

PD-ABF-706
ISN 819165



REACH

RESOURCES
FOR CHILD
HEALTH

TRIP REPORT ON EPI VACCINE ACQUISITION IN UZBEKISTAN, KYRGYZSTAN AND TURKMENISTAN

25 October - 30 November 1992

TRIP REPORT ON
EPI VACCINE ACQUISITION
IN
UZBEKISTAN, KYRGYZSTAN AND TURKMENISTAN
OCTOBER 25 to NOVEMBER 30, 1992

Dian Woodle
REACH CONSULTANT

Provided under sub-contract with
Program for Appropriate Technology in Health
PATH
Seattle, Washington

December 15, 1992

Resources for Child Health (REACH) Project
1616 N. Fort Myer Drive, Suite 1100
Arlington, VA. 22209, USA

USAID Contract Number: DPE-5982-Z-00-9034-00
Project Number: 936-5982
Activity Number: 1717-041

TABLE OF CONTENTS

INTRODUCTION	1
I. SUMMARY CONCLUSIONS AND RECOMMENDATIONS	2
II. BACKGROUND AND FINDINGS	3
III. ACTIVITIES	9
IV. RECOMMENDATIONS	12

APPENDICES

- Appendix 1 - Uzbekistan
- Appendix 2 - Kyrgyzstan
- Appendix 3 - Turkmenistan

ANNEXES

- Annex 1: Acronyms
- Annex 2: Persons Contacted During Visit
- Annex 3: Summary Vaccination Schedules and Wastage Factors
- Annex 4: Summary of 1993 Antigen Requirements and Suggested Donation Amounts in Doses
- Annex 5: 1993 EPI Vaccine Budget Estimates
- Annex 6: Information on the October 1992 Meeting Between Republic and Tarasevich Institute/Russian Suppliers
- Annex 7: Draft Vaccine Procurement Manual Documents
- Annex 8: Scope of Work
- Annex 9: Responsibility Flow Chart

INTRODUCTION

During November 1992 technical assistance was provided to the Central Asian Republics of Uzbekistan, Turkmenistan, and Kyrgyzstan, aimed at assessing the EPI vaccine supply situation and helping the republics to plan for future vaccine acquisitions. This report addresses the current situation and areas of potential difficulty, and provides recommendations for the next step. An attempt was made to answer the following questions about the 1993 EPI vaccine supply for each republic visited: (1) what and how much is needed, (2) where will it come from, (3) what will it cost, (4) how will it be paid for, (5) how can quality be assured, and (6) what are the associated problems?

Because the three republics are at different stages of development in their ability to cope with vaccine supply issues, the focus of each visit differed accordingly. Visits to Uzbekistan and Kyrgyzstan centered on costs and sources of supply, while the visit to Turkmenistan focused on vaccine quantity needs. Appendices 1, 2, and 3 contain observations and information specific to each republic.

The mission was undertaken as part of the USAID humanitarian assistance program of emergency immunization support and was designed to build upon the efforts of earlier visits by REACH personnel as well as an existing short-term resident team of REACH cold chain and EPI management experts. Reports covering these previous visits are available through REACH headquarters and no attempt has been made to repeat information contained in them.

I. SUMMARY CONCLUSIONS AND RECOMMENDATIONS

Observations and Conclusions:

The EPI programs in Uzbekistan, Kyrgyzstan, and Turkmenistan do not have access to a reliable supply of safe, effective vaccines in quantities adequate to fill their needs. Financial and sourcing issues, as well as deficits in the cold chain, are primary difficulties. These are greatly exacerbated by structural political factors including the recent independence of the Central Asian Republics and an abrupt switch to a free market economy.

Donations of EPI vaccine for at least part of 1993 requirements appear to be necessary to sustain the immunization programs in Uzbekistan, Turkmenistan, and Kyrgyzstan at an acceptable level. Shortages in the domestic supply of EPI vaccines are anticipated based on the 1992 performance of the Soviet producers. Measles vaccine is expected to be in especially short supply with shortfall estimates from 60% to 80%. Ruble funds to pay for domestic vaccines are in doubt due to rapidly increasing prices and severe budget cuts. Emergency funds and/or reserves for outbreak control have been exhausted. In addition, there is a banking disturbance that currently hinders transfer of funds from the republics to the Russian producers; in a number of instances, payments have simply been "lost."

The other possibility for covering anticipated 1993 domestic vaccine shortages in the three republics is hard currency purchases from foreign sources, and the EPI programs generally do not have the funds, the access to hard currency, or the expertise to pursue this option. The cost of most foreign vaccine is from five to thirteen times higher than domestic vaccine, even at public sector prices. In the case of BCG, foreign vaccine is over one hundred times more costly than the domestic vaccine. As an example, the dose price of OPV from a Western supplier is around 0.08 USD while the dose price of domestic OPV is equivalent to 0.006 USD (at an exchange rate of 390 rubles per 1 USD). In every case, immunization program personnel were shocked by the prices of Western vaccine.

In Uzbekistan and Turkmenistan, there is virtually no hard currency available for purchase of foreign vaccines and ruble transactions are not acceptable to Western manufacturers. Even the UNICEF supply program will not accept rubles because of the financial risks associated with instability and inconvertibility. In Kyrgyzstan there is a small possibility that some hard currency from World Bank funds may be available in the spring of 1993, but the immunization program must compete with many other MOH needs.

A substantial amount of hard currency has been made available to the three republics by the EC, but these funds are reportedly being used for food and emergency medicines; vaccines are not seen as a priority. In Kyrgyzstan, all decisions regarding the EC funds have been made, many of the contracts have been awarded, and there is no possibility of using any of this resource for the immunization program.

Very little foreign procurement capability exists within the institutions visited, as this function was formerly centered in Moscow. It is important to develop international skills at the MOH level in each republic so there can be alternatives to the FSU vaccine producers when hard currency is available. Competition with foreign suppliers may serve as an incentive for domestic producers to improve the quality of their vaccines and packaging rather than lose customers. This concept was explained as a good example of how free market economies work.

Barter arrangements have been suggested as an alternative to hard currency purchases but they have not proven practical because of additional expenses, length of time required to complete transactions, and special handling requirements. One recent barter arrangement resulted in the supply of vaccine with only a few months of shelf life remaining.

Key portions of the cold chain in Uzbekistan, Kyrgyzstan, and Turkmenistan are inadequate as previously reported by REACH, and all vaccines, domestic and Western, are at risk of deterioration by the time of delivery to children. Vaccines from the FSU producers are dispatched in wooden boxes with only some cotton batting for protection; they have no insulation and no ice. Even though Western vaccines are dispatched with appropriate cold chain packing, proper handling and storage after arrival is still a concern. Many improvements to the cold chain have recently been made through the generous donations of USAID but assistance needs to be continued into 1993.

Domestic vaccines have generally been acknowledged as less potent than comparable Western vaccines due to manufacturing variables and lack of cold chain packing at the producer level. To compensate for this, vaccinations are repeated several times in an effort to ensure protection and serosurveys are used to check on the effectiveness of the local programs. Immunization personnel are generally aware that WHO vaccination schedules require substantially less vaccine but need vaccine which meets WHO quality standards within a fully functioning cold chain.

There is no operational central regulatory authority for licensing and control of biologics in any of the three republics. A separate effort needs to be made to rectify this situation. WHO may be the appropriate institution to provide assistance in this regard. In the meantime, channels for independent testing of domestic and foreign vaccines need to be established.

Main Recommendations:

1. Donate at least part of the 1993 EPI vaccines required by Kyrgyzstan, Uzbekistan and Turkmenistan.
2. Establish a donor financial reserve to provide emergency assistance in the event of an epidemic or unanticipated vaccine shortfall.
3. Provide short term technical assistance and institutional development in supply acquisition and contracting.
4. Provide a hard currency allowance to each republic to cover the vaccine and incidental costs of a practice foreign procurement.
5. Develop a program of donor assistance tying aid to domestic vaccine producers with benefits for republics, matching the needs of the republics to the needs of the producers.
6. Provide funding for a consortium of republic representatives to meet with producers to discuss specifications and quality needs/expectations.
7. Provide assistance in establishing a central regulatory authority for licensing and control of biologics in each of the three republics. As appropriate, provide assistance in establishing national control laboratories.

II. BACKGROUND AND FINDINGS

Source of Supply:

Since the dissolution of the Soviet Union more than one year ago, the republics have been responsible for contracting directly with suppliers and making their own arrangements for delivery and payment.

Previously all EPI vaccines for Kyrgyzstan and Turkmenistan were provided through arrangements between the central government in Moscow and various Soviet producers. Plans and requests were generated within the republics, Moscow consolidated the requirements, ordered the vaccines, and eventually they were dispatched by the producers, via air, to designated points in the delivery system. It is not clear if Uzbekistan also followed this procedure.

So far, most of the vaccine contracts have been with domestic producers, but there is great interest in how to contract with Western vaccine manufacturers. This interest has a two-fold origin: (1) the FSU suppliers have not been able to provide the quantities of vaccine which they promised in 1992 and new sources are needed to make up anticipated shortfalls for 1993 (in the case of measles vaccine, this may reach 80%), and (2) many of the MOH epidemiologists see Western vaccines as safer and more potent than the domestic vaccines and would like to use them in their immunization programs.

Financial:

The Ministries of Health in each of the three republics visited regard financial matters as their most difficult problem in maintaining an adequate supply of EPI vaccines. This applies to the ruble as well as to hard currency.

Inflation is running about 100% per month by some accounts, and price increases in selected sectors are simply announced and take effect immediately. During a week-long visit in Uzbekistan, for example, taxi rates, food, electricity, and various other prices were increased overnight by 250%.

Domestic vaccine prices have risen 300% to 400% since January 1992. The value of the ruble against hard currencies is dropping at an alarming speed. In March 1992, the exchange rate was about 100 rubles per US dollar; on October 1, 1992 it was 211 rubles per US dollar; at this writing (December 1992) it is over 400 rubles per US dollar.

Over the past several months, Ministries of Health have suffered numerous emergency budget cuts and at least one (Kyrgyzstan) has not been able to pay for fourth quarter, 1992 EPI vaccines. Domestic vaccine prices are increasing so rapidly that it has not been possible to assign budget figures for anticipated 1993 needs.

Although rubles are still accepted by the FSU producers, they now insist on being paid in full three months in advance of any shipment, and transfer of funds is a problem due to a disturbance in the banking relationship between the republics and Moscow. In some cases, advance payments made through the banking system have not reached the supplier.

Currently, it is not possible to transfer funds between the republics and the Russian Federation through the banking system in Moscow. At least two of the three republics visited have some hard currency on deposit, but these assets have been frozen. Efforts are underway to normalize relations, but the republics want changes from the old system. Advice has been offered by the World Bank and International Monetary Fund to both sides; however, international institutions are not expected to participate directly in negotiations.

In Uzbekistan and Turkmenistan, there is virtually no hard currency available for purchase of Western or East European vaccines. In Kyrgyzstan there is a small possibility that some hard currency from World Bank funds may be available in the spring of 1993, but the immunization program must compete with many other MOH needs.

A substantial amount of hard currency has been made available to the three republics by the EC, but these funds are reportedly being used for food and emergency medicines; vaccines are not seen as a priority. In Kyrgyzstan, all decisions regarding the EC funds have been made, many of the contracts have been awarded, and there is no possibility of using any of this resource for the immunization program.

Forecasting Procedures:

Within the FSU, there is an elaborate and quite precise system for planning and recording childhood immunizations. Most births occur at maternity facilities of some kind and are therefore recorded. Home births are likely to be reported as well due to the observance of block matrons or other "official" persons. Babies are routinely taken to community health centers for care and follow-up, where their records are maintained.

In the fall of each year, the various children's health clinics review their client records and calculate the number of children in each age group needing a particular vaccination or vaccinations during the following year. At about the same time, the number of expected births for the coming year is estimated at the regional level. This information is sent on up the line and consolidated at the oblast level. Oblasts set immunization targets for each age group using the clinic information and the number of expected births multiplied by the particular vaccination schedule¹ adopted by the republic. If any special campaigns are planned that would increase the vaccine requirement, this is factored in. Allowances are also made for children who did not receive the scheduled vaccinations in the previous year. In the past, funds were available in Moscow for additional emergency supplies. Currently, republics would like to purchase extra vaccine for outbreak control, but generally are unable to do so because of severe financial constraints and production shortages.

At the Republican SES level, the oblast records are checked and converted into units of purchase. Rather than doses, as calculated by many donors, CIS units of purchase are as follows: BCG in thousands of sets (1 set = 20 infant doses); DTP in liters (1 liter=2,000 doses); measles in thousands of doses; and polio in thousands of doses. Vaccine needs for small and weak babies, such as BCG-M, are estimated.

Targets, which are differentiated by age group (extending to 17 years), are sorted into primary vaccination and re-vaccination for each vaccine. Anticipated vaccinations for adults are added. Wastage factors, which differ between vaccines according to the way the vaccine is handled and administered, are then applied and any vaccine remaining from the previous year is subtracted from the total requirement to net a purchase quantity.

Vaccination schedules and wastage factors for each republic appear in Annex 3. While Kyrgyzstan is still maintaining about a 30% wastage factor on domestic DTP, Polio, and OPV, Turkmenistan has reduced its wastage allowance to around 10% because of recent shortages. Uzbekistan wastage factors were not made available.

International EPI advisors often estimate wastage at 35% per 10-dose vial and 50% per 20-dose vial. The republics, however, have difficulty taking vial/ampule size into consideration in calculating wastage because they have no control over what they receive from the FSU producers. Sometimes they receive 20-dose vials or ampules; sometimes they receive 2-dose or 5-dose

¹Republic vaccination schedules differ from WHO recommendations:

WHO immunization schedules assume the use of vaccine meeting WHO standards within a fully functioning cold chain; republic immunization schedules compensate for lower potency domestic vaccine and deficiencies in the cold chain by increasing the number of vaccinations required.

presentations. They definitely prefer smaller sizes, reducing the chance for error and resulting in less wastage.

BCG vaccine wastage rates are much higher than the other three EPI vaccines. A BCG ampule is opened before newborn babies are discharged from the maternity center. In rural settings, as little as one dose may be used per day, with 19 doses discarded. Kyrgyzstan calculates an average use of 5 doses required for one vaccination regardless of age. Other republics make other wastage assumptions. The Uzbekistan calculation is unknown.

A summary of 1993 infant vaccine requirements is shown in Annex 4. Donors may wish to address different segments of the 1993 vaccine requirement according to their own institutional philosophies. For instance, one donor may target only primary vaccination while another would wish to include boosters for children up to five years old. Several possible options follow:

- Provide primary EPI vaccines to cover the anticipated 1993 domestic producer shortfall and/or primary EPI vaccines that cannot be purchased from domestic producers in 1993 due to lack of funds;
- Provide all primary EPI vaccines;
- Provide primary and booster EPI vaccines to cover the anticipated 1993 domestic producer shortfall;
- Provide all primary and booster EPI vaccines.

Vaccine Costs:

The price of EPI vaccines from the lowest priced Western sources is from five to thirteen times higher than the latest prices quoted by the FSU producers; in the case of BCG vaccine, it is more than 100 times higher. FSU producer prices are increasing rapidly so these margins may already be in error, but it gives insight into the shock expressed by program personnel in the republics over Western prices. Some are concerned that FSU prices may begin to approach Western prices. Given current financial limitations, price increases present a very serious problem for the immunization programs. From the producer side, however, some Western experts feel that domestic price increases will be necessary if quality improvements are to be made. Additional revenue would be needed to cover the cost of new equipment, cold chain packaging, and better quality vials/ampules.

A comparison of UNICEF, Western Producer and Soviet Producer vaccine prices, based on recent quotations, appears in this document as Annex 5.

Contracting Procedures:

Procedure for Contracting with Domestic Producers

The Republican SES under the MOH formulates quantity and antigen requirements (the "plan") for the coming year based on prior year EPI statistics. In the old system, these requirements were sent or taken to Moscow and consolidated into contracts with the various Soviet vaccine producers.

Since the dissolution of the Soviet Union, the domestic producers have been initiating transactions directly with each Republican SES; the buyer is relatively passive, uses the seller's contract form, and makes no written contractual demands on quality or the conditions of the transaction.

The various producers send order forms (they refer to them as specifications) to the Republican SES along with a signed contract. There are two copies of the order form, one exactly duplicating the last annual order and one blank to be used if changes from the previous year are required. These forms have columns for the amounts required in each quarter and for the total annual requirement. A contract (in two originals), which has been signed by the supplier, accompanies the order form. The Republican SES needs only to make any necessary changes in the quantities or types of vaccines to be supplied by that particular enterprise, sign the contract, and send it back. The supplier is responsible for notifying the buyer if the requirements cannot be met.

Unlike last year, the domestic producers are now demanding payment before shipment. About three months prior to the expected delivery date, the republic will receive an invoice. If it does not pay, it does not receive the vaccine. In the past, the producer included prices on the order forms and these were considered firm. This year, the order forms do not include prices and the republics must pay what the supplier demands on the pre-shipment invoice.

Procedure for Contracting with Foreign Producers

To date, there are no government rules or procedures for contracting with Western suppliers; both of the current main sources of hard currency, the World Bank and EC, impose procedural requirements on the use of its funds. Purchases can be made by the recipient government directly with manufacturers or arrangements can be made with a UN agency to act as a procurement agent for a fee, usually 6% of the price of the goods. In some cases, alternate procurement agents can be employed if approved by the lending institution.

The World Bank specifies procedures in their loan documents and, in the case of direct purchase by the recipient government, usually requires an open international tender process whereby notices of the procurement requirements for goods and/or services are sent to trade associations and embassies. Interested suppliers provide price offers on a sealed bid basis, and the best offer is selected. The contents and terms of the contract are stipulated by the World Bank. The purchaser, i.e., MOH, directs its bank to issue a letter of credit to the supplier, and the supplier is often required to provide performance security in the form of a bank guarantee. EC requirements are similar to World Bank requirements.

In the case of funds being used for critical imports, as is anticipated in Kyrgyzstan, some of the procedural requirements may be relaxed. It should be noted that the international tender is a lengthy and complicated process, but one required by many governments and international lending institutions, as well as by donors, to ensure fair competition and honest transactions. This process requires at least six months to complete and often takes more than one year.

It is, as yet, undetermined how customs entry and delivery of vaccines purchased from foreign sources would be arranged by the republics, but there seems to be no intention of imposing taxes or duty on health related items.

Procedure for Contracting with UNICEF

UNICEF, through its Copenhagen facility, has a procurement service for governments and NGOs directed at the health and welfare of children. It is a major supplier of WHO approved EPI vaccines both on a donation and a purchase basis. UNICEF generally charges 6% on top of the commodity cost for purchased vaccine but this option eliminates the need for international competitive tenders by the requesting government. Vaccines can often be made available within a short time due to UNICEF's long-term, high-volume contracts with a substantial number of producers. If MOH wishes to use this service, it will need to work with its local UNICEF representative. In the Central Asian Republics, Mr. Ekrem Birendic is in the process of opening an office. Formal contracts and advance payments are required.

Other:

While supply and funding issues have been the focal point of planning for 1993 immunization needs, there are other less visible problems created by the fragile economic situation and recent structural political changes that are impacting the immunization programs.

Cold Chain

Air transport to destinations other than to the major cities has either disappeared or is sporadic. In the case of Uzbekistan, this is having a major impact on the logistics system because vaccines were formerly sent directly from the manufacturer to the oblast or regional levels. Now, all vaccines will be sent to Tashkent for further distribution. The Tashkent Republican SES does not currently have adequate cold room facilities to store large quantities of vaccine and, therefore, must engage in a more elaborate supply plan that provides for frequent small shipments.

Central cold chain requirements were discussed at a recent meeting in Moscow (see Annex 6) and producers were advised that the republics are not satisfied with the conditions of transport from Russian suppliers. Vaccines from FSU producers are dispatched in wooden boxes without insulation or ice. Only some cotton batting is provided. Before the dissolution of the Soviet Union, the Russian producers had promised to begin using cold chain monitors, but this has not occurred. At the recent meeting, Russian representatives told republic representatives that they are developing cold chain standards in cooperation with the State Sanitary Inspection Committee of Russia. These standards are expected to be signed and adopted soon, but the date when they will be implemented is undetermined because there is a problem with lack of containers, and the producers are reported to be in severe financial distress. The republics are pleased, however, that packing standards have at least been accepted in theory.

Quality Assurance and Regulatory Issues

Central regulatory authority for licensing and control of biologics was previously handled in Moscow based on testing performed by the Tarasevich Institute. Tarasevich simply approved or disapproved the use of a specific batch; no certificate of analysis or other documentation was provided. At the Moscow meeting mentioned above, Tarasevich proposed continuation of this arrangement and has asked the governments of the republics to sign contracts for their services. Payment for testing domestic vaccines would be made by the producers but would be passed on to the republics via price increases. Testing of any foreign vaccines would be by direct payment of the requesting republic to the Tarasevich Institute.

Within the republics, ideas of domestic laboratory capability for testing incoming vaccines were vague and often proved to be at odds with internationally acceptable standards. While each of the three republics will need a central authority for licensing and import approval, only Uzbekistan has tentative plans to develop its own central control laboratory. Kyrgyzstan is considering the idea and has some very good candidates, but questions the need since they have no indigenous production. Turkmenistan is not ready to consider these issues.

General Confusion

Throughout the republics, procedures and details for dealing with the new system are not yet fully defined. There is uncertainty about who will do what, both within individual ministries and between ministries. There is also confusion about what is and is not permissible. Rules and responsibilities are often created on an as-needed basis, and many new precedents are being set. This offers a window of opportunity for expert advisors to assist in the development of workable system:

Documentation and procedures for transferring goods across borders between the Newly Independent States (NIS) have not been clearly established. This became apparent when several days of effort and negotiation were necessary before USAID-donated freezers could be transported from Uzbekistan to Kyrgyzstan.

In considering procurement of EPI vaccines from international sources, there is an almost complete lack of knowledge regarding interface with foreign suppliers, rights of the customer, what to ask for, and what to expect. There seem to be no traditional government procurement rules in place. There is a general lack of knowledge regarding the resources available locally and uncertainty as to which ministry would actually be responsible for managing a foreign purchase and signing a contract. International procurement experience, existing within one department of a ministry of health, was unknown to another department.

In one republic, there was serious apprehension about signing contracts with former Soviet producers for the full amount of EPI vaccines required for fear of retribution through the courts, if it was later necessary to reduce the quantities because of donations or lack of funds.

III. ACTIVITIES

The major activities of this technical assistance visit centered on: (1) an attempt to answer questions related to the 1993 EPI vaccine supply for each of the three republics; (2) a review of current procedures for estimating needs and acquiring the EPI vaccine supply; (3) an assessment of existing capability for purchasing vaccines from foreign sources; and (4) providing resource documents and suggestions to aid in the development of a reliable supply of safe, effective vaccines in quantities adequate to fill the annual needs of the individual republics. Findings were accumulated through a series of interviews, observations, working sessions, field visits, and a review of various documents in each of the three republics. Annex 7 contains a list of the reference materials and resource documents provided that have not otherwise been attached to this report. One set is being sent to REACH as a file copy.

Although based on the original Scope of Work appearing in Annex 8, the actual trip activities and output were recast based on the situation and needs existing at the time of the visit and, in some cases, by limited time frames and availability of data. In each case, an effort was made to be responsive to the interests exhibited by the host ministries and to provide some immediate benefit rather than to join the ranks of the many donor agencies circulating in the republics asking the same questions over and over again. It was obvious that the Ministries of Health and their sub-departments were feeling harassed and possibly insulted by many of these "missions," complaining openly about never hearing back, never getting anything. USAID and the REACH project, on the other hand, were accorded much appreciation for emergency vaccine supplies and received compliments for visible and substantial contributions to cold chain improvements.

Among the documents and resources furnished during the trip, the republics were most interested in discussing specifications, international vaccine prices, and international vaccine sources.

A. Specifications

Draft procurement requirements showing what kind of information to include when contracting with a manufacturer for the supply of vaccine were translated into Russian and provided to each republic. The technical aspects of these "requirements" were based on WHO Biological Requirements but designed without reference to formal GMPs (Good Manufacturing Practices). This was done so that Russian producers who have process, equipment, and plant limitations, but are nevertheless able to provide high quality finished vaccines, would not be eliminated from competition for vaccine contracts.

Cold chain packing, shelf-life requirements, and provisions for pre-shipment inspection appearing in the draft procurement requirements were pointed out as a means to protect against receiving short-dated or sub-standard vaccine.

Each republic was informed that the draft requirements were examples of wording representing a minimum procurement specification and should be augmented or adjusted according to particular needs and national requirements. It was also explained that requirements of this sort might be used to establish interim, achievable goals for domestic production should the various Ministries of Health choose to begin exerting pressure on the FSU manufacturers to improve their products. WHO specifications for the four EPI vaccines were provided for reference. These documents are included in the Annex 7 list. There are plans to have them translated into Russian during the early part of 1993.

In conjunction with discussions of vaccine specifications, a draft pre-shipment compliance program and a statistical sampling plan was presented and explained. This material held less immediate interest but was left for future reference. It had been translated into Russian as well.

B. Procurement Procedures

Basic international procurement procedures, sample forms, and documents were consolidated into a draft Vaccine Procurement Reference Manual and provided to each of the republics. Samples of international transport documents were included to introduce standard requirements for international commerce involving pharmaceuticals and biologics. A flow chart summarizing the steps, sequence, and interactions of a public sector international procurement process was used to introduce each chapter. It is replicated in Annex 9 of this document. With the exception of intense interest in Kyrgyzstan and subsequent long discussions, the procurement procedure materials were reviewed briefly and set aside for future reference.

C. Sourcing

Each republic was given specific contact information on international sources of supply, including a list of those vaccine producers who have been approved by WHO. Pros and cons of contracting with non-WHO approved producers, both domestic and international, were discussed and appropriate protections were described. Contact information for international inspection and testing services was provided as well.

Kyrgyzstan and Uzbekistan were interested in independently soliciting prices from international vaccine producers and a draft letter of inquiry was developed to assist them in this activity.

D. Pricing

Domestic and international vaccine prices were compared and discussed. A copy of the worksheet showing recent prices from six international manufacturers, UNICEF, and the domestic producers was left in each republic. (See Annex 5.) In every case, the republics were shocked by the international prices. It was explained that the UNICEF prices included all of the administrative services, purchasing, inspection, testing, etc., that would otherwise need to be accomplished by the republics in contracting directly with international producers.

Disposable syringe prices and supplies were ignored due to lack of interest. There is, however, a demand for donations of disposable 0.05 ml syringes specifically for BCG immunization; these are not otherwise available in the Central Asian Republics. Syringes are provided by another division of the MOH and meet up with vaccine at the immunization centers. Although disposable syringes are preferred, reusable syringes are employed for vaccination when the disposable type are not available. In some cases, parents purchase disposable syringes on the open market and

bring them to the immunization center with the child.

E. Budgets and Procurement Plans

"What-if" exercises were undertaken for each republic in order to develop budget estimates for the 1993 EPI vaccine supply under various scenarios. These exercises relied upon demographic data, not actual plans, to generate the number of immunizations needed in each age group for each antigen, and thus need to be refined when all of the oblasts have submitted their actual 1993 needs. The lowest international prices and the estimated domestic prices appearing in the Annex 5 worksheet were used for the calculations. These calculations should also be adjusted when the specific source and firm price are known.

Uzbekistan and Kyrgyzstan "what-if" exercises used the following three scenarios:

1. 85% of the BCG, DTP, and polio vaccine would come from domestic producers; the remaining 15% would come from the lowest priced foreign supplier. 40% of the measles vaccine would come from domestic producers; the remaining 60% would come from the lowest priced foreign supplier.
2. All of the vaccine would come from international producers.
3. All of the vaccine would come from domestic producers.

For Turkmenistan, two additional scenarios were calculated:

1. All of the primary vaccines would be donated; the remaining vaccine would come from domestic producers.
2. All of the vaccine for children under age two would be donated; the remaining vaccine would come from domestic producers.

Copies of the what-if exercises may be found in the separate republic reports.

F. Phased Delivery Schedules

FSU vaccine producers generally contract on the basis of quarterly deliveries, but actual deliveries vary according to supply. The republics have very little control over this. "Theoretical" cold-room capacity is said to be adequate for quarterly deliveries in Kyrgyzstan and Turkmenistan. Actual capacity varies according to the efficiency of the existing refrigeration equipment.

Theoretical cold room capacity in Uzbekistan is not adequate to support a quarterly delivery schedule. Therefore, a phased, monthly schedule was prepared and left with the MOH for consideration.

G. Wrap-Up

Wrap-up discussions were held with the highest ranking principal contacts in each republic and included a review of the findings, work accomplished and resource materials provided. The activity in each location was very much a process of discovery for both the consultant and the immunization program personnel; projecting how vaccine acquisition might be handled in the future in many cases uncovered locally available information and resources that had previously been unknown.

IV. RECOMMENDATIONS

1. Donate at least part of the 1993 EPI vaccines required by Kyrgyzstan, Uzbekistan, and Turkmenistan. Donors may wish to address different segments of the vaccine requirement according to their own institutional philosophies. For instance, one donor may target only primary vaccination while another may include boosters for children up to five years old. Examples of several different options follow:
 - a) provide primary EPI vaccines to cover the anticipated 1993 domestic producer shortfall and/or primary EPI vaccines that cannot be purchased from domestic producers in 1993 due to lack of funds;
 - b) provide all primary EPI vaccines;
 - c) provide all primary and booster EPI vaccines to cover the anticipated 1993 domestic producer shortfall; and
 - d) provide all vaccines to cover the primary and booster EPI requirement.

Option (a) should be regarded as the minimum donation, while option (d) reflects the maximum requirement.

2. Establish a donor financial reserve to provide emergency assistance in the event of an epidemic or unanticipated vaccine shortfall. An amount equal to ten percent of the annual cost of primary vaccines is suggested.
3. Provide short term technical assistance and institutional development in supply acquisition and contracting. At a minimum, this should include procedures for contracting with foreign suppliers and strategies for gaining improvements in domestic vaccine quality and cold chain handling. It should also include development of formal procurement requirements (specifications) and resource development and coordination.
4. Provide a hard currency allowance to each republic to cover the vaccine and incidental costs of a practice foreign procurement. These funds could be protected and managed by depositing the hard currency in the local AID mission account for transfer to a special MOH collateral account when a letter of credit is issued.
5. Develop a program of donor assistance tying aid to domestic vaccine producers with benefits for republics, matching the needs of the republics to the needs of the producers. Examples of needs and tied benefits follow:

Republic needs

- proper vaccine transport from suppliers, including insulated containers, icepacks and monitor cards
- price guarantees for vaccines
- delivery of full quantities of vaccines ordered
- high quality vaccines
- small size vials to reduce wastage

Producer needs

- hard currency to purchase imported supplies
- equipment

- cold chain information and materials
- assistance with foreign procurement
- GMP training

Tied benefits

- production supplies/equipment tied to vaccine quantity and ruble price guarantees for specific republics
 - hard currency advances for purchase of imported supplies to produce vaccines of the same value for specific republics; procurement assistance if needed
 - cold chain transport packing assistance in return for cold chain guarantees to specific republics; elements of this assistance might include:
 - * assessment and detailed proposal
 - * initial supplies and technology transfer
 - * development of local resources
 - * trial program in coordination with regulations now being established by the State Sanitary and Epidemiological Commission and the MOH of Russia
6. Provide funding for a visit to Russian producers to negotiate the tied benefits scheme described in 5. above.
 7. Provide funding for a consortium of republic representatives to meet with producers to discuss specifications and quality needs/expectations.
 8. Establish short term pre-paid contracts with international third party testing laboratories to monitor the quality of Soviet EPI vaccines during and after assistance proposed in 5. above.
 9. Provide assistance in establishing a central regulatory authority for licensing and control of biologics in each of the three republics. As appropriate, provide assistance in establishing national control laboratories.
 10. Organize study tours made up of vaccine producers, relevant republic representatives and donor/facilitator(s).

These tours might include visits to Western manufacturers to observe facility design and maintenance, modern production processes, GMP's (Good Manufacturing Practices) and cold chain packing. Training at a GMP institute and visits to central regulatory laboratories of other countries should also be considered.
 11. Translate technical, international trade and procurement reference/training documents into Russian. At the present time, documents in English or other Western languages are available but not useful.
 12. Re-evaluate the situation in one year with emphasis on the economic circumstances and experience/capability level in each of the three republics; update needs for further assistance.

APPENDICES

APPENDIX 1

APPENDIX 1

UZBEKISTAN

Of the three republics visited during November 1992, Uzbekistan falls somewhere between Kyrgyzstan and Turkmenistan in its ability to arrange for adequate supplies of EPI vaccines. Representatives at the Ministry of Health (MOH) were distracted by a cholera epidemic in Samarkand during much of the Uzbekistan visit and, therefore, the information leading to this conclusion may be incomplete. They did, however, welcome discussions and resource documents about contracting with Western manufacturers and were especially interested in Western vaccine prices.

Supply:

Orders have been sent to Russian manufacturers for the entire 1993 EPI vaccine requirement but an official reply has not been received and, thus, no contracts are in place. Under these circumstances, it is not possible to do more than estimate how much vaccine might need to come from other sources. Given the urgent need to provide for the entire 1993 supply, one reasonable option would be to plan based on 85% of the DTP, Polio, and BCG and 40% of the measles vaccine coming from domestic producers.

Requests have been made by the MOH to various donors, including bilateral donors, for assistance with vaccine requirements in various amounts. This assistance is characterized as a back-up mechanism to fill the gap between what the Russian manufacturers are able to provide and the full requirements of the Uzbekistan immunization program.

Hard Currency:

Hard currency for 1993 vaccine purchases is probably not going to be available from the government of Uzbekistan although it has been requested. Because of its current level of progress in economic policy, access to hard currency through a soft loan from the World Bank is not in the immediate future either, according to the regional CIS World Bank representative. The "Bank" has, however, solicited a project proposal from Uzbekistan that includes vaccine supplies, freezing equipment, and rehabilitation of the BCG factory in Tashkent. Ministry officials are said to be much more interested in infrastructure, i.e., buildings and equipment, than in vaccine supplies.

If hard currency through any source is made available for 1993 vaccines, a simple and speedy approach would be to make purchases through the UNICEF supply service. This could be arranged with UNICEF directly by contacting the UNICEF representative in Tashkent. In the case of World Bank funds, the other alternative is to go through an international competitive bidding procedure that may require up to one year to complete.

Procurement Experience:

UZMEDIMPEX, the Uzbek Foreign Trade Association, makes external (foreign) purchases. In the case of vaccines, they would be responsible to select suppliers, but the MOH could use its own links abroad, contact manufacturers, and offer suggestions to UZMEDIMPEX. The MOH would make an official request to UZMEDIMPEX by letter outlining its requirements and providing detailed specifications.

UZMEDIMPEX makes inquiries to several manufacturers and decides which shall be awarded the contract. The decision is based on (1) quality, (2) price, and (3) date of delivery. UZMEDIMPEX looks at technical data during this decision-making process. It also takes care of all banking and payment arrangements. Payment can be by letter of credit. Any World Bank funds used by the MOH would be administered by UZMEDIMPEX using World Bank rules. It appears that UZMEDIMPEX would also interact with UNICEF if purchases were made through that agency.

Regulatory:

A system of control and testing is just forming in Uzbekistan. There is a special control commission to deal with licensing, and a special laboratory is being set up to test pharmaceuticals. This laboratory will not be able to test vaccines, so a separate laboratory will need to be organized. These laboratories will deal with domestic as well as foreign products. Vaccine that has not previously been used in Uzbekistan need to go through a registration process. In the case of donated goods, only certificates and test papers are necessary. In the case of purchased vaccines, testing will be required and this will have to be done on a cash basis through the Tarasevitch Institute in Moscow for the time being. However, this is considered expensive (approximately 25% of the cost of the vaccine). In addition, some reports indicate the Tarasevitch Institute is booked through 1992 and any testing for the MOH would be delayed until 1993. The registration process may take up to one year, but if there is an urgent requirement it could be expedited. Registration in Russia is not regarded as qualification for registration in Uzbekistan.

Deliveries:

Given an efficient cold chain, deliveries of vaccine should be made on a quarterly basis; in theory, the Uzbekistan MOH agrees with this. UNICEF supply programs are also geared to this cycle.

In the past, all vaccine for Uzbekistan was shipped directly to the oblast level. Only a small emergency supply was kept at the central warehouse in Tashkent.

Recently, air-cargo services between Moscow and the Uzbekistan oblasts has become severely limited, and it appears that vaccines will now need to be route through the central warehouse in Tashkent from which oblasts will collect their orders. This will put an enormous additional burden on the cold room facilities in Tashkent. Cold chain experts assisting with the immunization program have determined that refrigeration in these existing rooms is inadequate and must be upgraded to safely handle the volume of product that will be arriving. Although a new warehouse and cold room are under construction, it is clear that this facility is not expected to be complete in the near future.

Because of the constraints mentioned above, the vaccine delivery schedule for the MOH should continue to provide for frequent small shipments, i.e., generally once a month for each oblast, with necessary adjustments for polio and measles, which are not given during the summer months. When adequate space and a proper refrigeration system is available at the central warehouse, a more convenient and less expensive schedule of quarterly deliveries should be instituted.

Miscellaneous:

The long-term goal of the MOH is vaccine and pharmaceutical manufacturing capability within the CIS involving international manufacturers. Rehabilitation of the BCG factory in Tashkent is a high priority.

Last year the immunization program did not provide measles immunization to 200,000 children because of shortages. Russian producers had promised to provide the entire requirement but could not make good on their promises. This was attributed to restoration projects which interfered with production; this work is said to be finished so the situation may improve.

There is strong sentiment within the MOH that centralized procurement of vaccines is necessary to control quality, expiration date, delivery dates, and overall value. Recently, oblasts have been making contracts with suppliers directly and paying for them with their own funds. Recently one oblast entered into a barter agreement for the supply of hepatitis B vaccine from SmithKline. By the time the vaccine passed through several middlemen and was delivered to the oblast, only a few

months of shelf life remained; even if initial vaccinations were given immediately, the vaccine would expire before the second injection was due. The middlemen involved in this transaction instructed the MOH not to discuss these problems directly with SmithKline. The consultants advised that direct contact with SmithKline is very important and should be initiated immediately.

Suggestions for Follow-up:

The Uzbekistan Ministry of Health is ready for limited institutional development in international supply acquisition and contracting. It has the interest, but hard currency resources are not imminent. Of the technical assistance activities suggested in the main Trip Report, there are several that would be immediate value to the MOH:

- Strategies for gaining improvements in domestic vaccine quality and cold chain handling; contracting with former Soviet Union producers
- Specification development (procurement requirements)
- Assistance in locating existing resources and coordinating inter-ministry inputs and approvals

A two-week technical assistance visit would be adequate to cover these activities.

UZBEKISTAN

PROCUREMENT PLAN OPTIONS: WHAT-IF EXERCISES FOR 1993 VACCINE SUPPLY (A B C)

A. Majority Russian, Balance Foreign

Vaccine	Unit	Quantity	Domestic Percentage	Domestic Quantity	Domestic Cost	Domestic Cost Total
BCG	1000 sets	238	0.85	202	4100	829,430
OPV	1000 doses	7030	0.85	5976	2500	14,938,750
Measles	1000 doses	1429	0.4	572	12000	6,859,200
DTP	liters	1927	0.85	1638	3500	5,732,825
TT	liters	271	1	271	2000	542,000
						----- 28,902,205 Rubles

Vaccine	Unit	Quantity	Foreign Percentage	Foreign Quantity	Foreign Cost	Foreign Cost Total
BCG	1000 sets	238	0.15	36	\$2,500	\$89,250
OPV	1000 doses	7030	0.15	1055	\$82	\$86,469
Measles	1000 doses	1429	0.6	857	\$150	\$128,610
DTP	liters	1927	0.15	289	\$115	\$33,241
TT	liters	271	0			
						----- \$337,570 131,652,203 Rubles -----

101

B. All Russian

Vaccine	Unit	Quantity	Domestic Percentage	Domestic Quantity	Domestic Cost	Domestic Cost Total
BCG	1000 sets	238	1	238	4100	975,800
OPV	1000 doses	7030	1	7030	2500	17,575,000
Measles	1000 doses	1429	1	1429	12000	17,148,000
DTP	liters	1927	1	1927	3500	6,744,500
TT	liters	271	1	271	2000	542,000
						42,985,300 Rubles

C. All Foreign

Vaccine	Unit	Quantity	Foreign Percentage	Foreign Quantity	Foreign Cost	Foreign Cost Total
BCG	1000 sets	238	1	238	\$2,500	\$595,000
OPV	1000 doses	7030	1	7030	\$82	\$576,460
Measles	1000 doses	1429	1	1429	\$150	\$214,350
DTP	liters	1927	1	1927	\$115	\$221,605
TT	liters	271	1	271	\$74	\$20,054
						\$1,627,469
						634,712,910 Rubles

2

APPENDIX 2

APPENDIX 2

KYRGYZSTAN

Of the three republics visited during November 1992, Kyrgyzstan is the most developed in its ability to arrange for adequate supplies of EPI vaccines. Representatives at the Ministry of Health (MOH) expressed interest in independent procurement of vaccines from foreign as well as domestic sources and were anxious to have information on contracting with Western manufacturers.

Supply:

Contracts for the 1993 supply of vaccines have been signed with almost all of the Russian manufacturers, although there are serious doubts about the ability of these producers to fill the entire vaccine requirement. In addition, Kyrgyzstan still owes Russian manufacturers 600,000 rubles for 4th quarter, 1992, vaccine and does not expect new orders to be filled until they pay for their earlier commitment. Banking disturbances, which currently prevent transfer of funds from Kyrgyzstan to the Russian producers, is a third element of uncertainty.

Hard Currency:

Although a substantial amount of hard currency is being made available to the Government of Kyrgyzstan by the EC and the World Bank, there is heavy competition among the various ministries and programs for access to these funds. In the case of the EC loan, all decisions have been made, many of the contracts have been awarded, and there is no possibility of using any of this resource for the immunization program.

In the case of World Bank funds, decisions have not yet been made and can still be influenced. The MOH needs to send its requirements to the Ministry of Finance and Economic Affairs, and the immunization program needs to make its case to the MOH. There is a difficulty associated with this in that no one knows how much vaccine the Russian producers will be able to supply to Kyrgyzstan and how much would need to come from hard currency sources. Cost estimates have been prepared on a "what-if" basis, making three separate assumptions for 1993: (1) Russian producers will be able to supply 40% of the measles vaccine and 85% of the other vaccines, (2) Russian producers will be able to supply all of the vaccine requirements, and (3) all vaccine requirements will come from foreign sources. These worksheet estimates are included at the back of this section.

If a portion of the 1993 EPI vaccine is financed by World Bank loan funds, time requirements for international tender and bid processes will need to be considered. Since these procedures can take up to one year to complete, it may be necessary to rely upon the UNICEF supply service for immediate needs. At the same time, producers can be invited to bid for contracts on the next requirement.

When there is hard currency available, the Ministry of Finance and Economic Affairs receives requests and requirements from the different ministries and makes a recommendation on how the funds should be divided. It retains 10% for administrative fees. After an amount is assigned to the MOH, the MOH decides for itself how to spend the funds.

The immunization program will need to compete within its own ministry for access to World Bank funds as there is a feeling among some that imported emergency medicines, anesthetics, and specialized drugs for a few very critical cases should have precedence over vaccines. The immunization program might support its request by emphasizing long-term economic benefit. EPI

studies* have shown that the cost to treat one case of measles is approximately ten times more than the cost of immunization. An epidemic would be a financial disaster under the present circumstances. In addition, the cost for one year of vaccine coverage is a relatively insignificant amount when compared to the large amounts in hard currency aimed at reconstruction and rehabilitation.

Procurement Experience:

To date, there are no government rules or procedures for contracting with Western suppliers. However, Pharmacia, through the MOH Department of External and Economic Relations, is in the process of administering about 40 foreign contracts using EC procurement rules and procedures. These are similar to World Bank procedures and include an open international tender process. If foreign vaccine procurement were to become a reality, Pharmacia would be able to manage the procedural matters while the vaccine program would be responsible for developing technical requirements and evaluating bids.

Regulatory:

Kyrgyzstan has signed an agreement with the Tarasevich Institute in Moscow to provide QA regulatory assistance for domestic vaccines. The MOH, however, thinks they should not rely on the laboratories of a different country and will eventually set up their own. They may develop the SES Bacteriological and Virus Laboratories for this purpose. Currently, they have no materials and no animals to support laboratory development and no immediate need since there are no drugs or vaccines manufactured in Kyrgyzstan. Recently, however, they had wanted to test the effectiveness of measles vaccine and asked the Tarasevich Institute for the Standards; Tarasevich declined to provide these. Organization of testing laboratories has recently been discussed with UNICEF and assistance may be provided at some time in the future.

Suggestions for Follow-up Assistance:

The Kyrgyzstan MOH is ready for institutional development in international supply acquisition and contracting. It has the interest and probably resources necessary to take advantage of technical assistance in this regard. If vaccine funds become available through a World Bank loan, the MOH needs to be in a position to work with the World Bank procurement requirements, which are based on widely accepted international tendering procedures. While all parts of the Recommendations appearing in the main body of this document are applicable to Kyrgyzstan, particular emphasis should be put on a practice international procurement of EPI vaccine. Specific elements of this exercise follow:

- Provide hard currency to Kyrgyzstan MOH to pay for some amount of foreign vaccine (to be controlled by the local AID mission).
- Assist the MOH to develop tender documents for their first international vaccine procurement including:
 - * vendor qualifications
 - * specifications (procurement requirements)
 - * contracts
 - * inspection plans and protocols
 - * testing requirements
 - * shipping and customs clearance procedures

* Pointe Noire, Congo 1985 EPI Cost Data. *Measles Control in Africa*. The Lancet, F Dabis, et al and Congo MOH, July 19, 1986.

- Assist MOH in accessing locally available information and resources related to international transactions
- Provide instruction on international trade terms and practices including:
 - * INCOTERMS (International Commerce Terms)
 - * Letters of Credit
 - * Shipping Documents
 - * Performance Guarantees

A three-week technical assistance visit would be adequate to organize and initiate the practice procurement.

KIRGYZSTAN

PROCUREMENT PLAN OPTIONS: WHAT-IF EXERCISES FOR 1993 VACCINE SUPPLY (A B C)

A. Majority Russian, Balance Foreign

Vaccine	Unit	Quantity	Domestic Percentage	Domestic Quantity	Domestic Cost	Domestic Cost Total
BCG	1000 sets	75	0.85	64	4100	261,375
OPV	1000 doses	1340	0.85	1139	2500	2,847,500
Measles	1000 doses	330	0.4	132	12000	1,584,000
DTP	liters	335	0.85	285	3500	996,625
DT	liters	223	1	223	2000	446,000
Mumps	1000 doses	154	1	154	11600	1,786,400
						7,921,900 Rubles

Vaccine	Unit	Quantity	Foreign Percentage	Foreign Quantity	Foreign Cost	Foreign Cost Total
BCG	1000 sets	75	0.15	11	\$2,500	\$28,125
OPV	1000 doses	1340	0.15	201	\$82	\$16,482
Measles	1000 doses	330	0.6	198	\$150	\$29,700
DTP	liters	335	0.15	50	\$115	\$5,779
DT	liters	223	0			
Mumps	1000 doses	154	0			
						\$80,086
						31,233,443 Rubles

B. All Russian

Vaccine	Unit	Quantity	Domestic Percentage	Domestic Quantity	Domestic Cost	Domestic Cost Total
BCG	1000 sets	75	1	75	4100	307,500
OPV	1000 doses	1340	1	1340	2500	3,350,000
Measles	1000 doses	330	1	330	12000	3,960,000
DTP	liters	335	1	335	3500	1,172,500
DT	liters	223	1	223	2000	446,000
Mumps	1000 doses	154	1	154	11600	1,786,400
						11,022,400 Rubles

C. All Foreign

Vaccine	Unit	Quantity	Foreign Percentage	Foreign Quantity	Foreign Cost	Foreign Cost Total
BCG	1000 sets	75	1	75	\$2,500	\$187,500
OPV	1000 doses	1340	1	1340	\$82	\$109,880
Measles	1000 doses	330	1	330	\$150	\$49,500
DTP	liters	335	1	335	\$115	\$38,525
DT	liters	223	1	223	\$74	\$16,502
Mumps	1000 doses	154	1	154	\$150 est	\$23,100
						\$425,007
						165,752,730 Rubles

DWCISWQ1.WQ1

Handwritten mark

APPENDIX 3

APPENDIX 3

TURKMENISTAN

Of the three republics visited during November 1992, Turkmenistan is perhaps the least developed in its ability to arrange for adequate supplies of EPI vaccines. Representatives at the Ministry of Health (MOH) expressed dependence upon vaccine donations and were anxious to have concrete donor commitments for 1993. UNICEF and USAID are regarded as primary sources; bilateral support from Iran and Finland were mentioned as other possibilities. The focus of this technical assistance visit was erroneously thought to be a USAID donation. It was explained that this was not the case, but that quantity and cost figures would be developed for donor consideration. To this end, supply records, demographic data, and oblast immunization requirements were made available for analysis.

Supply:

At the time of the visit, orders had not been placed with domestic Russian manufacturers for 1993 vaccine deliveries. This exercise was apparently being delayed until donor commitments were in place and unfilled requirements could be calculated. Concern was expressed over punishment through the court system if contracts had to be revised downward or canceled because of donations.

The MOH is expecting donations of EPI vaccine for children up to one year of age and hope that vaccines for children up to two years of age will be included. Where they get vaccine for older children depends on new prices from the Russian suppliers and availability.

Hard Currency:

Turkmenistan was the recipient of about \$16 million in EC credits. Part of these funds were used to purchase drugs from Eastern Europe, but nothing was made available for vaccines. The World Bank has been in contact with the Ministry of Finance of Turkmenistan but currently has nothing planned for the republic.

Procurement Experience:

As in the other republics, Pharmacia is the purchasing arm of the MOH. In the past, its principle responsibility was to gather information from the lowest levels of the vaccine distribution system and organize the required "procurement" from Moscow. Now the functions of declaring the requirements, receiving the vaccine, and payment will be divided between the Republican SES and Pharmacia.

The MOH, as yet, has no experience in foreign contracting other than for activities that are closely supervised by EC. Pharmacia was asked to find pharmaceutical suppliers in one or another Eastern European countries and found it quite difficult. They have never executed a sealed bid process, and it has not been decided if they would be responsible for contracting procedures if vaccine is purchased from foreign sources. The Ministry of Foreign and Economic Affairs may offer some foreign procurement experience, but this avenue was not pursued due to

lack of time and an absence of early potential for hard currency.

Regulatory:

Turkmenistan has an agreement with the Tarasevitch Institute in Moscow for QA regulation and testing. Turkmenistan's existing laboratories do some limited vaccine testing but they are not ready to consider independent capability.

Miscellaneous:

According to the MOH, emergency stock has been depleted. In the past, 10% of the vaccine consignments were kept in Ashgabat for emergency purposes. Now, all of the stock is sent out because there is not enough to fill normal needs.

Republican SES personnel are interested in discussing revisions to the vaccination schedule and were looking forward to the policy seminar that was to have taken place in December (delayed).

They also mentioned that the medical staff seems to be afraid of imported vaccines and prefers domestic vaccine because of Russian language labeling and long-standing experience. Foreign vaccines have varying characteristics such as numbers of infective units and different reactogenic properties.

Plan for Follow-up:

Re-assess the EPI vaccine program situation in one year with emphasis on the economic picture and MOH interest in developing independent acquisition and contracting skills. A one-week visit would be adequate for this assessment and might include some preliminary training activities. Additional short-term technical assistance including a practice foreign procurement should be provided if appropriate.

TURKMENISTAN

PROCUREMENT PLAN OPTIONS: WHAT-IF EXERCISES FOR 1993 EPI VACCINE SUPPLY (A B C D E)

24

A. Majority Russian, Balance Foreign (except all BCG-M from CIS producers)

Vaccine	Unit	Quantity	Domestic Percentage	Domestic Quantity	Domestic Price	Domestic Cost Total	
BCG	1000 sets	68.5	0.85	58	4100	238,723	
BCG-M	1000 sets	6.0	0.85	5	2950	17,700	
OPV	1000 doses	1490	0.85	1267	2500	3,166,250	
Measles	1000 doses	237	0.4	95	12000	1,137,600	
DTP	liters	250	0.85	213	3500	743,750	
						-----	5,304,023 Rubles
Vaccine	Unit	Quantity	Foreign Percentage	Foreign Quantity	Foreign Price	Foreign Cost Total	
BCG	1000 sets	68.5	0.15	10	\$2,500.00	\$25,687.50	
BCG-M	1000 sets	6.0	0.15	1	\$1,250.00	\$0.00	
OPV	1000 doses	1490	0.15	224	\$82.00	\$18,327.00	
Measles	1000 doses	237	0.6	142	\$150.00	\$21,330.00	
DTP	liters	250	0.15	38	\$115.00	\$4,312.50	
						-----	\$69,657.00
							27,166,230 Ruble Equiv.

							32,470,253 Ruble Equiv.

13

B. All from CIS Producers

Vaccine	Unit	Quantity	Domestic Percentage	Domestic Quantity	Domestic Price	Domestic Cost Total
BCG	1000 sets	68.5	1	69	4100	280,850
BCG-M	1000 sets	6.0	1	6	2950	17,700
OPV	1000 doses	1490	1	1490	2500	3,725,000
Measles	1000 doses	237	1	237	12000	2,844,000
DTP	liters	250	1	250	3500	875,000

7,742,550 Rubles

C. All Foreign (except BCG-M from CIS producers)

Vaccine	Unit	Quantity	Foreign Percentage	Foreign Quantity	Foreign Price	Foreign Cost Total
BCG	1000 sets	68.5	1	69	\$2,500.00	\$171,250
BCG-M*	1000 sets	6.0	1	6	\$1,250.00	\$0
OPV	1000 doses	1490	1	1490	\$82.00	\$122,180
Measles	1000 doses	237	1	237	\$150.00	\$35,550
DTP	liters	250	1	250	\$115.00	\$28,750
						\$357,730

139,514,700 Ruble Equiv.

*not available from foreign sources

32

D. Primary series by donation; Boosters from CIS producers (except all BCG–M from domestic producers)

Vaccine	Unit	Quantity	Donated Percentage	Donated Quantity	Donated Price	Donated Cost Total
BCG	1000 sets	68.5	32.44%	22	\$2,500.00	\$55,554
OPV	1000 doses	1490	35.38%	527	\$82.00	\$43,227
Measles	1000 doses	237	54.54%	129	\$150.00	\$19,389
DTP	liters	250	75.76%	189	\$115.00	\$21,781

						\$139,951

Vaccine	Unit	Quantity	Domestic Percentage	Domestic Quantity	Domestic Price	Domestic Cost Total
BCG	1000 sets	68.5	67.56%	46	4100	189,742
BCG–M	1000 sets	6	100.00%	6	2950	17,700
OPV	1000 doses	1490	64.62%	963	2500	2,407,095
Measles	1000 doses	237	45.46%	108	12000	1,292,882
DTP	liters	250	24.24%	61	3500	212,100

4,119,520 Rubles

25

E. Under two age group by donation; Over two age group from domestic producers

Vaccine	Unit	Quantity	Donated Percentage	Donated Quantity	Donated Price	Donated Cost Total
BCG	1000 sets	68.5	32.44%	22	\$2,500.00	\$55,554
OPV	1000 doses	1490	61.83%	921	\$82.00	\$75,544
Measles	1000 doses	237	54.54%	129	\$150.00	\$19,389
DTP	liters	250	75.76%	189	\$115.00	\$21,781
						\$172,267
Vaccine	Unit	Quantity	Domestic Percentage	Domestic Quantity	Domestic Price	Domestic Cost Total
BCG	1000 sets	68.5	67.56%	46	4100	189,742
BCG-M	1000 sets	6.0	100.00%	6	2950	17,700
OPV	1000 doses	1490	38.17%	569	2500	1,421,833
Measles	1000 doses	237	45.46%	108	12000	1,292,882
DTP	liters	250	24.24%	61	3500	212,100

3,134,257 Rubles

ANNEX 1

ANNEX 1
ACRONYMS

BCG	Bacillus Calmette Guérin (tuberculosis vaccine)
CIS	Commonwealth of Independent States
DPT	Diphtheria-Pertussis-Tetanus vaccine
EC	European Community
EPI	Expanded Program on Immunization
FSU	Former Soviet Union
GMP	Good Manufacturing Practice
IMF	International Monetary Fund
ISI	John Snow, Inc.
MOH	Ministry of Health
NGO	Non-Governmental Organization
NIS	Newly Independent States
QA	Quality Assurance
QC	Quality Control
REACH	Resources for Child Health
OPV	Oral Polio Vaccine
SES	Sanitary Epidemiological Station
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
USD	United States Dollars
WHO	World Health Organization

35

ANNEX 2

ANNEX 2

PERSONS CONTACTED DURING VISIT

REACH

Carl Hasselblad, Senior Technical Officer

Gordon Larsen, EPI Consultant

John Pott, EPI Consultant

Robert Steinglass, Technical Director

US GOVERNMENT

Sylvia Babus, US Embassy

Paula Feeney, USAID
General Development Officer
Kazakhstan and Central Asia

UZBEKISTAN

Tulkin Iskandarovich Iskandarov
First Deputy Minister of Health

Dr. Daron ALimovna Tursunova
Chief Specialist, Epidemiology

Vladimir Alexandrovich Andrianov
Chief Doctor's Representative
Republican SES

Adulkarim Sarimaskov
National Committee for the
Reception of Humanitarian Aid

Svetlana Kayfanova Alieva, Director
Virus & Bacteriological Laboratory
Republican SES

Camalova Nuritina
Director of Scientific Research
Enterprise "Vaccine" (BCG Factory)

Mirakhmat Mirabzalov, General Director
UZMEDIMPEX

Professor Najmiddine
Deputy Minister of Health
Chairman of special

Bukhtior Calanov - Translator (Tashkent)

KYRGYSTAN

Dr. Boris Moiseevich Shapiro
First Deputy Minister of Health

Kafan Abdumaminovich Subanbaev
Second Deputy Minister of Health in Charge of Finance

Svetlana Firsova
Director of Epidemiological Department'
Ministry of Health

Vladimir Israelevich Genis
Chief of Epidemiological Sector

Ms. Liudmila Vasilevna Roshkova
Assistant to Chief of Epidemiological Sector

Ms. Emma Egorovno Konosova, Deputy Minister
Ministry of Finance and Economics

Marat Galievich Galiev, Deputy of General Director Pharmacia

Ms. Matveeva Lubov, Chief of Department
External Economic Relations
Pharmacia

Ruma Abdulovna Kueryakova, Deputy of Chief Doctor
Republican SES

Dr. Victor Mikalovich Glinenko
Chief Doctor of Infective Diseases
Department of Maternal and Child Health

Courmanbic Omuraliev, Chief Doctor
Republican SES

Osmanali Jaldoshbiaf, Chief Doctor
Kalininski Regional SES

Ms. Naderda Vasilivna Statsanko
Chief of Epidemiological Department
Kalininski Regional SES

Lena Chernova - Translator (Bishkek)

TURKMENISTAN

Dr. Juma Leonn Kuliavich Akmanmirdov, Chief
Immunology, Ministry of Health

Anatoly Michalovich Abramov

Greta Vedieva, Coordinator of Immunization Program
Republican SES

Lydia, Coordinator of BCG Immunization

Victor Savelgevich Ushenko, Vice Chief
Pharmacia

Olga Shagalina - Translator (Ashkabad)

OTHERS

Parvez Hasan, World Bank Representative
Tashkent

Robert Snyder, Public Health Advisor
Centers of Disease Control

Frederick van Loon, M.D., PhD.
Internist, Epidemiologist
Centers for Disease Control

Vladimir Yastrejembski - Translator (Moscow)

COMMERCIAL CONTACTS

Andrei Kuteinikov, Manager, Business Development
Merck Sharp & Dohme, Moscow

Felix Kizhner, Marketing Manager
Merck Sharp & Dohme, Moscow

David Velez, Managing Director
Merck Sharp & Dohme, Moscow

Andrej Chernyshev, Deputy General Director
Soviet-French Joint Venture
"Sugar Trading Company Ltd."

Paul Mandel
Director Adjoint "Logistique"
Sucden Kerry, Paris

ANNEX 3

SUMMARY VACCINATION SCHEDULES (A)
WASTAGE FACTORS (B)

A. VACCINATION SCHEDULES:

	BCG PRIMARY	BCG BOOSTER	BCG TOTAL	DTP PRIMARY	DTP BOOSTER	DTP TOTAL	OPV PRIMARY	OPV BOOSTER	OPV TOTAL	MEASLES PRIMARY	MEASLES BOOSTER	MEASLES TOTAL
UZBEKISTAN	1	2	3	3	1	4	3	5	8	1	1	2
KIRGYZSTAN	1	3	4	3	1	4	3	6	9	1	1	2
TURKMENISTAN	1	3	4	3	1	4	4	5	9	1	1	2

B. WASTAGE FACTORS

	BCG PRIMARY	BCG BOOSTER	BCG TOTAL	DTP PRIMARY	DTP BOOSTER	DTP TOTAL	OPV PRIMARY	OPV BOOSTER	OPV TOTAL	MEASLES PRIMARY	MEASLES BOOSTER	MEASLES TOTAL
UZBEKISTAN			UNKNOWN			UNKNOWN			UNKNOWN			UNKNOWN
KIRGYZSTAN			500%			40%			30%			30%
TURKMENISTAN	650%		220%			10%			10%			10%

CIS22.WQ1

15

ANNEX 4

ANNEX 4

**SUMMARY OF 1993 ANTIGEN REQUIREMENTS AND
SUGGESTED DONATION AMOUNTS IN DOSES**

Doses of Vaccines				
COUNTRY	BCG	POLIO	DPT	MEASLES
KYRGYZSTAN	249,300	232,800	255,500	137,000
TURKMENISTAN	518,100	183,000	266,000	157,700
UZBEKISTAN	648,800	506,000	506,000	1,021,100
TAJIKISTAN	493,800	456,800	358,000	187,900
TOTAL	1,910,000	1,378,600	1,385,500	1,503,700

ANNEX 5

5/2

1993 EPI VACCINE BUDGET ESTIMATES US DOLLARS

Units:	DTP BCG Measles OPV	liters (2000 x 0.5 ml) 1000 sets (20 doses/set) 1000 doses 1000 doses	MANUFACTURERS*																LOWEST IMPORT PRICE In US Dollars	CIS PRODUCERS (Sept '92)			
			UNICEF			BEECHEM		CONNAUGHT		CONPHARMA		HOECHST		BIOCINE SCLAVO		PASTEUR		USD equiv		RATIO			
			Dose Price (DP)	DP plus 6% fee	Unit Price	Dose Price	Unit Price	Dose Price	Unit Price														
BCG Infant BCG over 1yr	20	1000 sets	0.075	0.080	\$1,590			0.071	\$1,420	0.0625	\$1,250	soldout					0.19	\$3,800	CONPHA	\$1,250	\$2,500	\$11	119
Measles	10	1000 doses	0.18	0.191	\$191	0.219	\$219	0.185	\$185	0.15	\$150			0.165	\$165	0.23	\$230		\$180		\$31	5	
OPV	20	1000 doses	0.08	0.085	\$85	0.082	\$82	0.087	\$87			soldout							BEECHM	\$82		\$6	13
OPV	10	1000 doses	0.095	0.101	\$101	0.092	\$92							0.085	\$85	0.122	\$122						
DTP	20	liters	0.07	0.074	\$148			0.082	\$164	0.0575	\$115	0.0747	\$149						CONPHA	\$115		\$9	13
DTP	10	liters	0.09	0.095	\$191			0.105	\$210	0.075	\$150			0.125	\$250								

* Based on a response to September 1992 requests for a quote

1993 EPI VACCINE BUDGET ESTIMATES

RUBLE EQUIVALENT (3000/USD)

Units	DTP BCG Measles OPV	Mers (2000 x 0.5 ml) 1000 sets (20 doses/set) 1000 doses 1000 doses	MANUFACTURERS																LOWEST IMPORT PRICE in Ruble Equiv.		CIS PRODUCERS		
			UNICEF			BEECHEM		CONNAUGHT		CONPHARMA		HOECHST		BIOCINE SCLAVO		PASTEUR							
			Vial Doses	Cost Units	Dose Price (DP)	DP plus 6% fee	Unit Price	Dose Price	Unit Price	Dose Price	Unit Price	Dose Price	Unit Price	Dose Price	Unit Price	Dose Price	Unit Price	Dose Price	Unit Price	RUBLE	RATIO		
BCG Infant BCG over 1yr	20	1000 sets	29.25	31.005	620,100			27.69	553,800														
								54.6	1,092,000			24.375	487,500	soldout									
Measles	10	1000 doses	70.2	74.412	74,412	85.41	85,410	72.15	72,150			48.75	975,000				74.1	1,482,000	CONPHA 487,500 975,000	4,100	119		
OPV	20	1000 doses	31.2	33.072	33,072	31.98	31,980	33.93	33,930			58.5	68,500			64.35	64,350	89.7	89,700	58,500	12,000	5	
OPV	10	1000 doses	37.05	39.273	39,273	35.88	35,880							soldout						BEECHM	31,980	2,500	13
DTP	20	Mers	27.3	28.938	57,876			31.98	63,960							33.15	33,150	47.58	47,580				
DTP	10	Mers	35.1	37.206	74,412			40.95	81,900			22.425	44,850	29.133	58,266					CONPHA	44,850	3,500	13
												29.25	58,500			48.75	97,500						

ANNEX 6

Information on the October 1992 Meeting Between
Republics and Tarasevitch Institute/Russian Suppliers

In October 1992, a meeting was held in Moscow between the republics, the Tarasevitch Institute, and the Russian vaccine suppliers. It was officially devoted to "the control system of bacteriological preparations and testing". The State Sanitarian Epidemiological Inspection Committee of the Russian Federation (separate from the Russian MOH) was the organizing party. Uzbekistan and Georgia did not send representatives.

Issues of supply and quality were included as secondary topics. Of the Russian producers, only Imunogen and Biomed were present, but these organizations are said to cover most of the Russian vaccine production.

The Russian producer representatives assured the participants that they would be able to provide all of the vaccine needed by the CIS in 1993 "if the situation doesn't change". Although the Russian producers are said to have enough raw materials for 1993, there is a problem with quality and production was stopped in 1992 because of QC.

Informed parties think there will be no problem with DPT and polio vaccine supplies but there will be a problem with BCG and measles vaccine. The measles vaccine supply has been reduced from 24 million doses in 1988 to 8 million doses in 1992; it appears only 5 million doses will be available in 1993 for all of the former Soviet Union. Informed sources thought 4.8 million doses would be required by "the republics" alone. Uzbekistan, Kyrgystan and

Turkmenistan together would require about 1.96M doses for 1993.

The manufacturers were asked about "worn out measles virus" but declined to give an answer even though directly asked by the representative from the Ukraine. They claim the quality of the vaccine is adequate. Specialists in at least one republic believe the quality is not good and the virus needs to be replaced.

At the present, only Russia has a national regulatory control system. An agreement was developed to ask Tarasevitch Institute to control quality for the other republics. The cost of the control testing would be added into the price of the vaccine. Tarasevitch may introduce an additional price to be paid directly by the republics and claims the cost for the control system has increased "1000 times".

Under the new proposal it would not be necessary to make individual contracts with the Tarasevitch Institute, only with the State Sanitary Epidemiological Commission of Russia. Kyrgyzstan agreed to this proposal.

If vaccine comes from suppliers other than the Russian producers, the republics can ask Tarasevitch to test it, but only for payment. Tarasevitch claims to be able to test all vaccines but there are no details as to which tests are performed and no one asked. Tarasevitch says it uses WHO standards but it has never given information about the results of tests it administers or what they are.

During this meeting, the republics made it clear that they are not satisfied with the conditions of transport from the Russian suppliers. Cold chain needs were discussed and the producers said they are working with the State Sanitary Inspection Committee of Russia to develop standards. One of the requirements will be to use thermal containers. Procedures will be developed to check the manufacturers' capacity to meet these requirements. The new regulations will be signed and adopted soon but the date when they will take effect has not been indicated because the system of delivery has not been worked out and they do not have enough containers. The republics, however, are pleased that the point is included in the regulations.

ANNEX 7

Draft Vaccine Procurement Manual Documents

Part I

Draft Vaccine Procurement Manual - *developed by PATH , D. Woodle author*

Part II

Sample Compliance Program - revised for EPI vaccines

EPI Vaccines - Tests on Final Product

Annex I - General Requirements for Manufacturing Establishments and
Control Laboratories - *World Health Organization*

General Requirements for the Sterility of Biological Substances
- *World Health Organization*

Biologics, <1041> - *U.S. Pharmacopoeia XXII*

General Biological Products Standards - *21 Code of Federal Regulations, Part 610*

BCG Vaccine Section

Sample Procurement Requirements - *developed by PATH, D. Woodle author*

UNICEF information on BCG Vaccine

U.S. Pharmacopoeia information on BCG Vaccine

*21 Code of Federal Regulations, Part 620, Subpart E -
Bacillus of Calmette and Guerin (BCG) Vaccine*

Annex 2, Requirements for Dried BCG Vaccine (Requirements for Biological
Substances No. 11) - *World Health Organization, 1985*

Annex 12, Requirements for Dried BCG Vaccine (Requirements for Biological
Substances No. 11) Amendment - *World Health Organization, 1987*

List of BCG Manufacturers (according to country) - *World Health Organization*

DPT Vaccine Section

Sample Procurement Requirements - *developed by PATH, D. Woodle author*

UNICEF information on DPT Vaccine

U.S. Pharmacopoeia information on DPT Vaccine

21 Code of Federal Regulations, Part 620, Subpart A - Pertussis Vaccine

ANNEX 8

SCOPE OF WORK"ESTABLISHING VACCINE PROCUREMENT MECHANISMS/FUNDING" ASSIGNMENT

- I. Develop a rational, phased delivery schedule that coordinates cold chain capacity with supply requirements. Note: This activity will be based on the prior collection, by other REACH consultants, of selected supply information.
- II. Develop budget estimates for vaccines and syringes; provide information on international sources of supply with contact information, lead time and estimated cost.
- III. Assess existing capabilities and mechanisms for both international and domestic procurement of vaccines. Note any major deficiencies and outline what would be needed to ensure smooth and effective procurement of vaccines and syringes at Republic level and Oblast level.
- IV. Define and investigate areas of potential difficulty related to international transaction such as licensing and regulatory issues, quality assurance issues, customs duty/clearance situation on imported vaccines, airport/port clearance procedures, and banking issues including foreign exchange and letter of credit transactions.
- V. Solicit information on areas of potential difficulty related to domestic transactions.
- VI. Where oblast-by-oblast procurement exists, explore the problems, benefits, and acceptability of consolidated procurement of vaccines and syringes.
- VII. Where consolidated procurement is already carried out or is an acceptable option, suggest a plan for procurement implementation to include criteria for the choice (or development) of a local procurement unit or agent. Suggest appropriate units or agent(s) for procurement responsibility based on assessment conducted under III above.
- VIII. Develop the Procurement Plan based on the most cost effective options.
- IX. Develop generic task lists and timelines for the activities needed to ensure delivery of vaccines and related commodities according to schedule. If international procurement will be necessary, provide information on international procurement procedures to those who have been selected to implement procurement.
- X. With special emphasis on procurement from CIS producers, provide sample specifications and contractual clauses designed to ensure delivery of high quality, safe and effective vaccines and related products. In addition to basic formulations, this material would include shelf life requirements, packaging, cold chain provisions, QA requirements and inspection and testing protocols as well as acceptance and payment criteria. (Note: Some of the information would be standard procurement guidelines which would need to be developed prior to arrival in country).

- XI. Address financing and financial issues - identify possible schemes and options for covering hard currency requirements. (Note: this would include in-country discussion followed by research on implementation and feasibility issues upon return to Seattle).
- XII. Provide trip report and documentation to REACH officer in charge of visit which includes (for each country):
- Phased syringe and vaccine delivery schedule
 - Budget estimate for vaccines and syringes showing expected source (CIS or external CIS)
 - Procurement Plan (to include suggested unit or agent for procurement)
 - Generic task list and timeline for activities needed to ensure delivery of vaccines and syringes/needles
 - Sample specifications and contractual clauses (formulation, expiration dates, packaging, cold chain provisions, QA requirements, acceptance and payment criteria).
 - prioritized schemes and options for covering hard currency requirements
- XIII. Provide technical input to REACH coordination with WHO, UNICEF and World Bank to identify feasible financing/ conversion options (throughout assignment and in Seattle).

ANNEX 9

Responsibility Flow Chart











