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# **KYRGYZSTAN TB DRUG MANAGEMENT SYSTEM ASSESSMENT**

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**CENTRAL ASIA TB CONTROL PARTNERSHIP**

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## **EXECUTIVE SUMMARIES**

### **Purpose:**

Ralph Rack and Natalia Cebotarenco from JSI, and Mavlyuda Mahmudova, Regional Drug Specialist from Project HOPE and Jyldyz Ysykeeva, Drug Management Specialist from Project HOPE, Kyrgyzstan and Nurgul Asankadyrova from the National Tuberculosis Program carried out this assignment. Their work benefited greatly from the constant and highly effective support of the Ministry of Health's National TB Program and the Project HOPE country team.

The general objective was to assess the current state of TB drug management in Kyrgyzstan, with particular focus on drug management and logistics. The terms of reference intended that to the extent possible, the assessment was to be comprehensive, that is, attempting to cover the following topics: logistics management information systems (LMIS), product selection, forecasting, procurement, inventory control procedures, warehousing and storage, transport and distribution, organizational support, product use, and financing. The intention is that findings from this exercise will drive plans for upgrading drug management operations within the country.

### **BACKGROUND: Kyrgyzstan**

In May 2005 Project HOPE/ JSI carried out a two-week assessment of the supply chain and drug management practices of the National Tuberculosis Program of Kyrgyzstan. This initial assessment is the basis for determining a technical assistance program, in conjunction with Project HOPE and its partners, for ensuring the continuous availability of quality TB drugs for the National TB Program.

It is important to mention that the assessment was started initiated through meetings with high level decision makers such as officials from the Ministry of Health, Department for Drug provision and Medical Equipment of the MOH, National Center of Phthiology, as well with representatives of the Global Fund project and KFW that play the key role in the realization of the DOTS in Kyrgyzstan. In aiming to achieve a comprehensive view for the TB drug management the team visited different levels of TB drug supply chain: central, oblast, rayon.

The consultants must note frankly that the assessment was somewhat limited in geographical scope. As a result, two oblast TB centers, 2 dispensaries (TB facilities at city level for TB patient treatment) and 3 primary health care (PHC) facilities (for TB outpatient treatment) were visited. In addition, officials visited were very welcoming and open to discussion concerning the supply chain and its current strengths and weaknesses. One notable limitation was the cancellation of a visit at the Central Warehouse for the National TB Drug Supply Coordinator, scheduled for the first week of the assessment. This led to some uncertainty in the report of the details for forecasting and drug procurement.

The JSI-developed Logistics System Assessment Tool (LSAT) was used as a framework for the assessment in addition to a one day workshop with 14 participants. Actual interviews were

carried out without a formal questionnaire, but the questioning followed the general concept of the *draft Pharmacy and Supply Chain Management Assessment Tool*.

Numerous documents have been written about the National TB Program in Kyrgyzstan; this report is intended to focus on the supply chain and drug management aspects of TB treatment according to DOTS. Obviously, the supply chain interacts strongly with treatment and policy decisions of the program. As such, conclusions of this report, while focusing on supply chain issues, will acknowledge that supply chain decisions will take into account other important program issues, as well.

## **Key Findings:**

### **Introduction**

To achieve better health throughout Kyrgyzstan, the efforts to control TB, depends on political commitment from the government and support for the Internationally Accepted TB Treatment also known as DOTS (Directly Observed Treatment Short course) from health professionals. In this it is essential to develop a framework of drug policies and laws which uphold public commitment to essential drug supply (WHO) and thusly will complete the drug management cycle. Kyrgyzstan's policy and legal framework needs to define national goals for drug management. In this regard, it is important for those concerned with policymaking and the TB programme managers to participate in developing and advocating for pharmaceutical laws and regulations that promote the following:

1. The National Drug Policy (NDP) should have a TB component. The NDP should aim to achieve optimal availability and use of drugs for patients. The NDP should prioritize the supply of essential drugs for TB, and include comprehensive strategies to achieve their appropriate use, and be supported by legislation
2. The registration process or licensing of TB drugs should be enhanced. This should occur through the country's regulatory agency with authority to examine each drug's quality, safety, and efficacy. Drug registration prior to procurement is one way to ensure that drugs meet international quality standards (such as those established by WHO). Poor-quality drugs or drugs from unreliable manufacturers can jeopardize successful TB treatment. Drug quality assurance policies cover assessment of manufacture, importation, and distribution of drugs. They establish responsibility for monitoring drug quality, specify laboratories for drug testing, and establish formal systems for reporting product complaints. These regulations and quality standards assist in the procurement and distribution of reliable, high-quality TB drugs. Further to this, such policies generally define procurement methods, drug quality standards, price limits and distribution and storage guidelines for drugs approved for procurement.
3. For the rational use of TB drugs, drug policies and laws help toward guaranteeing that drugs will be used rationally i.e. appropriately, safely, and only when required. Such policies also serve to restrict adverse or confusing drug promotion, require training for public health providers, limit drug dispensing to trained persons, and help to encourage public education.

From an international perspective, having well-defined policies in place can put Kyrgyzstan in a better position to respond to global initiatives, as with the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM). In addition, a strong, supportive policy and legal framework coupled with a well conceived programmatic response based on the drug management cycle, is in a much better position to provide the GFATM with evidence of a Kyrgyzstan's national commitment and need.

The NTP should formalize itself with the May 2005 –“Guide to the Global Fund’s Policies on Procurement and Supply Management”. The aim of this guideline is to support the procurement of quality assured medicines and other health products in sufficient quantities, reduce cost inefficiencies, ensure the reliability and security of the distribution system, encourage appropriate use of health products, and continuously monitor and evaluate the procurement process.

## **Key Findings**

1. Central warehouse inventory records indicate a possible stock-out of two TB drugs in the third quarter of 2005. Communication with donors should occur as soon as possible to avoid any violation of recommended schemes and dosages of treatment as a result of a stock out.
2. There are discrepancies in such documents as the DOTS standard treatment guidelines, DOTS product registrations and the National Essential Drug List that undermine the long term sustainability of DOTS product selection decisions. Non-registration of donor supplied drugs could result in a situation where it is not possible to accept tenders in competitive procurements.
3. Overall, the distribution system is rational. However, the drug logistics management information system, as it currently functions, does not provide reliable data on consumption, losses and adjustments that can be used for procurement and distribution purposes.
4. Observations at the small sample of sites visited for this assessment suggest that there may be widespread problems related to rational drug use, such as prescribing mistakes, irregular drug intake, interruptions of treatment, incorrect dispensing and self administer treatment (drug intake without DOT).
- 5 In spite of the fact that DOTS covers the whole country there are a certain number of TB patients that cannot be counted according DOTS. The treatment for this category of patients is provided by the State and Local budget that is insufficient. In addition, ensuring the quality of the anti-tuberculosis drugs purchased with this budget is questionable.
- 6 In the structure of the National Centre of Phthisiology there is the Centre of Monitoring and Epidemiology whose primary responsibility is the coordination of drug management. The Oblast report quarterly addresses the TB drug consumption, stock on hand, and the needs for the next quarter based on the expected number of patients. In spite of this fact the amount of issued TB drugs from the central level to the Oblast does not comply with its requisitions.
- 7 Drugs in the Kyrgyzstan's MOH system are distributed through a network of warehouses and Oblast storerooms that varies from 2 to 4 tiers (levels). Both DOTS and non-DOTS TB drugs

move through this system. The distance between warehouse and the national TB hospital represents 2 tiers, between the central warehouse and the lowest level SDPs, 4 tiers.

The team gathered some information on how the distribution system works, but generally it is fragmented. There is some routine quarterly reporting of logistics information, at least between the Oblast and the central office; however, it is not clear what the reporting and/or delivery cycles are through the levels of the system.

8 Despite the current distribution system, there is still no means in place by which decision-makers can routinely monitor quantities of drugs in stock or consumption rates.

9 The NTP is currently wholly dependent on the Kreditanstalt fuer Wiederaufbau (KfW) for financing and procuring its DOTS drug supply. Procurement of non-DOTS drugs is decentralized to the oblast and rayon levels. While there is information available on TB drugs registered for use in Kyrgyzstan, little is known about what products are actually available in the retail sector.

## **Recommendations**

As part of an effective in-country sector wide approach, Kyrgyzstan's TB programme managers have the potential to build a sustainable drug management system in order to: avoid crises through effective political, financial, managerial and logistical planning; select TB drugs according to agreed treatment protocols or guidelines, and correctly qualify needs; secure sufficient resources to procure TB drugs effectively and efficiently; ensure a human resource base with the necessary skills, and the relevant protocols in place for distribution and inventory management; coordinate with health management systems set up to harmonize (coordinate) treatment, and develop a rational approach to using available TB drugs appropriately.

In addressing the above components, it is important to understand the role of each activity in the cycle. This is essential since any impediment to the drug management cycle that interrupts the patients' appropriate use of TB drugs, may lead to the failure of treatment and the consequence of promoting the spread of drug-resistant TB.

## **Product Selection**

The selection of the appropriate anti-tuberculosis drugs involves: reviewing prevalent health problems; identifying the best clinical treatments by adopting an evidence based medicine approach or using internationally accepted treatment protocols; selecting individual drugs, dosages, and dosage forms; and deciding where these drugs will be available within the health care system.

1. At the earliest possible moment, follow through with plans to have only one standard dosage scheme for dosing calculations in accords with the WHO 2003 publication entitled "Treatment Guidelines for National TB Program", (Table 4.1) to replace the current three different dosages schemes that exist now. Recognize that this important step will incur training and communication costs, especially in those oblasts and rayon levels in which the standard will be changing.

2. To ensure a continuous supply of anti-tuberculosis drugs, drug manufacturers must begin fast tracking submission of the documentation needed by Global Drug Facility (GDF) or IDA Foundation to the KR Drug Regulatory authority. It is vitally important, that all TB drugs must be registered in Kyrgyzstan. as soon as possible so procurement can be implemented within an agreed time frame.

3. When the dosage formulation changes for TB drugs it should be assured that all of the products appear on the National Essential Drug List

4. It is imperative that control be strengthened and mandatory registration of adverse reactions for TB Drugs at all levels. With the DOTS programs used for fixed dose combination there is a great need to enforce KR MOH Order #535 Pharmacovigilance. Post-marketing control of TB drug adverse reactions is critical to improving the quality of disease prevention services for the populations of the Kyrgyz Republic.

5. The NTP should included a pediatric formulations line for all TB drugs when forecasting for future

## **Procurement**

To procure high-quality anti-tuberculosis drugs requires various integrated strategies which include: quantifying drug requirements; ensuring available finance, selecting the procurement methodology; managing the purchasing or tendering process; establishing contract terms, assuring drug quality, and ensuring adherence to contract terms. All of these stages should be governed by a monitoring and evaluation process.

6. Project HOPE needs to work with the NTP to help them better understand the expectations and requirements of donors/investors such as GDF, and indeed the increasing regulatory and legislative requirements from many donors and stakeholders. Consideration should also be taken of WTO agreements and TRIPS (Trade Related Intellectual Property Rights). Fortunately all TB drugs are out of patent.

Examples include preparing GFATM applications, writing quarterly progress reports, TB Drug procurement forecasting procedures and related activities by utilizing proven quantification methodologies.

Project HOPE should also be prepared to extensively support them in these activities. With a view to developing capacity to deal independently with donors and financing bodies, continue to involve NTP staff in all activities.

7. The Thematic Working Groups (TWG) on DOTS and the Project HOPE team needs to work to ensure that the issue of long-term TB drug commodity security becomes a priority topic within its mandate. This will be a first step in working with the TWG to develop a long-term commodity security plan. In accords with KR MOH Order # 794, Point 3.2, December 1998 "On the Body regulating drug supply" needs to be amended to state that the NTP will be responsible

for the first-line TB drug supply and ensure essential drug reserves at health facilities. Currently, the only commodity security for ensuring TB drugs is a contract with the international donors.

8. Make an up to date estimate of the period of time for which the financing available from KfW and GFATM will finance a full supply of DOTS drugs and non-DOTS treatment. Illustratively this will require the following steps: Make a systematic review of all available data upon which needs quantifications can be based. Since the data currently supplied by the LMIS seems to represent an unknown proportion of all storage and rayon facilities, it should be used with greatest caution, if used at all. It is important to use case finding and treatment data plus assumptions for program expansion to create up-to- date projections of annual drug needs.

9. The National TB Program has several different schemes for TB drugs supply (donated drugs, the state budget and special account) which leads to double procurement of some items. All procurement should be coordinated with the NTP with a focus of purchasing only high quantity TB drugs with documented quantity analysis.

10. Work closely with donors and provide quarterly reports of TB drug stock status to better coordinate delivery schedules with donors and eliminate potential stock-outs.

11. When local procurement of TB drugs occurs, develop guidelines for the Tender Commissions to specify detailed requirements (i.e. drug analysis document) which the procurement specialist involved in the tenders can adhere and follow.

## **LMIS and Distribution**

Distribution is a critical part of the drug management process, and essentially describes the way in which the TB Program receives, transports, and stores their drugs. The distribution process includes clearing drugs through customs, transporting the drugs from a central point to stores and health facilities where they are dispensed, and the management of these stores and health facilities to adequately control and account for the stocks.

12. Work with the current LMIS forms and procedures and develop an improved design that will use reporting of logistics data and logistics system performance indicators to provide at rayon, oblast and national levels information that can be used for quantifying needs and monitoring product availability at all storage and clinical facilities.

13. Recognize that testing and implementing the new LMIS will require a substantial commitment of time and money for pilot testing and training, after the system design is approved

14. Review the policy of limiting safety stocks at primary health care Facilities, Rayon and Oblast levels. This may be sufficient in urban settings where polyclinics are geographically close to rayon dispensary store rooms, but remote sites should have safety stocks that are calculated on the basis of patient loads and delivery intervals.

15. The (NTP with assistance from Project HOPE) DOTS program needs to develop an LMIS and distribution system design that is suitable for DOTS system. The mapping will cover such points as how stock is received, stored, accounted for, issued and/or dispensed at all levels of the system. Details such as forms used, the timeline of reporting and distribution, and personnel resources should be covered.

16. After this work is complete, the country team, with support from the HOPE Regional Office, the Drug Management Coordinator for Kyrgyzstan, and JSI, should plan to organize an "LMIS and Distribution Design Workshop" to present, discuss, and develop suitable designs for these program components.

17. Document the current logistics management information system(s). This work needs to be based on interviews and observations at all levels of the system. It would not be surprising to find some variations in the way tasks are carried out, and the design efforts would benefit from incorporating the best ones.

18. On the basis of the information collected for the preceding point, hold a "design workshop" for developing and finalizing a logistics management information system to be used by all partners.

## **Product Use**

The use of distributed drugs at health facility level is part of the process of diagnosing, prescribing, labeling, repackaging, and dispensing drugs, and most importantly, securing the patient's adherence to drug treatment. Achieving rational drug use requires effective interventions, such as active use of standard treatment guidelines, training linked to improved drug supply, and guided discussions amongst both patients and providers.

19. Develop and implement a simple survey to verify and quantify the types of rational drug use problems known to be occurring. Prescribing that is incorrect as to categories and weight bands, and concerns that DOT may not be strictly observed does not insure efficacy of treatment. Such a study could be carried out through the existing monitoring and supervision system done by the TB specialist.

20. Consider changing the policy on migration of TB patients from the rayon to another level and include them in the count as patients treated under the DOTS program.

21. Insert exact daily dosages of TB Drugs into official TB -01 form which will act as a safety measure for alternative dispensers and therefore eliminating dosage errors.

22. Modify existing electronics TB surveillance software developed by CDC to include information on gaps in treatment, change in drugs and current drug therapy.

## **Long Term Vision**

Time is not far off when all stakeholders will be asking themselves how to guarantee the availability of DOTS drugs into the future in a changing environment in which, at the very least, donors will play a reduced role in drug financing. It is important to view both the current commitment by KFW and the Global Fund, working with USAID Central Asia TB Control Project, as assets whose availability provide an opportunity to plan for the security of the DOTS drug supply for the future.

This "commodity security" can only exist when the MOH and NTP have the capacity to independently manage the following activities:

- \* Know at all times through knowledgeable estimation what quantities of different drugs are required now and for several (five) years into the future.
- \* Have the capacity to independently manage drug procurements, whether by donation or purchase.
- \* Have capacities for storage and transport to assure the uninterrupted availability of drugs for clients at TB service delivery points (SDPs).

While it will take time to develop a credible and continuous commodity security strategy for national TB needs, the preparatory work should start now. Accordingly, some of the recommendations are for information gathering activities that will contribute to building this strategy.

The vision for the future should include implementation of recommendations based on the findings of field work, and capacity building using the DOTS Strategy to Control TB. As this strategy is part of a global standard recommended by the WHO, it should by design, include the strategy's five elements:

The Government of Kyrgyzstan's must make a commitment to a National TB Program; case detection by sputum smear microscopy among symptomatic patients who voluntarily report to health services (in contrast to detection through mass screening); a standardized treatment regimen of six to eight months for at least all patients with positive sputum smears, with directly observed therapy for at least the initial two months; a regular, uninterrupted supply of all essential TB drugs; and a standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control program's overall performance.

When used consistently, DOTS increases TB cure rates by 20 to 50 percent and decreases the proportion of patients who die by 10 to 30 percent. DOTS is also believed to prevent further emergence of drug-resistant strains of TB. The success of this strategy depends on direct

observation during the first two months that the patient takes the drugs to ensure that the patient follows the regimen. Treatment observations can be made by anyone who is willing, trained, responsible, acceptable to the patient, and accountable to those managing TB services.

It has been extensively documented that the main advantage of DOTS is that the patient does not bear sole responsibility for adhering to treatment. All government health care workers as well as the communities share responsibility and should if trained be able provide a range of the support services necessary for patients to continue and finish treatment. This is particularly important if treatments are being managed in prison communities, or other institutional settings.

The Kyrgyz Republic has been considering several additional measures that could have a positive impact on TB control: decriminalization of drug use to decrease overcrowding in prisons; decreasing the time in prison before sentence; and not permitting amnesty for prisoners with TB. What is also needed is a consistent treatment strategy to assure that prisoners released with TB have a specific facility to be treated and to receive social support. Long-term success in controlling TB in prisons may depend upon an approach that goes beyond the technical aspects of DOTS.

## **ASSESSMENT FINDINGS**

The ten topics listed in the TOR could not be explored in equal detail. Therefore, for this preliminary report, we have grouped the findings and recommendations under four major headings (functions) that summarize the drug management cycle. They are product selection, procurement, logistics management information systems (LMIS) and distribution, and product use.

The information summarized below is based on interviews and document reviews carried out at: National Centre of Phthisiology, Project HOPE Kyrgyzstan Office, Ministry of Health, Department of Drug Provision and Medical Equipment of MOH, GFATM office in Kyrgyzstan, CitiHope, International Pharmaceutical Benefit Initiative program, two oblast TB Centre, City TB Department of the territorial hospital, two Family Medical Centers and two Family Medical Groups, and all storerooms at the visited sites.

### **Product Selection**

Implementation of DOTS strategy in Kyrgyzstan started in 1995, with the opening of pilot sites in Issyk-Kul oblast. DOTS has been implemented in the entire country since 1996.

There was no Essential Drug List during Soviet times and drugs were freely available. The first Essential drug List was developed in 1996 based on WHO Model list. The Essential Drug Formulary was printed and distributed in 1998. EDL is revised every two years and the last version was adopted by the Government regulation KR # 312 from April 29, 2004 and includes 295 items.

Kyrgyzstan has adopted in 2002 Standard Treatment Guidelines for DOTS treatment of TB that conforms to WHO norms. According to government regulation KR #531 from 15.12.95 National Program “Tuberculosis - I” was adopted for the period from 1996 until 2000. According to government regulation KR# 263 from June 6, 2001 National Program “Tuberculosis –II” was adopted for the period from 2001 until 2005. This program was directed to the implementation of the DOTS strategy in the TB service of the republic.

Product selection should be based on WHO Guidelines for National Programmes (2003). The formulation from the Essential Drug List (2004) does not comply with the Treatment of Tuberculosis of WHO Guidelines for National Programmes (2003). TB drugs that are included in Essential Drug List (2004) are presented in the Table 1.

Table 1. TB drugs from Essential Drug List of Kyrgyzstan

Name	Form	Strength
Pyrazinamide*	Tab	500 mg**, 750 mg**
Isoniazid*	Tab	50 mg**, 100 mg, 150 mg**, 200 mg**, 300 mg,
	Amp	100 mg/ml-5 ml**
Ethambutol*	Tab	100 mg, 400 mg
	Caps	250 mg**
Rifampicin +Isoniazid*	Tab	150 mg+75mg; 150 mg+100 mg**, 300mg+150 mg, 450 mg+300 mg**
Rifampicin +Isoniazid+Pyrazinamide*	Tab	450 mg+ 300 mg+750mg**, 150 mg+400 mg+ 75 mg***
Rifampicin + Isoniazid+Pyrazinamide+Ethambutol*	Tab	450 mg+ 300 mg+750mg x 2+800 mg**, 150 mg+400 mg+ 75 mg+ 275 mg ***
Streptomycin	Powder for injection	0.5 g**, 1.0 g
Rifampicin	Caps, tab	100 mg** 150 mg, 300 mg, 450 mg**, 600mg**
	Gran for susp.	100 mg/5 ml**

\* - Drug primary used in specialized health facilities

\*\* - Not in accordance with WHO Guidelines for National Programmes (2003)

\*\*\* - These formulations are not properly formatted

As it is shown in the Table 1. Z, H, HR, E, HRZE are marked in EDL for use only in specialized health facilities. But the other two TB drugs S and R are unmarked. Pyrazinamide and HRZ strengths do not correspond to WHO Treatment of Tuberculosis of WHO Guidelines for National Programmes (2003). H, E, HR, HRZE, S and R are presented in both forms of the EDL in accordance with WHO Guidelines, but not the correct strength. Formulations such as H30R60, H60R60, H30R60Z150 for pediatric use, as well as H150R150 and H150R150Z500 are not included in EDL of Kyrgyzstan as it is required according to WHO Treatment of Tuberculosis of WHO Guidelines for National Programmes (2003). It should be mentioned that some formulations in EDL are not properly formatted (see Table1).

The main sources for TB drugs for the DOTS implementation in the country were drugs donated by KfW since 1998. The first shipment of FDC occurred in December 2004 from GDF. All donated products except 4FDC are manufactured by the SANAVITA in Germany. 4 FDC (HRZE) is produced by Macleods Pharmaceuticals LTD Mumbai, India.

Table 2. TB drugs donated by KFW

Name	Strength
Isoniazid	100 mg
	300 mg
Rifampicin	150 mg
	300 mg
Pyrazinamide	500 mg**
Ethambutol	400 mg
Streptomycin	1.0 g
Isoniazid +Rifampicin	100mg+150 mg**
Isoniazid+Rifampicin	30mg+60 mg
Isoniazid+Rifampicin	60mg+ 60 mg
Forkox N 672 (HRZE)	75 mg+ 150 mg+ 400mg + 275 mg
Forkox N 1000 (HRZE)	75 mg+ 150 mg+ 400mg + 275 mg

\*\* -Not in accordance with WHO Guidelines for National Programmes (2003)

Table 3. Registration status of the TB drugs supplied through KFW

Name	Strength	Registration status	Manufacture	Data of the registration
Isoniazid	100 mg	NO	SANAVITA, Germany	-
	300 mg	YES	SANAVITA, Germany	18.06.99 <sup>1</sup> # R99-191 0561
Rifampicin	150 mg	NO	SANAVITA, Germany	-
	300 mg	NO	SANAVITA, Germany	-
Pyrazinamide	500 mg**	YES	SANAVITA, Germany	N/A
Ethambutol	400 mg	YES	SANAVITA, Germany	03.07.98 <sup>1</sup> # P98 - 167 0138
Streptomycin	1.0 g	NO	SANAVITA, Germany	
Isoniazid+Rifampicin	100mg+150mg **	NO	SANAVITA, Germany	-
Isoniazid+Rifampicin	30mg+60mg	NO	SANAVITA, Germany	-
Isoniazid+Rifampicin	60mg+ 60mg	NO	SANAVITA, Germany	-
Forkox N 672 (HRZE)	75mg+150 mg+ 400mg+275 mg	YES	Macleods, Pharmaceuticals, LTD, India	2004 #N/A

Forkox N 1000 (HRZE)	75mg+150mg+ 400mg+275 mg	YES	Macleods, Pharmaceuticals, LTD, India	2004 # N/A
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\*\* -Not in accordance with WHO Guidelines for National Programmes (2003)

## Procurement

The National TB program has at least three different schemes for TB drug supply: donated TB drugs, the state budget, and special accounts (local enterprise). Since 1998, the National TB Program of Kyrgyzstan has received drugs from KfW. The Centre of Monitoring and Epidemiology of the National Centre of Phthisiology is primary responsible for forecasting and distribution. In spite of the fact that the number of new cases of TB patients is in accordance with forecasting there were stock outs of a few drugs at the time of the visit such as R300 and H300. One of explanations to the team was the fact that the reserve stock was done improperly. The coordinator of the Centre of Monitoring and Epidemiology told the team that they calculate the reserve stock for 6 months at the Central Level only. The State Budget scheme for the procurement is done both at the oblast and rayon level. The procurement occurs in a parallel system in discordance that leads to double procurements for the same items. The procurement of anti-TB drugs requires special knowledge and skills for the TB specialists at the oblast and rayon level. Even though large quantities of streptomycin were available at the central Warehouse, streptomycin was also procured by Chui oblast and Bishkek city due to lack of communication. For example, Isoniazid 300 was obtained by using three different schemes: the state budget, KfW and from the special account.

## Product Use

- During the sites visits approximately 30 patient treatments cards (TB-01) were randomly selected and reviewed. The team made the re-calculation of the prescribed dosage according to WHO Guidelines for National Programmes (2003). In 10 % of the cases treatments schemes were found to be overdoses of prescribed TB drugs. One of the reasons, was using old recommendations of WHO (1994) instead of the WHO Guidelines for National Programmes (2003). In the Family Medical Centers we discovered insufficient treatment schemes in adults because of the use of children's formulations (H60R60).
- Lot numbers did not corresponding to lot numbers of the product. In some places the lot number on the drug' bottle was did correspond to the register of the drugs in the ledger. In the storeroom of the NCPH TB drugs with different lot numbers were observed in a box with an external label showing only one lot number.
- Using of old labels in some TB drugs, e.g. HR100+150 is labeled as Isoeremfat.
- Shortage period of Donated drugs is covered by drugs procured from budget.
- Using wrong formulation (children's' only form for adult patients and opposite). Instead of using adult formulation in some polyclinics children's forms were used. But in the same time in some places the team was told that they do not have children's' forms and had to crush tablets from adults dosage forms. The team analyzed the report from the Bishkek city department. In children's department were used 13,000 tablets of H300 during the first quarter (2005) but in the same time no one pill from 100 received in

children strength H60R60. Moreover, the Children Hospital Number 1 in Bishkek returned 10,600 tablets of H60R60 to the storeroom in Bishkek TB dispensary.

- Substitute different sources for TB drugs: state budget, KfW and local enterprise. The TB drugs are bought by different sources: KfW, State budget and “special account” (financed from local enterprise).
- Rifampicin is freely available in the pharmacies; there is no restriction in dispensing of these drugs. Even more, Rifampicin is included in the National Guidelines for the treatment of brucellosis and can be prescribed by general practitioners.
- Products are not properly labeling. The packaging format and color looks very similar for all products which can lead to confusion for the dispensers.
- Drugs are not properly stored at the PHC level. At some PHCs nurses used bottles for TB drugs inside containers used for other drugs. No information about lot number or expire date was written on the label of the bottles.
- Strength and formulations are not identified in TB01 form Part C. Drug Dosage.
- There is no adequate supply of materials for Streptomycin injections. In all visited sites the supply of needles and syringes needed for Streptomycin injection were procured by the State budget only. There was a lack of reserve stock of needles and syringes at each health facility.

Improper dosing based on variations of three different schemes were observed. The schemes vary by weights.... In Chui they used two different tables for dosage calculations, one for five different weight bands and categories with a fixed strength. The second table contained milligram per kilogram for each TB drug. Then in Baligchi they used a table with a fixed quantity of tablets only, according to weight per category.

## **LMIS and Distribution**

### **Rayon and PHC level**

According the TB National Program the DOTS treatment starts with the intensive phase at the hospital level and then continues at the PHC level. The family doctor takes the responsibility for the DOTS treatment in the continuation phase in the Family Medical Group (the service delivery point). The PHC facilities have two forms: TB01 and a hand-drawn ledger for each patient. The TB01 form has been transferred from the hospital to the TB specialist of the Family Medical Centre or TB Control Centre (former TB dispenser). The TB specialist calculates the dose for the continuation phase. The Head Nurse of the TB Control Centre dispenses TB drugs to the nurse of Family Medical Centre. One Family Medical Centre unites from 5 to 8 Family Medical Groups. According the National Program “Manas -2” of the Health Care Reforms the main responsibility for the continuation phase of DOTS treatment is delegated to the Family Doctors at the PHC level. At the same time in the Family Medical Center in Bishkek there still exists the old system of dispensing TB drugs for the continuation phase through DOTS-room that serves TB patients for all Family Medical Groups. The head nurse of the Family Medical Center should have the identification documents and the ability to take the drugs from the TB storeroom. TB drugs are dispensed for the full course of the continuation phase for each patient.

The TB01 form specifies that the regimen to be followed by the patient. The first page of the hand-drawn ledger for each patient is completed by the TB specialist and contains the patient’s name, the treatment regimen with TB drug names and a lot number of each drug. The ledger has a column for each day of the month, a column for issued tablets for each day and for each

drug, and two columns for the nurse and patient signature. TB01 form is not sufficient and requires additional paper work before treatment will start.

### **Oblast level**

There is the system for quarterly TB drug supply from the Central level to the Oblast level based on the quarterly report. This quarterly report form includes a few tables with different information (expected number of patients for the next quarter, drug needs for next quarter, drugs needs for chemoprophylaxis, request for treatment and for chemoprophylaxis for the next quarter). It should be mentioned that this form is not an official document and is not approved by the Ministry of Health. The same form is used for the quarterly report from the rayon to the oblast level. Usually the Head Nurse from Family Medical Center or/and Head Nurse of the Rayon hospital TB department sends a monthly report about issued drugs and drug balance in their facility. The list of issued drugs of the NCPH is based on quarterly reports from the oblast. Although the quarterly reports are sent to the central level from the oblast regularly, the lead time for TB drugs varies depending upon many reasons such as of availability of transportation from rayon to oblast, and the time for the analyze of all oblast reports by the Centre for Monitoring and Epidemiology to be completed.

The team received the information that in some oblast there is the system for collecting the monthly and quarterly reports from the Family Medical Centers only, but in some places from the rayon hospitals additionally. This process leads to confusion in the LMIS system. CDC provided the computers and electronic programs that can be used for the TB drugs reports as well. At the present time the reports are sent using electronic format to the central level from the oblast level only. Because of the lack of access to the internet and trained personal at the rayon level the reports are stored in the computer and not transmitted to the central level. Summary reports are not accessible due to lack of software programming.

Although the Centre for Monitoring and Epidemiology of the NCPH collects quarterly, information on drug needs for the next quarter, with a buffer stock for 3 months of TB drugs, this buffer stock is not included into the final issued quantities. This means that important information for informed forecasting and procurement is available but the Central Level doesn't use it properly.

The oblast and rayon levels are taking responsibility for TB drug transportation from the highest to the lowest level. Most rayons and oblasts have transportation mainly by ambulance, though it has to serve multiple purposes and not wholly dedicated to drug supply, but they do not have special budget line for the transportation.

There are no unified stock keeping records for oblast and rayon levels approved by the Ministry of Health. Different hand-drawn ledgers with TB drugs records were observed in some TB health care facilities.

At the small number of storage and dispensing venues we visited, it appeared that stock accounting was carried out correctly.

## The Central Level

During the Assessment visit the team could not tour the Central Warehouse that is located in Bishkek. The official explanation was that the facility was blocked with new humanitarian aid. The assessment team did discuss with the Coordinator of the Center of Monitoring and Epidemiology of NCPH the situation with TB drugs at the Central Warehouse. Discussions about the Central Warehouse were conducted, but actual observations were not done. As it is shown on Table 4 at the time of the visit it was clear that the National TB Program will have the stock outs of Rifampicin 300 and Isoniazid 300. At the same time overstock of Streptomycin with an expiration date on June 2006 was noted. The director of the NCPH told the team that they recognized the problem of stock-outs for the third quarter of this year and see a few ways for a solution. Additional financial support from KfW, using a GFATM grant, can be used for organizing the local tender and the procurement of TB drugs based on the State budget.

Table 4. The stock level of TB drugs at the Central Warehouse on March 30, 2005

Drug name	Number of tab/vial in one bottle	Quantity on Hand in bottles
H100R150	100	25563
4FDC	692	1515
S 1000 mg	10	27180
R150	100	1894
R300	100	67
H100	100	1479
H300	100	51
E400	100	1218
Z500	100	3644

During the assessment visit the team raised the question of how to use the vast quantity of Streptomycin. One of the solutions given was for Streptomycin to be prescribed to 80% of patients of category I (instead of 20% according WHO recommendations), and to give Streptomycin to all patients with the chronic form of TB. In spite of the fact that at the Central Level there was a huge amount of Streptomycin, in Chui oblast and Bishkek TB City Dispenser this drug was again procured by the State budget. The explanation was given that the oblast and the city did not know the amount of Streptomycin at the Central level.

## **Summary**

### **Effective TB Drug Management**

In order to effectively manage TB drugs, public health policymakers, program managers and health care workers at all levels who confront the spread and persistence of TB must work to improve the supply and the use of essential TB drugs. This of course should take into consideration continuous efforts to minimize the costs of purchasing, distribution, and treatment. Using a strategic approach it is possible to prevent TB drug shortages, avoid many of the common problems in supply management, and help towards reducing sickness and death.

Again it has been documented by the WHO that through such measures as effective drug management, those charged with managing the programs can:

Often avoid crises through effective political, managerial, logistic, and financial planning; be in a position to select TB drugs according to treatment protocols and correctly quantified needs; secure sufficient resources to procure TB drugs effectively and efficiently; ensure sufficient staff skills and protocols for distribution and inventory management; coordinate with health management systems set up to harmonize (coordinate) treatment; and use available TB drugs appropriately.

With a proper understanding and application of the components of the drug management cycle it is possible to achieve an uninterrupted drug supply and thereby develop a systematic approach to improving the control and treatment of TB.

Based on the findings of this study it is both recommended and proposed that a strategic planning workshop be held covering all the components of the procurement and logistics cycle where all the essential elements can be discussed for working towards sustainability and the vision of a preferred future.

**List of interviewees for the TB drug assessment**  
**May 10-20, 2005**

<sup>1</sup>	<b>Organization</b>	<b>Name</b>	<b>Title</b>	<b>Contact</b>
1	Therapy and Disease Prevention Department under KR MOH	T.S. Kutukeev	Head of the DTPD MoH KR	+ 966 312 66 26 08; <a href="http://www.med.kg">http://www.med.kg</a>
2	Therapy and Disease Prevention Department under KR MOH	Kuhranova Elena Viktorovna	MOH TB Specialist	
3	National Center of Phthisiology	A. Sh. Alisherov	Director General of the NCPH	+966 312 47-09-25; fax: + 966 312 47-09-24; <a href="mailto:manumet@ktnet.kg">manumet@ktnet.kg</a>
4	Department for Drug Provision and Medical Equipment of KR MOH (DDP)	R.A. Kurmanov	Depute DG of DDP	+966 312 54 30 90; <a href="mailto:ddp@elcat.kg">ddp@elcat.kg</a> <a href="http://www.pharm.med.kg">http://www.pharm.med.kg</a>
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9	Chui oblast TB Hospital	B.R. Hamitov	Director	+966 312 590356
10	Chui oblast TB Hospital	K.S. Asankanova.	Drug Supply Coordinator	+966 312 590356
11	Tokmok PHC	B.A. Bolotbecov	Director	+966 312 6-18-93
12	Balykchi PHC	N.S. Musaeva	TB room, TB specialist	
13	Balykchi Territorial Hospital	Ch.A. Sarmanova	TB department Chief	
14	Bishkek city TB Control Center	M.M. Moydunova	Director	+966 312 664409

15	Bishkek city TB Control Center	T.N. Novoselova	Head of TB Monitoring Centre	+966 312 664409
16	Bishkek city TB Control Center	E.L.Pesina	Deputy Head Doctor, Therapeutic division, Drug Supply Coordinator	+966 312 664409
17	FMC #1	L.A.Smirnova	Deputy Head Doctor, Therapeutic division	
18	FMC #1	D.U.Manapova	TB specialist	
19	Bishkek Territorial MMIF	K.B.Mambetov	Deputy Director	+996 312 214957
20	Global Fund to Fight AIDS, TB, malaria/Kyrgyzstan	A.A. Khan	Project manager	+966 312 510337 <a href="mailto:Tbinstitute@infotel.kg">Tbinstitute@infotel.kg</a>
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