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**REACH**

RESOURCES  
FOR CHILD  
HEALTH

**SUMMARY REPORT ON  
EPI VACCINE ACQUISITION  
IN UZBEKISTAN, KYRGYZSTAN  
AND TURKMENISTAN**

**EMERGENCY CHILDHOOD  
IMMUNIZATION SUPPORT PROGRAM**

**OCTOBER 25 to NOVEMBER 30, 1992**



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## ACRONYMS

<b>EC</b>	<b>European Community</b>
<b>EPI</b>	<b>Expanded Program on Immunization</b>
<b>FSU</b>	<b>Former Soviet Union</b>
<b>GMP</b>	<b>Good Manufacturing Practice</b>
<b>JSI</b>	<b>John Snow, Inc.</b>
<b>MOH</b>	<b>Ministry of Health</b>
<b>REACH</b>	<b>Resources for Child Health</b>
<b>OPV</b>	<b>Oral Polio Vaccine</b>
<b>USAID</b>	<b>United States Agency for International Development</b>
<b>USD</b>	<b>United States Dollars</b>
<b>WHO</b>	<b>World Health Organization</b>

## INTRODUCTION

During November 1992 technical assistance was provided to the Central Asian Republics of Kyrgyzstan, Turkmenistan, and Uzbekistan aimed at assessing the current EPI vaccine supply situation and helping the republics to plan for future vaccine acquisitions. An attempt was made to answer the following questions about the 1993 EPI vaccine supply for each Republic visited: (1) what and how much do they need; (2) where will it come from; (3) what will it cost; (4) how will they pay for it; (5) how can they insure quality; and (6) what are the associated problems.

For the purpose of this report, EPI vaccines are Measles, Polio, BCG (TB), and DTP. Primary immunization targets the under-one age group but includes the first measles vaccination given to children at twelve months of age. All other EPI vaccinations are classified as boosters.

## SUMMARY CONCLUSIONS

The EPI programs in Kyrgyzstan, Turkmenistan, and Uzbekistan do not have access to a reliable supply of safe, effective vaccines in quantities adequate to fill their needs. Financial and supply 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 the 1993 requirements appear to be necessary to sustain the immunization programs in Kyrgyzstan, Turkmenistan, and Uzbekistan at an acceptable level. Shortages in the domestic supply of EPI vaccines are anticipated based on the 1992 performance of the Former Soviet Union (FSU) producers. Measles vaccine is expected to be in especially short supply with shortfall estimates from 60% to 80%. Sufficient 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."

Aside from donations, the only other viable option for covering anticipated 1993 domestic vaccine shortages in the three republics is by hard currency purchase from foreign sources and the EPI programs generally do not have the funds, the access to hard currency, or the expertise to pursue this avenue. 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 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 at the cost of Western vaccine.

In Turkmenistan and Uzbekistan there is virtually no hard currency available for purchase of foreign vaccines. Ruble transactions are not acceptable to Western manufacturers and 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 loan funds may be available in the spring of 1993, but the immunization program must compete with many other MOH needs.

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A substantial amount of hard currency has been made available to the three republics by the European Community (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 is a function that was formerly centered in Moscow. It is important to develop these international skills at the MOH level in each republic so there can be alternatives to the domestic vaccine producers when hard currency is available. Under the stress of foreign competition, FSU producers may be inclined to improve the quality of their vaccines and packaging rather than lose customers to Western suppliers. This concept was explained as a good example of how a free market economy works.

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

Key portions of the cold chain in Kyrgyzstan, Turkmenistan, and Uzbekistan, 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 an issue. 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. 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.

Central regulatory authority for licensing and control of biologics was previously handled in Moscow based on testing performed by the Tarasevitch Institute. Tarasevitch simply approved or disapproved the use of a specific batch; no certificate of analysis or other documentation was provided. Tarasevitch proposes to continue this function and has asked the republics to sign contracts to that effect.

## RECOMMENDATIONS

The following recommendations are seen as an opportunity for effective intervention and are directed toward the donor community at large.

1. Donate at least part of the 1993 EPI vaccines required by Kyrgyzstan, Turkmenistan, and Uzbekistan. 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 of age. Several possible options follow:
  - a. donate primary EPI vaccines necessary 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. donate all primary EPI vaccines;
  - c. donate primary and booster EPI vaccines necessary to cover the anticipated 1993 domestic producer shortfall; and
  - d. donate all primary and booster EPI vaccines.
2. Establish a donor financial reserve to provide emergency assistance in the event of an epidemic or unanticipated vaccine shortfall. An amount equal to 10% 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 a local donor 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 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, ice packs 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
- Good Manufacturing Practice (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
  - assistance with cold chain packing for vaccine transport 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 prepaid contracts with international third-party testing laboratories to monitor the quality of FSU 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 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.