressional Notification required to permit obligation in excess of that amount. No funds for women's health activities will be obligated prior to completion of CN requirements.


Approved

Disapproved

3/24/94
Date

draft:mdj:2/24/94

Clearance:

ENI/DAA/PO:CPascual_____

NIS/DIHR:GDonnelly (draft)

NIS/DIHR:JKlement (draft)

NIS/PAC:PMatheson (draft)

NIS/FA:BKline (draft)

NIS/CONT:JWinn (draft)

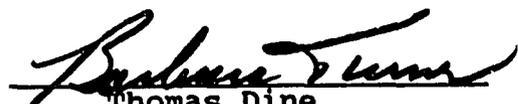
GC/ENI:RSarkar (draft)

S/NIS:HConley (draft)

**SECOND AMENDMENT
TO
PROJECT AUTHORIZATION**

Name of Region: New Independent States (NIS)
Name of Project: Health Care Improvement
Project Number: 110-0004

Pursuant to Section 201 of the FREEDOM Support Act of 1992 and the section entitled "Assistance for the New Independent States of the former Soviet Union" of the Foreign Operations, Export Financing, and Related Programs, 1994 (P.L. 103-87), I hereby authorize Amendment No. 2 for the Health Care Improvement Project. The life-of-project funding is hereby increased from \$100 million to \$194 million in grant funds, subject to availability of funds in accordance with the A.I.D. OYB allotment process, to help in financing foreign exchange and local currency costs of the Project, and the Project Assistance Completion Date is hereby extended from December 31, 1997 to December 31, 1998. All other conditions remain the same.


Thomas Dine
Assistant Administrator
Europe and New
Independent States Bureau

3/24/95-
Date

Clearance:Amendment No.2, Project 110-0004:

ENI/DAA/PA:BTurner B
ENI/DAA/PO:CPascual (draft)
GC/ENI:RSarkar (draft)
ENI/NIS/PAC:PMatheson (draft)
ENI/NIS/DIHHR:GDonnelly(draft)
ENI/NIS/FA:BKline (draft)
S/NIS:HConley (draft)



U.S. AGENCY FOR
INTERNATIONAL
DEVELOPMENT

MAR 31 1994

ACTION MEMORANDUM FOR THE ASSISTANT ADMINISTRATOR, ENI

FROM: Barbara Turner, A-DAA/ *BT*

SUBJECT: Delegation of Authority for Implementation of the
Russian Humanitarian Medical Assistance Activity:
Project 110-0004

Proposed Action: Your approval is needed to delegate authority to USAID/Moscow for the implementation of the Russian Humanitarian Medical Assistance activity.

Discussion: USAID/Washington has authorized Amendment No. 2 to the NIS Health Care Improvement Project, which provides an additional \$60 million in FY 1994 to finance the Russian Humanitarian Medical Assistance activity. The activity is part of the July, 1993, Tokyo G-7 meeting program announced for Russia, providing humanitarian medical assistance through medicines and pharmaceutical procurement and production. The activity has two components, one of which strengthens health information and response capability. The resources to be provided under this component include long and short-term technical assistance, training, workshops, equipment and a limited amount of essential vaccines and medical commodities. The activities are to be managed and carried out by USAID/Moscow.

The second component, Promoting Private Sector Production and Distribution of Medical Commodities, includes two activities: (a) strengthening regulatory, manufacturing and management practices, and (b) medical business development (Medi-business). For purposes of the timely and effective administration of this component, it is important that full implementation responsibility reside in the field Mission.

On January 28, 1994, the USAID/Moscow Concept Paper on Russian Humanitarian Medical Assistance was reviewed and approved by USAID/Washington and subsequently reviewed by an inter-agency health committee. Two issues were identified at the review which must be addressed by the Mission prior to implementation: (1) program components: There is some potential overlap of several

of the components related to procurement and investment in commodities. The Mission is asked to consolidate and closely coordinate as many of the commodity related components as possible, and to keep the number of separate units of management with the activity as limited as possible. (2) Mixed credits/tied aid: While the current proposal is to competitively bid procurement of goods and services, Mission should take into account the provisions of the Helsinki Accord package, wherein program activities financed through grants or export credits are covered by tied aid credit rules and procedures. The rules apply to all tied aid credits with a concessionality value below 80 percent and a value of SDR two million (USD 2.74 million) or larger. Since pharmaceutical and other health care industry firms expressing interest in bidding on this activity may also want to request loan financing from OPIC, EXIM, etc., Mission should review design carefully for conformance to the guidelines for officially supported export credits which have been supplied to the Mission. Because of the broad AID policy issues involved in the Medi-Business Component of the program, Mission is required to send final details of this element to USAID/W for concurrence by PPC/POL.

Implementation Authorities: The duties and responsibilities proposed for delegation to the Mission Director of USAID/Moscow for purposes of implementing the Russian Humanitarian Medical Assistance activity include the following authorities:

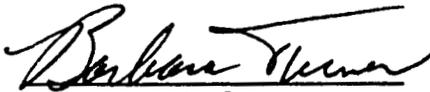
1. Memoranda of Understanding (MOUs). Authority to negotiate, execute and implement MOUs with host governments (central or local level) that do not obligate AID funds, in accordance with any ENI and/or agency guidance on the use and format of MOUs.
2. PILs. Authority to prepare, negotiate, sign, deliver and implement Project Implementation Letters and amendments thereto.
3. PIOs. Authority to sign or approve Project Implementation Orders.
4. Contracts. Authority to act as the Contracting Officer's Technical Representative (COTR) for all contracts involving the delivery of goods or services or both for implementation in the field.
5. PASA/RSSAs. Authority to sign statements that proposed PASA or RSSA agreements are exempt from OMB Circular A-76. (This circular generally allows other government agencies to provide goods or services to AID only if the goods or services cannot be provided by the private sector.)
6. Source, Origin and Nationality Waivers. Authority to waive, in accordance with Section 498B(h) of the Foreign Assistance Act, any other applicable statutes and regulations and the criteria contained in Supplement E of AID Handbook 1B, source, origin or nationality requirements to permit the procurement of commodities

and services (other than transportation services) in countries outside the authorized Geographic Code, subject to the following:

- (1) Each waiver shall be in writing and copies shall be sent to ENI/NIS/PAC;
- (2) Each waiver of the requirement that motor vehicles be manufactured in the United States shall contain a certification signed by the principal officer of the post that "special circumstances exist to waive the requirement of Section 636(i) of the FAA".

Delegation Authority: Pursuant to Interim Reorganization Delegation of Authority No. 1 dated October 1, 1993, and General Notice No. 1 of October 1, 1993, the AA/ENI has been delegated all authorities with respect to Europe and the NIS formerly held by the Assistant Administrator for Europe and the Director of the NIS Task Force. These authorities included authority to implement and manage programs and projects in the NIS, which you may redelegate to principal officers in field posts.

Recommendation: That by signing below, you hereby delegate the authorities specified above under "Implementation Authorities" to the Mission Director, USAID/Moscow. Prior to the exercise of the authorities delegated hereby, the Mission Director should seek appropriate technical and legal review. The authorities delegated hereby may, in the discretion of the Mission Director, be further redelegated to his/her deputy or the individual acting in such capacity and, for the authority to act as COTR, to any United States direct hire staff member.


Approved

Disapproved

3/31/94
Date

mdj/tg:3/11/94
Clearance:
GC/ENI:TGeiger (draft)
ENI/NIS/DIHHR:GDonnelly (draft)
ENI/NIS/PAC:PMatheson (draft)

RUSSIAN HUMANITARIAN MEDICAL ASSISTANCE
(Concept Paper March, 1994)

I. PROJECT SUMMARY

This concept paper proposes a four-year \$90 million Russian Humanitarian Medical Assistance sub-project to the Health Care Improvement Project (110-0004). To be obligated over two years, the subproject is comprised of two major components:

Component One **Strengthening Health Information and Response Capability**
(including humanitarian commodities)

Component Two **Promoting Private Sector Production and Distribution of Medical Commodities** (a) strengthening regulatory, manufacturing and management practices; and (b) medi-business development

II. BACKGROUND

A. Economic, Political & Social Context

Since the break-up of the Soviet Union, Russia is in transition toward democracy, privatization and a free-market economy, seeking to simultaneously liberalize prices and exchange rates, control inflation, reduce monopolistic power, and contain environmental problems. For both individuals and groups, this has led to declining production and plummeting purchasing power, increasing the difficulty to purchase essential health products and services.

The Russian Federation is committed to providing for the basic health needs of its population during the political and economic transition period. But health related issues must be monitored carefully to minimize human suffering, and to maintain progress towards political, social and economic growth. Recognizing the fragile state of Russia's transition, the U.S. Government has also committed itself to help restore the functioning of health care systems with market-oriented alternatives and to help address emergency health care needs during the interim.

B. Health Sector Overview

Impressive gains in health in Russia through most of the 1960s and 1970s have been followed by stagnation and even decline in the 1980s. Adult morbidity and mortality are similar to those commonly associated with modern, industrialized societies: dominated by cancer, cardiovascular disease, respiratory illness, and accidents. In addition there are serious problems with alcoholism, high abortion rates and health problems from environmental degradation. Children commonly suffer from respiratory infections, and congenital defects, both of which may also be linked to industrial pollution. In addition, there has been an alarming decline in vaccine coverage rates and a resurgence of vaccine preventable disease, including measles, polio and diphtheria. Current estimates for overall infant mortality are nearly double those of the United States.

The worsening of health indicators is due to a host of factors including the overall economic crisis, deteriorating service delivery and a virtual collapse of pharmaceutical and medical supply production and distribution.

Cutting across the sector are the health information and statistical reporting systems of the country which were at one time, well developed, but which must be modified to be most effective and useful.

C. Problems with Pharmaceutical and Vaccine Security

Prior to the break-up of the Soviet Union in 1991, the health system was already suffering from neglect and underfunding. Nevertheless, the central Ministry of Health maintained reasonable supplies of essential drugs and conducted an extensive immunization program with impressive achievements in child vaccination coverage. The health workforce was large and well trained and the basic infrastructure for effective service delivery and information gathering was in place.

With the dissolution of the Union came a disruption of supplies from other republics and Eastern European countries as well as a disruption of local production because of shortages of raw materials and hard currency. This disruption left Russia short of manufacturing capacity for key substances, materials and equipment.

During the early months of 1992, the U.S. Government and other international donors sponsored numerous visits by manufacturing and quality control experts to vaccine and pharmaceutical manufacturers in Russia. The findings of those and follow-up visits might be summarized as:

Findings Regarding Immunization and Vaccine Security

- While immunization services and supply distribution systems were severely upset, vaccine production did not collapse. Temporary deficits of EPI (Expanded Program Immunizations) vaccines occurred but production levels of most vaccines have now been (or soon will be) restored to levels which the Russians believe are sufficient to meet their demand;
- Quality assurance has been handicapped by antiquated equipment, low budgets, inadequate quality incentives, a lack of understanding of Good Manufacturing Practices and a lack of adequate regulatory testing facilities and procedures;
- Some western donors have expressed concern about the potential spread of vaccine preventable disease;
- There appear to have been at least some serious breakdowns in the vaccine cold chain; and
- There has been a serious decline in the public's confidence in Russian vaccines and immunization programs due to side-effects of the vaccines, shortages of disposable needles, and fears of HIV (AIDS) transmission.

Findings Regarding Pharmaceutical Security

- Many essential drugs and medical supplies are not produced in sufficient quantities in Russia including: antibiotics, analgesics, tranquilizers, insulin, cardiovascular drugs, cancer chemotherapy drugs, transfusion and infusion equipment, and sutures;
- Only an estimated one third of the pre-perestroika pharmaceutical demand is being met. Hospitals and polyclinics have consistently reported shortages of common and essential drugs as well as consumables such as sterile bandages and disposable syringes. An indeterminate number of illnesses and deaths have occurred for want of essential drugs;
- Depreciation of the real exchange rate have made medicines, especially imported drugs, too expensive for many people;
- Quality Assurance is handicapped by the absence of appropriate national quality control laboratories and standards; and
- Distribution systems are being transformed, but are complex, weak and inefficient. While detailed information is scarce, the trends clearly show that centralized purchasing is plummeting and being replaced in part with direct purchases, at

higher prices, by end users (hospitals, employers, individuals, etc.) which are increasingly served by rapidly growing private sector wholesalers and retailers.

In the case of both vaccine and pharmaceutical security, the visits have found that:

- Complete and detailed epidemiological information is difficult to find;
- Russia has a population sufficiently large to warrant its own production industry and the GORF is committed to local production of vaccines and critical pharmaceuticals;
- Most facilities and equipment is antiquated and inappropriate and most production does not conform to Good Manufacturing Practices;
- Major changes are underway about the administration of health care in Russia, and public regulation and quality control functions need to be clarified and strengthened;
- Substantial legal, policy and structural reforms are required to make Russia attractive to foreign investors; and
- While recognizing that the needs are urgent, Russian Federation officials and local producers in Russia all express a strong desire to strengthen local and/or regional production and distribution. To supply humanitarian aid in the form of finished products, except for minimum quantities of critical medicines and vaccines to particularly vulnerable groups, is considered undesirable and probably damaging to Russia's ambition to develop its own capacity. The Federation has not requested EPI vaccines.

The conclusion of these visits was that restoration of high quality local production capacity was absolutely essential but would be an expensive and long-term effort involving substantial new construction, installation of equipment, education and training. The visits also presumed that required expertise and capital would come through joint ventures with western companies and that western governments (including the U.S.) should help the Russian government create conditions favorable to investment.

The experiences of the last year and a half suggest that the U.S. Agency for International Development (USAID) and other donors underestimated the challenges of reestablishing productive capacity and stimulating foreign investment in an unfavorable investment climate. There has been a growing reluctance on the part of leading industrialized nations to provide supplier credits because of repayment problems and unsatisfactory progress on reforms. Registration and licensing of foreign manufactured drugs for sale in Russia continues to be very costly and time consuming. Moreover, few Russian producers have been privatized, and while a few investments have been made in the

sector, there has been continuing reluctance on the part of western manufacturers to invest in Russia until barriers to investment are reduced. At the same time, there has been some restoration of Russian vaccine production through the emergency provision of imported production inputs. It is now possible for foreigners to be majority owners of enterprises and, with the government no longer the only purchaser, there is a more direct link between producer and consumer.

D. Sub-Project Priorities, Rationale and Consistency with the FSA

The U.S.-Russian Expanded Cooperation Package signed in Tokyo in June 1993 includes a \$75 million component for "Humanitarian Medical Assistance: Medicines and Pharmaceutical Procurement and Production." The explicit objectives of that component include "procurement of essential supplies and medicines and assistance to Russian producers to move away from dependency on foreign providers." USAID believes that these objectives are compatible; that short-term assistance can also support long-term development; that assistance can and should be integrated into private non-governmental and commercial channels wherever possible; and that, given the size of the country and its population and the complexity of its history and systems, USAID assistance should serve as a catalyst to leverage other donor resources and to provide selected opportunities for host country replication and expansion.

The sub-project activities briefly described below are supportive of and consistent with the objectives of the Russia Assistance Strategy. The activities were developed in a collaborative effort by various U.S. government agencies and were based on numerous discussions with Russians and Americans in the health sector.

E. Prior USAID and Other Donor Involvement

The U.S. has already been involved in vaccine and pharmaceutical production and supply in Russia. Through private voluntary organizations (PVOs), USAID provided approximately \$55 million worth of pharmaceuticals (antibiotics, electrolytes, anesthetics, insulin, etc.) and medical supplies (rubber gloves, sutures, catheters, etc.) together with approximately \$3 million in transportation costs. USAID has also provided production inputs in order to restore short-term production of measles, polio and DPT vaccine production in Russia and has funded studies of the feasibility of U.S./Russian joint ventures in vaccine production. Additional U.S. assistance through the Department of Commerce and the Overseas Private Investment Corporation has funded trade and investment missions, conferences and seminars in order to develop necessary relationships and policies for future commercial ventures.

In a related area, Food and Drug Administration (FDA) has assisted with training in quality control and regulation of vaccine production. The Trade and Development Agency is supporting feasibility studies on pharmaceutical distribution and on containers for sterile solutions.

Through the \$120 million health component of its Rehabilitation Loan No. 1, the World Bank has provided imported drugs, spare parts and consumables, raw materials for pharmaceutical production and technical assistance on drug specifications. Additional funding for equipment and raw materials for vaccine and pharmaceutical production and limited assistance to the Tarasevich Institute is contemplated under Rehabilitation Loan No. 2, currently under negotiation.

Canada has provided technical assistance on immunization schedules and protocols. UNICEF has purchased pharmaceuticals and initiated a modest project in cold chain improvement. WHO has endeavored to serve as donor coordinator within the sector.

III. SUB-PROJECT DESCRIPTION

A. Sub-Project Objectives and Expected Achievements and Accomplishments

The draft Health Sector Strategy for the New Independent States concentrates on three strategic objectives:

1. Promote the security of critical vaccines, pharmaceuticals, medical equipment and supplies in the NIS;
2. Support health financing and service delivery system reform; and
3. Address critical country or region-specific health problems.

Furthermore, the strategy aims to use U.S. business in addressing these objectives where possible and where supportive of the strategy.

The Russian Humanitarian Medical Assistance sub-project focuses its support on the first and third objectives while a separate sub-project (Health Care Financing and Service Delivery Reform) addresses the second objective. The first objective will be pursued over the short-term by helping to address emergency health care needs and over the medium-term by strengthening Russian capacity (primarily private sector) to produce, acquire, distribute and use medical commodities. The sub-project will pursue the third objective by strengthening Russia's capacity to identify, analyze and respond to specific health problems.

In fostering these objectives, the sub-project will undertake two integrated and complementary components which, over the sub-project's four year life, will:

- Initiate activities to strengthen Russia's public health information, surveillance capacity and its capability to identify and respond to health emergencies and crises on a timely basis. To the extent requested by the Government of the Russian Federation (GORF), this component will also provide commodities essential to support emergency responses in the short and medium term;
- Demonstrate to Russian business and to the Russian people the value of programs to enhance quality control, good manufacturing practices, pharmaceutical management and rational drug use; and
- Accelerate investments by the U.S. private sector and initiate pilot activities by the Russian private sector in the production and/or distribution of medical commodities;

B. Sub-Project Outline and How it Will Work

1. Strengthening Health Information and Response Capability

Through this approximately \$30 million component, the sub-project seeks to strengthen key aspects of public health information, including early warning systems, as well as strengthen the capability of the government to respond to both emergency and regular health problems. The current diphtheria epidemic may serve as an immediate case model for this component. Health information about the epidemiology of diphtheria; about nutritional and environmental issues affecting the distribution of the disease; about vaccine effectiveness and adverse reactions; and about vulnerable groups are needed. An adequate response capacity includes a national diphtheria control policy and strategy; operational plans; a strong logistics system; public education; and a monitoring and evaluation system. Through this component, USAID will finance training, technical assistance, and limited commodities in support better diphtheria control in Russia. Similar approaches will be made to other problems.

Health Information: Regular and reliable health information from a variety of sources is a prerequisite for monitoring the health and nutritional status of the population and for developing cost-effective interventions. The unstable conditions currently prevailing in many parts of Russia have made the problem of vulnerable or at-risk populations more pronounced. Those conditions in turn make the need for such information even more critical. Russia's health monitoring system suffers from a history of inadequate quality controls and obsolete analytical methods. As such, it is unreliable for monitoring the health and nutritional aspects of the social safety net. Their epidemiology data

collection and reporting systems have been among the most complete in the world, yet a system faced with substantial problems including: uncertain specificity and reliability; incomplete appreciation of the value of surveillance data; lack of information feedback to the field; an over-concentration on communicable diseases; and delays in data analysis, data driven decision-making and development of strategies in response to health crises. In addition, there has been little effort to date to coordinate the production or distribution of medical commodities with epidemiological and related health information.

Health Response: USAID-financed assistance to strengthen response capacity will help develop the most cost-effective prevention and service delivery strategies for key public health problems. Particular attention will be paid to helping Russia respond in accordance with world technical standards, with vastly increased efficiency, with more optimal uses of scarce commodities, with vastly enhanced public participation, and through use of non-government organizations. Both assistance to the government and through U.S.-Russian joint PVO projects will be important approaches to strengthen the health response to vulnerable populations. Inputs for this component may include long-term and short-term technical assistance; short-term in-service training and workshops; equipment and supplies.

Humanitarian Commodities: This component also anticipates that, until local production capacity is in place, continued imports of certain essential commodities will be required over the short-term to address fundamental humanitarian needs in specific vulnerable areas or crises situations. The commodities and target regions or organizations will be collaboratively selected by USAID, the Department of State and the Russian Commission for Humanitarian Assistance. Oblast or regional selection criteria might include the significance of the health problems being faced by the underserved or "vulnerable" populations; the degree of economic collapse, the size and extent of commercial networks in the region, the political importance of the region, etc. Particular emphasis will be given to women's health. Commodity selection criteria might include critical or life-saving drugs or other health commodities and limited access to or no current capacity to produce the commodity in the region. To the extent possible, private sector distribution channels will be utilized from the manufacturer to the point where the commodities are transferred to the dispensing PVO in the target regions. PVOs/NGOs will handle final distribution or sale and provide technical assistance to assure that safety and efficacy is guaranteed by the transportation, storage, distribution, labeling and utilization practices followed.

2. Promoting Private Sector Production and Distribution of Medical Commodities

As initially outlined, Russia's economic reform package was to stimulate privatization and foreign investment. It included: price decontrols; deregulation; ruble convertibility and financial stabilization; privatization; market-driven institutional changes; a social

safety net for vulnerable groups; a structural shift toward consumer demand; and competitive markets.

Indeed, economic and market reforms have led to profound and probably irreversible changes. However, constitutional and political frictions, inappropriate regulations, bureaucratic conflicts, legal ambiguity and half-way institutional reforms have resulted in less progress than originally hoped. Besides the commonly understood and generic prerequisites to make any private sector ventures successful, the medical commodities sector must assure that additional conditions are in place. These conditions include a fair and transparent regulatory environment, a medical community which has adequate information about the use and availability of drugs and other goods, and public confidence in the product (particularly known safety and efficacy). In addition, a successful venture must of course identify a market willing to buy the products at prices sufficiently above the cost of production to assure a reasonable profit.

As a result, faced with numerous obstacles to successful investment in Russia, few U.S. firms have made long-term investments in medical manufacturing or distribution operations. Nevertheless, privatization is moving forward.

The objectives of this approximately \$55 million component are to promote conditions favorable to private enterprise and foreign investment in the health sector and to mobilize and leverage private sector resources in specific medical commodity production or distribution activities. Such activities could include development of chains of private pharmacies, pharmaceutical warehouses, local manufacture of cold boxes, filling and labeling operations, or more complex and more fully integrated pharmaceutical production efforts. All arrangements supported under this component will meet quality assurance and GMP standards.

USAID does not expect to achieve broad nationwide reform of private sector policies through this sub-project. However, in focusing on catalyzing actual private sector investment in the health sector, and in working with local and regional reformers, USAID expects that these efforts will contribute to broader policy reform.

The difficult challenge of the component is to identify and structure investment opportunities which will expand Russia's internal production and/or distribution capacity for medical products while generating adequate returns for local and U.S. partners and investors.

This component includes two primary elements. The first addresses areas which the governments (central, regional and local) can and should legitimately influence or oversee in promoting the medical commodities industry. The second element will accelerate and foster private investments and promote dialogue in support of broader reform efforts.

a. Strengthening Regulatory, Manufacturing and Management Practices for Pharmaceuticals and Vaccines

The assurance of the quality of vaccines and pharmaceuticals is an integral part of reestablishing productive capacity in Russia and an appropriate role for the government. Controls on safety and efficacy include registration and licensing; good manufacturing practices (e.g. quality control of raw materials, containers, labeling, maintenance of clean facilities); testing for safety, sterility, potency and toxicity; inspections; enforcement of standards; lot release; and monitoring of adverse reactions.

In addition, drug management and use need to be brought up to current international standards. For example, treatment protocols are frequently not in line with current international recommendations, e.g. newborns are routinely sedated with phenobarbital which may result in adverse reactions. Many drugs banned in western countries are still on the Russian formulary. Physicians frequently prefer the use of "state of the art" drugs when less expensive alternatives are available. Generally, there is an inadequate flow of current drug information and foreign drugs are frequently found without adequate instructions and contra-indications in Russian. Moreover, Russians have little experience with competitive or international bidding.

This component of the sub-project, totaling approximately \$5 million will promote Russian capacity to regulate, produce, procure and use modern pharmaceuticals. Through long and short-term technical assistance, in-service training and modest upgrading of equipment, the component will help:

- Reform and automate the vaccine/drug approval and registration systems;
- Establish standards and/or guidelines for product labeling and expiration dates;
- Develop a Russian drug formulary;
- Expand drug information resources and promote rational drug use;
- Upgrade product testing practices and equipment for control laboratories;
- Establish standards for and Promote Good Manufacturing Practices (GMP); and
- Rationalize procurement, inventory management, pricing policies and distribution.

b. Medi-Business Development

While many of the conditions impeding private sector investment in the health sector are comparable to those which other sectors face, the critical and unique needs and technical qualities of the health sector dictate a focus on both the generic issues of private sector development in the Russian context and specific issues applicable to the health sector.

This component seeks to foster the pre-conditions to sustainable private sector investment in medical commodities and provide a variety of financial and technical incentives to speed or attract that investment.

1) Catalytic activities will include technical assistance, training, and limited start-up capital directed to the Russian small, private, medical business sector to help them launch and/or expand production and distribution activities. Long-term and short-term technical services will help specify criteria and conditions essential to the success of particular ventures and help assure that those conditions pertain. The technical assistance may be utilized to address highly technical questions or specific barriers to private sector investment in the health sector at local, regional or national levels.

Should financing be identified as a major constraint to specific projects, the assistance might also help broker opportunities with domestic and foreign investment partners or provide a percentage of start-up capital generally less than \$250,000 or alternative financing mechanisms. Further, a promising catalytic venture might have easier access to other larger sources of funding. For the catalytic ventures element to be successful, the organization managing it would have to include financial entities prepared to lend in Russia. The availability of such organizations will be examined during final design.

The medi-business component will also provide long-term and short-term technical services to promote policies and other conditions in the target regions (or at the national level) which are favorable to medical enterprise development. Required skills are expected to include asset valuation, commercial law, capital markets, property rights, investment banking, ownership schemes, etc.

2) Technology Transfer for technical inputs from the U.S. private sector will be developed. Development of world class medical commodity production and or distribution operations in Russia will require substantial investments in capital for facilities and equipment, focussed technical assistance, technology transfer, and worker training. While funding might be sought from a variety of sources, and while technical assistance might be obtained through more traditional channels (i.e., consultants), USAID's affiliation with the production or distribution of potentially life-saving commodities mandates that it use the highest quality technology and technical assistance. Such technology and assistance is available only through companies which, themselves are experienced and effective producers and which themselves have resources and reputations at stake in the venture, e.g. U.S. pharmaceutical and other medical commodities companies.

Several of these companies already have a presence in Russia, most of them only a sales presence. They are mainly sophisticated investors well aware of the opportunities and challenges of doing business in Russia and needing little or no outside technical assistance. Through this component, USAID would seek to accelerate investments by U.S. entities which are already predisposed towards a specific U.S.-Russian joint venture activity in the medical commodities field, but which are hesitating. The USAID awards (in the range of \$2 to \$5 million) would be competed and would be blended with investments from the JV partners at least (say) 2 1/2 times bigger than the USAID

award. The awards would help secure the best possible sources of technology and assistance and also encourage the sustainability of the activity.

Award competition would be conducted by one or more industry associations or financial organizations which would also be selected competitively. The selection criteria for the awards might include such factors as: the size of the JV contribution, the proposal's potential significance to the health sector in Russia, the technical and business soundness and thoroughness of the proposal, and the anticipated implementation period.

To date the Enterprise Fund has carefully avoided opening sector-specific investment windows for fear that it might skew the financial market. Given the specialized and important nature of investments in medical commodities, however, additional discussions will be held with the Fund regarding the possibility of opening such a window. The final design will also examine alternatives to complex revolving fund and loan programs including such possibilities as analogous contributions towards community development or outreach programs. In comparison to the leveraged awards program, most of the businesses privatized through this mechanism are expected to be relatively small and local or regional in nature, such as local pharmacies or regional distribution operations.

3) Miscellaneous Sub-Project Activities and Project Management

A final amount of approximately \$5 million is reserved for cross-component activities, related activities and for project management and support as well as information exchange efforts. This element may include such activities as donor coordination; trade or investment promotion; conferences, workshops and study tours; other unallocated short-term technical assistance; sub-project evaluations and audits; sub-project coordination and implementation support.

4) Additional On-Going Programs

\$15 million in FY 1994 funds allocated for Russian humanitarian medical assistance will be provided for the Russia portions of two on-going programs:

Health Care Financing and Service Delivery Reform - Abt Associates Inc., will be working with USAID to introduce market-oriented reforms in health financing and health care provision in the NIS. The purpose of the new contract is to help increase efficiency, improve quality of care and increase access and provider choice. This should help make the transition from a centralized, imbalanced healthcare infrastructure to one which will better serve the needs of the people in the emerging decentralized system.

Hospital Partnerships - Through the American International Health Alliance (AIHA), 8 partnerships have been established involving hospital/health system and medical schools. These provide clinical and administrative training in both the U.S. and Russia.

IV. DESIGN AND IMPLEMENTATION CONSIDERATIONS

This sub-project will be developed, authorized and implemented as a sub-project of the NIS Health Care Improvement project (110-0004). Once this concept paper is approved in Washington, authority for all design and implementation will be delegated to the Director, USAID Mission to Russia. As such, USAID/Moscow will assume responsibility for the final sub-project design; execution of the Memoranda of Understanding with the Ministry of Health, the State Committee on Sanitation and Epidemiology and other Russian organizations, as appropriate; and all contracting actions. The Mission's Office of Environment and Health will have primary implementation responsibility and a Project Manager will be funded under the project.

Preliminary thinking is that sub-project implementation will involve the following contracting actions:

ELEMENT	ANTICIPATED CONTRACTING ACTION
Strengthening Health Information and Response Capacity	-Information: Contract with UNC, PASA with CDC -Response: Buy-in to BASICS; amend Medical Partnerships; PVO grants; unsolicited proposals -Humanitarian Commodities
Promoting Private Sector Production & Distribution of Medical Commodities	
A) Strengthening Regulatory, Manufacturing and Management Practices	-PASA with the Food and Drug Administration (FDA) -Add-ons to Rational Pharmaceutical Management Project
B) Medi-Business Development	-Catalytic Support (RFP) -Investment Fund: buy-in to Enterprise or RFP
Miscellaneous & Project Management	-PSCs -IQCs, purchase orders

It is readily apparent that the strengthening health information and response component and the regulatory, manufacturing and management practices component both anticipate collaborative efforts between the Department of Health and Human Services, contractors under existing USAID projects, and PVOs. Generally speaking, within the regulatory, manufacturing and management practices component, FDA will be responsible for standards and the regulatory environment at the national level while RPM will take the lead in operational systems such as drug lists and formularies, labeling, distribution,

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procurement, prescribing practices, planning and costing. Similarly, CDC's strengths lie in surveillance and in the science and epidemiology while BASICS, Medical Partnerships, and PVOs offer more operational and management skills. The complementary strengths of these actors will require negotiation and clarification of their roles during final sub-project design and close collaboration during sub-project implementation.

Sub-project support for quality control and GMP as well as for the production of pharmaceuticals, vaccines and other medical supplies could have positive or negative effects on the environment. The potential environmental effects of each private sector development activity and the QC/GMP component will be assessed on an individual basis.

The primary implementation actions include:

- Agreement on the basic criteria for selection of medical commodities and for selection of the target oblasts or regions. If appropriate, development of a preliminary procurement list and agreement on target regions;
- Finalization of the medi-business component, especially verification of U.S. industry interest and preliminary agreement on criteria for catalytic private sector activities. Preliminary examination of potential locations and eligible types of enterprises. Analysis of technical assistance and alternative financial mechanisms essential to launch the enterprises;
- Field development of detailed proposals from CDC and FDA, scopes of work from current USAID contractors for add-ons or buy-ins to existing USAID projects; development of PVO grant mechanism; and
- Discuss the sub-project proposal with other bilateral and multilateral donors, U.S. producers and distributors of medical commodities, and the NGO community. Modify the proposal as appropriate.

Each of these tasks will be undertaken in collaboration with the Russian Federation Ministry of Health, the State Committee on Sanitation and Epidemiology, the Russian Commission for Humanitarian Assistance and various regional/local authorities and private entities.

ILLUSTRATIVE BUDGETARY ALLOCATIONS

RUSSIAN HUMANITARIAN MEDICAL ASSISTANCE

ELEMENT	CONTRACT/GRANT	FY 94	FY 95	LOP	COMMENTS
		(DOLLARS MILLIONS)			
I. HEALTH INFORMATION & RESPONSE	INFORMATION	5	0	5	full funding in FY 94
	RESPONSE: TA	15	0	15	full funding in FY 94
	RESPONSE: COMMODITIES	10	0	10	
	SUBTOTAL	<u>30</u>	<u>0</u>	<u>30</u>	
II. PROMOTING PRIVATE SECTOR PRODUCTION & DISTRIBUTION OF MEDICAL COMMODITIES					
	A) REGULATION & MGT PRACTICES	5	0	5	full funding in FY 94
	B) MEDI-BUSINESS DEVELOPMENT	22	28	50	add'l funding in FY 95
	SUBTOTAL	27	28	55	
III. MISCELLANEOUS ACTIV. & MGT	SUBTOTAL	<u>3</u>	<u>2</u>	<u>5</u>	
	TOTAL	60	30	90	
IV. ON-GOING NIS PROGRAMS					
	HEALTH CARE FINANCE	11			
	PARTNERSHIPS	<u>4</u>			
	SUBTOTAL	15			
	TOTAL	75	30	105	

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