

**Rational Pharmaceutical Management Plus  
Global TB Drug Facility Monitoring Visit to Kenya: Trip Report**

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## **About RPM Plus**

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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## **Abstract**

The Global TB Drug Facility monitoring mission concluded that the Kenyan Government has made a serious commitment towards a well founded and better managed TB national program. The most important challenge is the implementation of a patient kit system. Although it may simplify the drug supply management, it is still necessary to formulate a comprehensive implementation plan. The monitoring visit report will be sent to the Technical Review Committee that will decide, based on this and other evidence, if the Government of Kenya will be granted the third and last disbursement of TB drugs for 2004/2005.

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## **Key Words**

Tuberculosis, Drugs, GDF

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## Acronyms

CDC	Center for Disease Control
FDC	Fixed Dose Combination
GDF	Global TB Drug Facility
GoK	Government of Kenya
KEMSA	Kenya Medical Supplies Agency
MSH	Management Sciences for Health
RPM Plus	Rational Pharmaceutical Management Plus
TB	Tuberculosis
TRC	Technical Review Committee
USAID	United States Agency for International Development
WHO	World Health Organization



## **Background**

The Global TB Drug Facility (GDF) is an initiative of the Stop TB Partnership to increase access to high-quality tuberculosis (TB) drugs. The aim of the GDF is to provide drugs for 10 million patients over the next five years and to treat 45 million patients over a 10-year period. The World Health Organization (WHO) has called for a commitment to this initiative of at least US\$ 250 million by 2005.

GDF support is provided in principle for a three year period, subject to availability of resources and satisfactory compliance with GDF conditions of support. The Government of Kenya was awarded a 3 year grant in 2001 and received its first disbursement of TB drugs in mid 2002. Each year of support is subject to annual assessments of program performance (including case finding and treatment outcomes), financing, and drug management. The first monitoring mission was conducted in conjunction with the Royal Dutch TB Institute (KNCV) in September 2002. Based on the mission report, and an independent audit thereof, the Technical Review Committee (TRC) of the GDF made a cautionary recommendation that Kenya was eligible for the 2<sup>nd</sup> year disbursement of TB drugs, with the third year disbursement for 2004 conditional on clear and verifiable progress on the part of the National TB Program towards addressing key weaknesses identified in relation to the GoK commitment to TB control and within the program itself.

Provision of drugs for 2004 is dependent partly on the monitoring visit that was coordinated with the National Tuberculosis Program. This document summarizes the findings of that mission conducted by the GDF Secretariat and Management Sciences for Health during January 19-23, 2004.

### **Purpose of Trip**

The monitoring team consisted of Robert Matiru, GDF Technical Officer; Thad Pennas, Advocacy Officer for the GDF/STP Partnership; and Edgar Barillas, MSH/ RPM Plus Senior Program Associate. The purpose of the monitoring visit was to assess:

- Adherence to GDF terms and conditions of support
- Program management (including case treatment outcomes) , financial management and drug management
- Drug needs for next year of GDF support
- Issues raised by the GDF Technical Review Committee (TRC) or during previous GDF visits

### **Scope of Work**

According to the terms of reference, as a member of the GDF monitoring team, Mr. Barillas was to:

- Brief senior USAID/government officials and other stakeholders on the role of the GDF
- Confirm fulfillment of the conditions for support from the GDF by accessing specific information requested by the Technical Review Committee

- Clarify the numbers of patients to treat, quantities and specifications of drugs required, and the preferred date of delivery
- Assess the current TB drug procurement and distribution system within the country and convey findings to relevant MSH technical staff
- Discuss with USAID / Kenya officials what options for a continuous supply of TB drugs after the termination of GDF support

## Activities

As a member of the RPM Plus GDF /TB team, Mr. Barillas participated in the following activities:

- **Brief national officials, donors/partners of the TB Program and other stakeholders on the role of the GDF:** The mission briefed the WHO Representative, the Director of Medical Services and representatives of various donors/partners agencies, including Dr. Bedan Gichanga, a USAID technical officer, on the role of the GDF and the objectives of the mission.
- **Confirm fulfillment of the conditions for support from the GDF by accessing specific information requested by the Technical Review Committee:** During the five-day mission the team was able to discuss the performance of the program with the NTP director, analyze the improvements in the distribution system with the director of JSI/Deliver project and the director of KEMSA, and explore the financial contributions to the program made by donors and other partners. The mission included visits to the central medical store–KEMSA–in Nairobi, the provincial store in Eldoret, the Kitale District Hospital, Alupe Provincial Store, Busia District Hospital, and at least two treatment centers. The interviews and observations allowed a comprehensive review of the performance of the TP program, particularly regarding the drug management component. The GDF in-country monitoring checklist (included in annex 2) provides details of these activities.
- **Clarify the numbers of patients to treat, quantities and specifications of drugs required, and the preferred date of delivery :** CDC has been supporting the NTP on the quantification of TB drugs. Their database includes epidemiological data, quantification of needs and financial information. The team worked with CDC consultant John Mansoer to specify the drug requirements. The conclusions (included in the monitoring visit report) are the following:
  - During 2003 the GoK provided (through regular fiscal budget or loans) 81% of the financial resources required for TB drugs.
  - With the 2003/2004 allotment the GoK will be covering virtually 100% of the new detected cases in categories I and III.
  - GDF grant for 2004 will be only required for:
    - Category II patients + Buffer Stock<sup>1</sup>
    - Treatment of nomadic population<sup>2</sup>

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<sup>1</sup> The NTP solicited a 100% buffer stock

<sup>2</sup> Nomadic population constitutes 10% of TB cases. Approximately 12,200 new cases in nomadic population are expected for the period July 2004 – June 2005. Because of their migration patterns (and consequently high default rate) they are treated as inpatients for 2 months. The regimens in use are: for new TB+ 2RHZE/2RHZ/3EH; for re-treatment (>15 y) 2 SRHZE/ 4RHZE.

- **Discuss with Kenya officials what options exist for a continuous supply of TB drugs after the termination of GDF support:** At the end of the mission, the team debriefed the WHO representative and the Health Minister. The team members shared the opinion that the performance of the NTP has improved since the last monitoring visit, and there is a serious financial commitment of the GoK to finance TB pharmaceuticals in the following years. Most likely the Technical Review Committee will approve the third disbursement of TB drugs as a complement to the important financial commitment made by the Kenyan Government for 2003/2004. For the financing of TB drugs during the following years, the GoK will also rely on other financial sources; the Global Drug Fund for AIDS, Tuberculosis and Malaria, has approved a grant for the country. Nevertheless, the GoK can still apply for a three year extension of the grant provided by GDF, but the application will take into consideration these additional financial sources, and the self-sustainability that the GDF promotes.

Other information discussed during the debriefing meetings is included in annex 2 (in-country monitoring checklist).

## **Collaborators and Partners**

Dr. Chacaya, the NTP Director, was a key player in the mission. He organized all the activities, including the field trip, and provided the necessary information. He accompanied the mission to the provinces and districts, allowing a continuous discussion and exchange of opinions during the field trip.

John Monsoer, CDC technical advisor for TB/ Leprosy Control in Kenya, provided valuable information regarding the situation of TB in Kenya, the availability of drugs and the quantification of needs. The database he uses is the most accurate source of information on these issues.

## **Adjustments to Planned Activities and/or Additional Activities**

The team participated in all the activities agreed and programmed by the NTP Director. No meeting was programmed with USAID officials because of a tight schedule of meetings and field visits. However, the USAID officer attending the initial briefing meeting—Dr. Bedan Gichanga—was informed about the background and objectives of the mission. The mission contacted Dr. Michael Thuo, MSH/RPM Plus Technical Advisor in Kenya to inform him of the outcomes of the mission.

## Next Steps

### Immediate Follow-up Activities

The Monitoring Mission report was finished and sent to the NTP on February 9, 2004. The Technical Review Committee will decide based upon the content on the report, if a *green light* is to be granted for the third disbursement of drugs to Kenya.

The mission also commented on two activities that deserve a close follow up by the NTP:

- The immediate procurement of Streptomycin (already at a critical level) to cover the needs of Category II patients.
- The preparation of a comprehensive plan to implement the patient kits system in Kenya. GDF will explore the possibility of providing technical assistance to the NTP before April 2004 in this area.

### Recommendations

The recommendations to the NTP are included in annex 2. Regarding TB drug management, the most important challenge during the following year is the implementation of the kits system. This activity deserves technical support from all partners, including RPM Plus, if it is solicited by the Kenyan Government. The participation of RPM Plus in the monitoring and evaluation will provide valuable lessons to other countries planning to implement TB patient kits.

### Agreement or Understandings with Counterparts

The overall impression of the mission is that the NTP has improved its performance during the last year, and most of the conditions for the last disbursement of drugs have been fulfilled. Now it is up to the TRC to make a final decision based on the monitoring mission report, and other sources of information.

The NTP and the national authorities agreed that the most important challenge is the kits management. GDF will consider a technical assistance mission to support the GoK in the preparatory phase of this process.

### Important Upcoming Activities or Benchmarks in Program

The monitoring mission report was finished and shared with the Kenyan authorities on February 9, 2004. The TRC will study the content of this report and decide in their next regular meeting about the clearance for the last disbursement. If the TRC gives a *green light*, the last shipment should arrive in Kenya before July 2004.

Around the same dates, a local provider will be delivering the first shipment of patient kits to the central warehouse (KEMSA). Before that date, a comprehensive plan for the implementation of the kits system should be completed (see proposed strategy in annex 2).

The expected delivery dates for other shipments are the following:

**Value and quantity of any pending TB drug deliveries from all sources**

<b>Drug</b>	<b>Source</b>	<b>Quantity</b>	<b>Value</b>	<b>Expected delivery date</b>
RHZ 120/50/300 mg	DARE	21,000,000	462,000	February / 04
Patient pack 4-FDC/2FDC	GoK	60,000	831,000	April/June 04
Patient pack 3-FDC/2FDC	GoK	40,000	441,600	April/June 04
Patient pack 4 FDC/2FDC	GF ATM	19,000		

## Annex 1: Monitoring Mission Schedule

January 19, 2004	
8:30	Briefing to WHO Representative
9:00	Briefing to the Director of Medical Services
9:30	NTP: Discuss program and issues related with the mission
11:15	JSI / Deliver Project – Steve Kinzette
12:00	Director of Kenya Medical Store –KEMSA-
14:00 – 16:00	NTP: Discuss program issues, drug requirements, review program reports
January 20, 2004	
9:00 – 11:00	Donors / Partners meeting
11:00 – 13:00	Discussion with NTP
14:30 – 16:30	Discussion with NTP
January 21, 2004	
7:30	Leave for the airport to Eldoret
8:30	Visit provincial KEMSA store in Eldoret
10:00	Depart for Kitale by road
11:30 – 13:00	Arrive at Kitale, visit the District Hospital
14:30 – 16:00	Visit 2 peripheral facilities
16:00	Depart to Kakamenga by road
17:30	Arrive at Kakamenga
January 22, 2004	
8:30	Visit Provincial Medical Officer West Province
9:00	Depart to Alupe Provincial Store
10:30	Arrive Alupe Provincial Store
11:30	Depart for Busia
12:00	Visit Busia District Hospital
14:30 16:00	Visit Nambale, Matiyo TB treatment centers
16:00	Check in Kisumo Airport
January 23, 2004	
9:00	Debriefing sessions Ministry of Health, Director of Medical Services
10:00	Debriefing WHO Representative
12:00	Collect additional information National TB Program



## **Annex 2: GDF In-Country Monitoring Checklist KENYA Year 2**

All recipients of GDF in-kind grants of first-line tuberculosis drugs agree, as a condition of support, to: *Regular assessments of program performance (including case finding & treatment outcomes), financing and drug management, to be carried out by an independent technical agency, with a complete assessment report provided to the GDF.*

This check-list will form the basis of the assessment report on the performance of GDF grantees within the *second year* of support. This report will be reviewed for completeness by an independent agent appointed by the GDF and then submitted to the Technical Review Committee, for review.

Country Visited:	<b>KENYA</b>	Date:	<b>19<sup>th</sup> – 23<sup>rd</sup> January 2004</b>
Data Collector(s) Name(s)	<b>(1) <u>Robert Matiru - GDF Secretariat</u></b> <b>(2) <u>Thaddeus Pennas – GDF Secretariat</u></b> <b>(3) <u>Edgar Barrillas – Management Sciences for Health</u></b> <b>(4) <u>Rene L’Herminez – KNCV<sup>3</sup></u></b>		
Team Leader’s Signature	_____		

***Note: To determine the best source of information for different questions in this checklist, ask the NTLP manager. If additional pages are needed for any section of this checklist please append to this document, clearly indicating the section number to which the additional page corresponds.***

### **CONTENTS**

- Main achievements and constraints/problems in the year of the monitoring visit
- National TB program management
- Financial management
- Port clearance
- Drug registration and quality
- Stock management
- TRC recommendations
- Recommendations from pre-delivery country visit

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<sup>3</sup> As excerpted from Progress Report 31 on the KNCV evaluation mission to Kenya, September 2003

- GDF request for next year
- Monitoring team feedback

## List of Abbreviations

AFB	Acid Fast Bacillus
AIDS	Acquired Immunodeficiency Syndrome
CCM	Country Coordination Mechanism
CDC	Centres of Disease Control and Prevention
CU	Central Unit
DARE	District AIDS and Reproductive Health project
DMS	Director of Medical Services
DOT	Direct Observed Treatment
DOTS	Direct Observed Treatment Short-course
DTLC	District Tuberculosis and Leprosy Co-ordinator
FDC	Fixed Dose Combination
FHI	Family Health International
GDF	Global Drug Facility
GFATM	Global Fund for AIDS, Tuberculosis and Malaria
GoK	Government of Kenya
HIV	Human Immunodeficiency Virus
JSI	John Snow Incorporation
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Agency
KNCV	Royal Netherlands Tuberculosis Association
MoH	Ministry of Health
NASCOP	National AIDS and STI Control Programme
NGO	Non-Governmental Organisation
NLTP	National Leprosy and Tuberculosis Programme
PMO	Provincial Medical Officer
PTLC	Provincial Tuberculosis and Leprosy Co-ordinator
TB	Tuberculosis
TBCTA	Tuberculosis Coalition for Technical Assistance
USAID	United States Agency for International Development
VCT	Voluntary counseling and testing
WHO	World Health Organization
E	ethambutol
H	isoniazid
R	rifampicin
S	streptomycin
Z	pyrazinamide

## **Main NTLP achievements and constraints in the year of the monitoring visit**

### **1. Main achievements<sup>4</sup>**

- a) Case detection continues to increase with 16% on annual basis, and case detection in Nairobi increased with 20%.
- b) The Central Reference Laboratory (CRL) has started culture and sensitivity testing and is now also involved in NLTP training and supervision activities. The appointment of a laboratory technician within the Central Unit (CU) of the NLTP has improved communication dramatically.
- c) Daily observation of treatment is being reintroduced and prioritised again, throughout the country.
- d) Treatment services are further decentralised especially in the large urban areas.
- e) Drug availability, distribution and monitoring of drug management has improved.
- f) The Government of Kenya has made a major contribution to the anti-TB drug supply of the country and with that fulfilled one of the critical criteria of GDF for the third year disbursement.
- g) Although progress is still slow, the appointment of a national TB-HIV co-ordinator has initiated several activities in the field of TB-HIV collaboration.
- h) A first draft of the national TB-HIV guidelines have been produced
- i) Even though the proposal to the GLC has been rejected, the initiative has triggered the NLTP and partners to critically evaluate the MDR problem and initiate some crucial improvements at the central reference laboratory.
- j) Routine supervision to the provinces and districts by a team of the CU has at last been initiated.
- k) An impressive amount of staff in the periphery has been trained. Additional staff have strengthened the capacity of the CU and the Nairobi team.

### **2. Main problems/constraints**

- a) **TB Drug Quality:** TB drugs supplied to Kenya are derived from a variety of sources (GDF, GoK, DARE and others) some of which are procured from suppliers who have not been pre-qualified by WHO as meeting *WHO and International Standards of Quality and Manufacturing Procedures*, raising concerns that sub-standard TB drugs may make their way in to the drug supply chain.
- b) **Pharmaceutical management:** The development of a central computerized database to track drug supply levels is a positive step forward in efficient pharmaceutical management. However, the system still relies on manual entry and tracking of drug shipments and deliveries. Manual entry and book keeping at the central KEMSA store is deficient with respect to entry and reconciliation of drug stock levels and can result in confusion between different drug formulations, missing entries and delays in accurate accounting.
- c) **Patient Kits:** The pending arrival of 100,000 TB patient kits does not yet benefit from a comprehensive plan for the introduction, distribution and storage of the kits.

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<sup>4</sup> As excerpted from Progress Report 31 on the KNCV evaluation mission to Kenya, September 2003

- d) **Emergency TB drug needs:** According to NLTP, the supply of Streptomycin is seriously low requiring the immediate procurement of 100,000 vials. A request has been made to the Government of Kenya to procure these vials as soon as possible.
- e) **TB-HIV Collaboration:** The establishment of effective TB-HIV collaboration within the routine public health services at district level to enable the program to test all TB patients for HIV and provide all HIV+ TB patients with ARV will be a challenge. The first draft of a TB-HIV guideline has been produced but needs urgent finalisation. The planned pilot study in Nakuru needs to be implemented if it still wants to function as a model set-up for 10 other districts, which will start similar initiatives as soon as GFATM funds become available.
- f) **MDR-TB:** A successful reapplication to the Greenlight Committee will require a considerable effort on the part of the NLTP, CRL and KEMRI to follow up on the necessary actions recommended in Annex 2 of the KNCV October 2003 Progress Report (31).

### National TB program management

3. **Has the annual WHO TB data collection form for 2002 been submitted to WHO?**  
YES  NO
4. **Collect the latest quarterly report on case findings and treatment outcomes of the NTLTP. Please provide comments on the data in these reports.<sup>5</sup>**

### *Case finding*

Case finding is reported quarterly by DTLCs, through the PTLCs, to the Central Unit. In the last decade, the number of reported TB cases has increased six-fold from 14,599 cases in 1992 to 82,114 cases in 2002. The 82,114 reported cases in 2002, is a 12% increase of TB compared to 2001. The number of sputum smear positive cases in 2002 was 34,337, an increase of 10% compared to the number of notified cases in 2001. Case Notification Rates (CNR) increased from 62/100,000 population for all forms of TB and 33/100,000 population for sputum smear-positive PTB cases in 1992 to 255/100,000 population and 109/100,000 population respectively in 2002.

Table 1: *Tuberculosis case-finding by province, average annual increase: 1997-2002*

Province	1997	1998	1999	2000	2001	2002	Average annual increase (%)
Nairobi	8,028	8,880	11,091	12,963	13,983	15,979	14
Central	3,723	4,642	5,301	5,387	5,906	7,075	13
Coast	4,849	6,099	7,195	7,714	8,305	9,313	13
Eastern	5,412	7,281	8,099	8,895	10,734	11,937	18
North Eastern	2,243	2,435	1,879	2,242	2,155	2,736	2
Nyanza	5,965	8,338	9,861	10,714	13,095	14,788	21
Rift Valley South	4,609	5,140	6,179	6,939	7,515	7,985	10
Rift Valley North	3,088	3,615	4,278	5,222	6,436	7,202	19

<sup>5</sup> As excerpted from Progress Report 31 on the KNCV evaluation mission to Kenya, September 2003

Western	2,114	2,956	3,803	4,083	4,888	5,099	20
<b>Kenya</b>	<b>40,031</b>	<b>49,413</b>	<b>57,686</b>	<b>64,159</b>	<b>73,017</b>	<b>82,114</b>	<b>15.5</b>

The table shows an overall average annual increase of cases of 15.5% during the past 5 years. For the provinces, the average annual increase ranges from 2% in North Eastern Province to 21% in Nyanza Province. The tempo of increase is not slowing down, and the rate of increase is still higher than expected from population data and the estimated impact of HIV, which indicates towards an increase of case detection, by the program. It is estimated that 50% of the estimated real incidence is being diagnosed and notified.

*This trend is continuing in 2003.* In the first 6 months 46,489 cases of tuberculosis were notified, an increase of >16% compared to the first half of 2002. The ratio sm+/sm- is stable around 1.1 and the percentage of extra-pulmonary TB, although with a lot of variation per province, is stable around 15%.

The number of re-treatments is increasing and is now >5% but the number of real relapses is still < 3% suggesting that the increase in re-treatments is most likely related to re-infection in HIV+ patients and not to the development of drug-resistance. The low percentage of treatment failure among all TB patients and the absence of treatment failures among re-treatment cases support this viewpoint.

### **The impact of HIV infection on case-finding**

A sentinel survey carried out in 1994 in 17 districts showed an HIV sera-prevalence among TB patients of between 11.8% and 79.6%. The average HIV sera-prevalence in TB cases was 40.7% for the 17 districts involved. It is estimated that HIV sero-prevalence among TB has increased to >60%, which need to be confirmed by ongoing and planned HIV sero-prevalence studies.

HIV prevalence among antenatal mothers has declined over the past three-four years indicating a levelling off or a decline of the HIV prevalence, which is currently estimated to be 10.5% among the adult population.

WHO estimates that the TB prevalence and incidence will still continue to grow although the rate of annual increase is expected to come down when HIV prevalence is declining?

### **TB-HIV surveillance**

To monitor the impact of HIV among TB patients especially in a time of changing epidemiological situation and the emergence of new TB-HIV strategies new surveillance activities are urgently needed.

**Recommendations** (As excerpted from Progress Report 31 on the KNCV evaluation mission to Kenya, September 2003).

- *It is recommended to develop and implement a more regular HIV surveillance among TB patients. The development of TB-HIV collaboration activities, which will be supported by a national TB-HIV strategy with guidelines, is a good opportunity to include detailed TB-HIV surveillance plan and activities. Part of the surveillance should now come from routine HIV testing of TB patients. Another part can still come from period anonymous testing of particular groups of TB patients.*
- *It is recommended to review the WHO/CDC guidelines on surveillance of HIV among TB patients by Erica Duffel et al.*

### **Laboratory services**

Diagnosis and treatment monitoring by smear microscopy are key components of DOTS and need to be strengthened under DOTS expansion. In March 2003, Dr. Armand van Deun and Mr. David Lawson

visited the program to assess the current tuberculosis laboratory network in Kenya. In general the supervision and quality assessment of NLTP laboratory services in Kenya has been weak. The laboratories are only supervised through the laboratory system and NLTP staff often do not have adequate capacity to supervise laboratory staff. Except for a few local initiatives, quality control of sputum examination is not in place. EQA was implemented in a few areas 5-6 years ago but was not well organised and collapsed in most places. Routine QC of central laboratory culture and sensitivity testing has never been in place.

The Central reference laboratory, situated underneath the KEMRI laboratory, under management of the National Public Health laboratories, has been out of function since 1997. A recent renovation (funded by FHI/USAID), the recent assessment visit by WHO experts and under-pressure of NLTP, which are urgently in need for a quality reference laboratory, has initiated the laboratory to start functioning again in April 2003.

The CRL has now been equipped with a BACTEC machine and two technologists attended a training course in South Africa to operate the BACTEC, which is now being used to process sputum samples from re-treatment cases in Nairobi.

The laboratory has cultured 800 sputum samples from Nairobi, 120 samples from Coast province and 80 from North Rift Valley since April-May. Both, BACTEC and the traditional LG method are being used. Other provinces have now also been requested to submit sputum samples of all re-treatment and failure cases to utilise the CRL maximum capacity.

Detailed results of these cultures and the DST are not yet available (At the time of the GDF mission in January 2004, this was still the case). The CRL has also established contact with the Supra-national Reference Laboratory in Brisbane Australia and are eagerly awaiting the results of the first batch of cultures (both Bactec and LG) that were sent for quality control.

In the meantime the CU has been strengthened with a laboratory technologist, Mr O.M. Njuguna who has commenced supervision in several provinces in collaboration with the head of the CRL, Mr. Mike Mayabi. Refresher training of laboratory staff has also taken off in several provinces and a team is now working on a draft of NLTP laboratory guidelines.

### Recommendations

- *CRL should finally agree with KEMRI and NLTP on specific role of CRL and means of collaboration and reporting. It is advised to keep research and routine operational activities (supervision, MDR surveillance, and training) separated which doesn't mean that CRL laboratory staff can't be engaged in research activities of KEMRI. KEMRI on the other hand should be able to access staff and equipment of CTR to be used in research activities.*
- *CRL should distribute universal bottles to all provinces. PTLC are requested to encourage sputum collection of all re-treatment and failure cases to be sent to CRL.*
- *Establish a continual supra national quality control with Mycobacterial Reference laboratory, Prince Charles Hospital, Brisbane in Australia.*
- *Analyse the results of the first culture and DST of samples of Nairobi, Mombasa and Rift Valley North. Reveal the number of samples received, number of samples cultured (per method), contamination rate per method, positivity rate per method and detailed drug resistance pattern of all DR cases*

- *Develop an annual plan of supervision and training of peripheral laboratories and develop a supervision/monitoring tool, which should assist NLTP/CRL to make an inventory of available services and quality. It is recommended to use the WHO guidelines on laboratory services and the WHO checklist for the assessment of laboratory services as a basis.*

### Monitoring and evaluation

*Supervision:* The arrival of three new staff members at the CU has created extra time and initiated the start of supervision of the provinces by a team of the CU.

Currently Mr. Pili Pili, Mr. Malusi and Mr. Njuguna form a well-balanced team (technical, laboratory and reporting specialists) that has already visited Central, Coast, Western, Eastern and part of Nairobi province looking at a wide range of issues.

Feedback of these visits was provided at the RTLC meeting in Thika on 30 September. Main problems identified were deficiencies in the registers, which ranged from missing the initial sputum entrée to missing treatment outcome results. In Molo 43/279=15.4% smears were not done, in Naivasha 64/211=30.3% smears were not done and in Mariakani only 25/114 smear positive sputum results had been checked at two months. Other places scored better.

In Nairobi one of the main problems is the start of treatment of patients without sputum examination. This mainly occurs in KNH and IDH. The more peripheral diagnostic units do make a serious attempt to examine three sputum samples.

The 11 Toyota Landcruisers, which arrived in the country in April have at last been cleared by customs and have now been distributed to the provinces. The number of motorcycles that fail to operate is increasing. The number that has been stolen has increased to four.

### Recommendations:

- *NLTP is advised to develop a supervision schedule for 2004 and to communicate this with the provinces. They are also advised to produce action point lists for every province that has been visited and provide regular feedback.*
- *The CU is advised to make an inventory of the current fleet of motorcycles and submit a request for new motorcycles to USAID and KNCV.*

*Recording and reporting system:* The excellent recording and reporting system is still maintained by Dr. Mansoer, an expatriate public health specialist contracted by CDC and partly attached to the CU. With regard to the sustainability of this system Mr. Paul Malusi, a health records and information officer was attracted to the CU in April this year. He will be responsible to maintain the current NLTP recording and reporting system. He is being introduced in data entrée and joins the CU supervision team with the specific task to check data collection and reporting in the periphery, to harmonise reporting and to provide on the spot training. He will also be responsible for drug and laboratory supply management and in this relation he has joint JSI teams checking distribution and stocks at the provincial and district warehouses. He will also participate in the coming IUATLD TB course in Arusha. Mr. Malusi is also involved in training, data entrée of several research projects and assists in routine work at the CU.

Recommendation:

- *The NLTP data should become available on a central server, which can be accessed by more computers at once.*
- *Investment should be made in “structural capital” i.e. back-ups of the data base, and guidelines to use and update it, manual of Standard Operating Procedures etc.*

***Treatment Outcomes<sup>6</sup>***

On the introduction of DOTS in the mid-nineties the NLTP policy was to provide Daily Observed Treatment during the intensive phase. In 1998-1999 however, the NLTP switched to weekly-observed treatment. Only those patients admitted for two months or more (incl. Manyattas), re-treatment patients and those who are a known risk to interrupt treatment are treated under observation by health staff on a daily basis during the intensive phase (hospitalised or ambulatory). The remaining patients in the intensive phase receive a one-week supply and swallow their daily dose self-administered or occasionally under observation of a guardian at home.

Following the recommendations of previous visits the program is now slowly returning to stricter DOT policies again. Where patients are able to attend nearby clinics on a daily basis, this is preferred especially in urban settings. In other cases, the process of appointing and educating treatment observers and the process of verifying daily treatment has improved.

In the meantime, cure - and treatment success rate, remain high. Of 15,084 new smear-positive cases enrolled on short-course chemotherapy (2SHRZ/6EH) in the first six months of 2002, 65% were declared cured, 80% completed treatment, only 0.3% failed, 5% died, 8 % defaulted and 7% were transferred to another region.

Of 1,269 previously treated smear-positive cases enrolled on short-course chemotherapy (2SHRZE/1HRZE/5HRE) in the first half year of 2002, 64% were confirmed cured, 76% completed treatment, 0.2% failed, 10% died, 7% defaulted and 7% were transferred.

Of 13,136 new smear-negative pulmonary TB cases enrolled on short-course chemotherapy (2HRZ/6EH) in the first half year of 2002, 75% completed treatment, 7% died, 11% defaulted and 7% was transferred.

Of 4,938 new extra-pulmonary cases enrolled on short-course chemotherapy (2HRZ/6EH) in the first half year of 2002, 74% completed treatment, 7% died, 11% defaulted and 8% was transferred.

The results of treatment at 4 months of 3,019 new smear-positive nomadic cases enrolled on short-course chemotherapy (2SHRZ/2HRZ/3EH) at Manyattas was even better. 83% was confirmed smear negative at four months, 90% completed treatment, 1% failed, 4% died, and 3% defaulted.

Treatment results of the cohorts of the last years are shown in Annex 8.

Recommendations:

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<sup>6</sup> As excerpted from Progress Report 31 on the KNCV evaluation mission to Kenya, September 2003

- *NLTP has been asked to analyse the treatment result of the different categories of re-treatment (relapse, return after default, failure, other) cases over the last two years to support the overall analysis of the drug-resistance situation in preparation of a new GLC proposal.*
- *NLTP should continue to emphasise DOT in the intensive phase.*

**5. What evidence is there that drugs provided by the NLTP are only used for people with TB?**

The only evidence assessed to this effect is as follows: (1) Documentation of drug distribution from the central to the peripheral levels following a bi-annual order cycle, was reviewed for completeness and accuracy, in two of Kenya's 10 provincial zones: North Rift Valley and Western Provinces (2) Physical stock counts were made at the central, provincial and district levels of North Rift and Western Province (3) Patients were interviewed about their consumption of TB drugs.

General: The TB program in Kenya is vertical: drugs are located in a separate cage in the central store (KEMSA), transported by JSI to provincial stores where the TB medicines are also stored in a separate space (at least in the visited sites). Finally the medicines are delivered to the district stores where the health services collect them. The drugs are dispensed by a nurse specifically assigned to the TB program. The monitoring mission found no evidence of leakages throughout this distribution chain. The team was assured by NLTP staff, that even Streptomycin was strictly used for TB patients in reference hospitals<sup>7</sup>.

**6. What evidence is there that TB drugs are provided free to TB patients?**

It is government policy in Kenya for TB drugs to be provided free-of-charge to all TB patients. This was confirmed by the NLTP manager and staff. Both health workers and patients<sup>8</sup> were interviewed and also confirmed the same. Sputum smear tests are free of charge in all the surveyed facilities, even in the not-for-profit hospital run by a religious mission, that the team visited<sup>9</sup>. Information was obtained through on-the-spot role playing and direct questioning.

Even though drugs are free for patients at the point of contact with the health service, patients in category II must visit the health facility daily for streptomycin injection. The cost of transportation may be as high as US \$ 2.00 daily<sup>10</sup>.

It has been necessary for the NLTP in 2003 to issue circulars to all the provinces/district DOT centres, re-emphasising that all TB services and drugs are to be provided free-of-charge to TB patients, following reports that in some health centres, individual health workers has been levying a fee on TB services provided to patients.

**7. What evidence is there that GDF drugs were only used in DOTS programmes?**

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<sup>7</sup> Streptomycin and rifampicin, as well as other TB drugs are available in private drugstores. This increases the risk of misuse and resistance. The prohibition of commercialization of these drugs in the private market may be considered by national authorities.

<sup>8</sup> Note: The patient interviews sought to obtain information on (1) patient knowledge of their disease and the type and duration of treatment they were receiving (2) whether they paid for the drugs and services they received.

<sup>9</sup> Kiminini Cottage Hospital

<sup>10</sup> Interview with two patients in Busia District Hospital

DOTS programme covers 100% of the population (considering the supervision at home by a family or community guardian, a valid version of the DOTS programme). Therefore, all drugs supplied by GDF are used in DOTS Programmes<sup>11</sup>.

**Financial management**

**8. Is there any evidence that GDF has displaced resources that would otherwise have been available from the government or other donors?**

No evidence to this effect was found. On the contrary, in relation to TB drug procurement, for 2003/2004 the GoK allocated 100 million Kenya shillings (Ksh) for the procurement of TB drugs. The government commitment for 2004/2005 and 2005/2006 is 130 million Ksh and 135 million Ksh, respectively.

- During 2003 the GoK provided (through regular fiscal budget or loans) 81% of the financial resources required for TB drugs.
- With the 2003/2004 allotment the GoK will be covering virtually 100% of the new detected cases in categories I and III.
- GDF grant for 2004 will only be required for:
  - Category II patients + Buffer Stock<sup>12</sup>
  - Treatment of nomadic population<sup>13</sup>

**(a) Proportion of TB funding from government**

Table 2: GOK Contributions to NTLP 2002-2004

Item	Contribution 2002 - 2003	Contribution 2003 - 2004
Salaries	<p><b>Direct:</b>            Program Doctors, PTLCs, DTLCs,            Laboratory technicians, Nurses, Other            staff: secretaries, clerks, drivers e.t.c            Total = Approx. <b>US\$ 5,000,000</b></p> <p><b>Indirect:</b>  <i>GOK pays salaries of Health workers            who are not program staff but discharge            service to TB patients during their daily</i></p>	<i>No significant change</i>

<sup>11</sup> This local version of the DOTS strategy is strictly followed by the personnel in the provinces that were visited.

<sup>12</sup> The NTP solicited a 100% buffer stock

<sup>13</sup> Nomadic population constitutes 10% of TB cases. Approximately 12,200 new cases in nomadic population are expected for the period July 2004 – June 2005. Because of their migration patterns (and consequently high default rate) they are treated as inpatients for 2 months. The regimens in use are: for new TB+ 2RHZE/2RHZ/3EH; for re-treatment (>15 y) 2 SRHZE/ 4RHZE.

	<i>work. The government is also responsible for consumables and the general health infrastructure. This government support to NLTP is difficult to quantify.</i>	
Drugs	<b>US\$ 942,733</b>	<b>US\$ 1,734,600</b>
Development budget: laboratory consumables, NLTP administrative costs e.t.c	Expenditure = Approx. <b>US\$ 70,000</b>	<i>No significant change</i>
Recurrent budget	Expenditure = Approx. <b>US\$ 8000</b>	<i>No significant change</i>

**(b) Proportion of TB funding from government vs. other sources**

**Table 3: GOK expenditure & budget vs. partners/donors expenditure and budget (2002 – 2005)**

Agency	Type of contribution	Expenditure (US\$) 2002-2003	Expenditure (US\$) 2003-2004	Budget (US\$) 2004-2005
Government of Kenya	Indirect and Direct support to NLTP: Infrastructure, salaries, drugs, development & recurrent budget	6,020,733	6,812,600	N/A
John Snow Inc.- DELIVER (USAID funded)	Direct support of the NLTP: transport, supervision and drug distribution by DELIVER. <sup>14</sup>	1,500,000		
Family Health International (USAID funded)	Indirect support through combined HIV/AIDS and TB program activities in urban TB initiatives in Nairobi, Mombasa, Kakamega and Nakuru.	3,600,000		

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<sup>14</sup> See Annex 7 for organogram of distribution system

CDC-Atlanta	Direct support of core NTLP activities, HIV- TB, TB in urban slums and Prisons, PPM, laboratory equipment, recording and reporting & operational research	6,00,000	750,000 <sup>15</sup>	800,000
WHO	Capacity building, Advocacy and communications, TB-HIV collaboration, Community TB care, Technical support.	Unavailable	210,000	511,860 <sup>16</sup>
World Bank	Multi-lateral through Decentralisation of AIDS/HIV and Reproductive Health (DARE) Project: Anti- TB drugs to NLTP	Included as GOK contribution above <sup>17</sup>		
Malteser	Support laboratory services, Urban TB control, Community based DOTS initiatives, TB-HIV collaboration.	63,000	252,000	252,000
CIDA/KNCV	Direct support of core NTLP activities such as provision of transport, laboratory supplies, capacity building and technical assistance	810,000	578,000 <sup>18</sup>	614,000
GDF	Anti- TB drugs, technical assistance, monitoring and evaluation	223,949	434,879	388,000
GFATM*	Development and implementation of joint TB and HIV/AIDS program activities, Urban TB control, DOTS expansion in difficult to reach areas, implementation of the national COMBI plan, anti-TB drugs	N/A	1,949,330	1,883,344

\* New donor since last monitoring visit

Other Partner support:

- AMREF (Assist with TB control among urban & nomadic populations)
- MSF (Technical advice on quality assurance, support for TB initiatives within context of HIV)

### Port clearance

#### **9. Report the port clearance time for the last GDF drug shipment:**

<sup>15</sup> Of which US\$ 500,000 is a carry over from 2002-2003. CDC is concerned about absorption capacity of the NLTP of its funding.

<sup>16</sup> This is the approved budget for the biennium. Planned costs are actually US\$ 817,000 representing a budget gap of US\$ 305,440

<sup>17</sup> The final installment of the 45,000,000 tablets of RHZ committed by WB through the DARE project over 4 years starting 2001 i.e. 21,000,000 tablets recently arrived in Kenya for use in 2004/2005

<sup>18</sup> Budget

GDF TB drugs for the second year of support arrived in two consignments and were cleared as follows:

<i>Consignment</i>	<i>TB Drug (s)</i>	<i>Date of arrival</i>	<i>Date delivered to Central Store</i>	<i>Clearance time</i>
1	<ul style="list-style-type: none"> <li>• Streptomycin 0.75g</li> <li>• Water for injection, 5ml</li> </ul>	03.06.03	04.06.03	1 day
2	<ul style="list-style-type: none"> <li>• R150/H75</li> <li>• E400/H150</li> <li>• E400</li> </ul>	28.07.03	29.07.03	1 day

Source: Dr. John Mansoer (CDC/NLTP)

- 10. Is there evidence that the government took full responsibility for any import duties and taxes levied on drugs supplied by the GDF?**  
 YES  NO

**Drug registration and quality**

- 11. Did all the drugs provided by the GDF meet all national drug registration requirements?** YES

- 12. Does the government carry out quality control of drugs used in the NTLP?**  
 YES  NO

Routine quality control of imported TB drugs is not carried out.

**Recommendation on implementation of a quality assurance program:**

*There are limited national resources for post-marketing surveillance; therefore a quality assurance program should be based on the pre-qualification of the manufacturers. GoK/NLTP should restrict future tenders, to suppliers on the WHO list of pre-qualified products and manufacturers.*

**Stock Management**

- 13. Total stocks at national level (Note: As reported by NTP/CDC)**

**Table 4: Total Estimated Stocks in-Country as of December 2003**

<b>Product</b>	<b>Quantity (tablets/vials)</b>
Streptomycin 0.75g	238,094
R120/H50/Z300	10,899,700
R150/H75	2,343,300
E400/H150	40,185,740
E400	6,246,800

Source: Data provided by NTP/CDC

**Table 5: Total Stock at Central Level (KEMSA Central store) as of December 2003**

Product	Quantity (tablets/vials)
Streptomycin 0.75g	70,500
R120/H50/Z300	253,000
R150/H75	150,000
E400/H150	20,137,000
E400	655,000

Source: Data provided by NTP/CDC

**Please provide data on the consumption of drugs if available :**

**Table 6: Distribution of TB from KEMSA Store Drugs - 3rd & 4th Quarters, 2003**

Commodity	Unit Pack	Beginning Balance	Receipts	Stock on Hand	Distribution to regions	Balance (end 4th quarter/03)	Physical Count (KEMSA Nairobi)
Streptomycin Injection, 750 Mg	Vials	0	400,000	400,000	310,500	89,500	70,500
Water for Injection	Vials	14,000	430,000	444,000	373,500	70,500	37,500
R/H/Z 120/50/30 mg Tablets Rifampicin/Isoniazid/Pyrazinamide	Tablets	3,958,000	0	3,958,000	3,685,000	273,000	235,000
Rifampicin/Isoniazide R/Z 150/75 mg	Tablets	42,000	2,200,000	2,242,000	2,339,000	-97,000	150,000
Ethambutol/Isoniazide E/H 400/150 mg	Tablets	126,000	31,873,000	31,999,000	12,596,000	19,403,000	20,137,000
Ethambutol Tablets, 400mg	Tablets	5,029,000	1,350,000	6,379,000	5,976,000	403,000	559,200

Source: Data provided by NTP/CDC

**14. Were any TB drugs out of stock<sup>19</sup> in MoH national stores during the last 12 months? YES**  
 NO

- There were no stock-outs during the last 12 months in the health facilities that were visited. Reportedly no patient interrupted or received incomplete treatment during that period. However, the mission team found TB drugs out-of-stock (RHZ x 30 days) in 1 district store (Musir) because all the remaining stock was recently delivered to peripheral health facilities.
- There is no explicit security stock (buffer) in provincial or district stores/health facilities; therefore there is a latent risk of stock outs.

<sup>19</sup> Time out of stock, or stock-out time, is defined as the number of days that a product was not present in a warehouse or health facility over a recent 12-month period (usually the 12 months preceding the one during which the monitoring takes place). To be considered a stock-out, there must have been none of an unexpired drug in stock. If even small quantities of an unexpired drug were present, the drug should be counted as in stock. Percentage of time out of stock is defined as the percentage of days during a 12-month period that a drug has been out of stock (based on inventory records).

**15. Did you find any expired TB drugs in the MoH national stores at the time of your visit?**

YES  NO

**16. Indicate the value and quantity of any pending TB drug deliveries from all sources, by source (donor, government procurement e.t.c) expected to be received in-country over the next 6 months.**

**Table 7: Value and quantity of any pending TB drug deliveries from all sources**

<b>Drug</b>	<b>Source</b>	<b>Quantity</b>	<b>Value (US\$)</b>	<b>Expected delivery date</b>
RHZ 120/50/300 mg	DARE	21,000,000	462,000	February 04
Patient kit 4-FDC/2FDC	GoK	60,000	831,000	June 04
Patient kit 3-FDC/2FDC	GoK	40,000	441,600	June 04
Patient pack 4 FDC/2FDC	GFATM	19,000	Unknown	Unknown

**17. Are the standard treatment guidelines for TB drugs comparable to the DOTS guidelines?**

YES  AND NO  See Sections 21 & 22 for details.

The treatment regimens used for the majority of patients (non-nomadic) are:

Category I: 2RHZE/6HE

Category II: 2SRHZE/1RHZE/5RHE

Category III: 2RHZ/6HE (< 15 years: 2RHZ/4RH)

*Note:* However, the RHZ used: R120/H50/Z300, does not conform to WHO specifications (R150/H75/Z400). The last DARE consignment of 21,000,000 tablets of RHZ will be used up 2004/2005 to treat Cat. III patients and in Cats. I & III of the nomadic regimens (see sections 21 & 22 of this report for details).

***Technical review committee (TRC) recommendations***

**18. There were TRC recommendations for follow up: YES  NO**

**Table 8: TRC recommendations and action taken**

<b><i>Recommendation</i></b>	<b><i>Action Taken &amp; Results</i></b>
1. Details of the existing drug management and distribution system of the NLTP should be provided to GDF.	An organogram on the drug management/distribution system for TB and other essential drugs, was provided to the GDF team during the 2 <sup>nd</sup> monitoring mission (see Annex 7). The NTLTP Programme Manual is currently being updated and will have a section dedicated to Drug Management procedures/protocols covering the NLTP, including the logistics requirements for the delivery and use of the TB patient kits. (Final document expected by June 2004).
2. TB drug support to Kenya from different sources (in-kind or monetary) should be closely coordinated so as to ensure that a standardized, full course of treatment is provided for patients in each category of treatment, preferably conforming with GDF packaging and formulations.	Deliveries of GDF, GOK (including DARE RHZ) were closely coordinated, with the GoK-procured drugs arriving in: March, May and June 2003, DARE drugs in Feb. and GDF drugs in June/July 2003. The quantities and formulations were calculated during the previous mission to complement each other to ensure full treatments and minimize wastage.
3. GOK/MOH should establish a separate, realistic, budget line for TB drugs.	A budget line was established for 3 years – 100m Ksh for 2003/2004, 130m Ksh for 2004/2005 and 135m Ksh for 2005/2006
4. Direct observation of treatment, monitoring of treatment, and reporting procedures, should be applied consistently across the country by the NLTP as per WHO/IUATLD standard recommendations.	Following the recommendations of previous GDF/KNCV visits, the program is now slowly returning to stricter DOT policies. <sup>20</sup> Where patients are able to attend nearby clinics on a daily basis, this is preferred especially in urban settings. In other cases, the process of appointing and educating treatment observers and the process of verifying daily treatment has improved. Monies have been committed by GFATM, WHO and CDC to introduce community-based DOTS first to 9 districts (as per original WHO plan) and then as many other districts as the resources and district-specific enabling environments <sup>21</sup> allow (GFATM & CDC). However, introduction of CB DOTS will require continued improvement of supervision, which is constrained by lack of human resources to supervise below district level at divisional and locational levels.
5. A feasible plan to address the deteriorating TB control services in Nairobi Province should be developed and implemented urgently.	With the appointment of additional staff and improved collaboration between the different partners, DOTS activities in Nairobi are improving. Expansion of diagnostic and treatment services is ongoing. The City Council, FHI (supported by USAID), Malteser and AMREF are the most important and active partners, which meet each other regularly in the Nairobi TB Steering Committee. It is anticipated that the GFATM funds will be available soon, which should initiate additional activities in the field of training, supervision etc. The association of Chest Physicians and Private Sector Doctors has increased support for DOTS in Nairobi via running private sector

<sup>20</sup> As noted earlier in this report, previous policy has been: weekly-observed treatment. Only those patients admitted for two months or more (incl. Manyattas), re-treatment patients and those who are a known risk to interrupt treatment are treated under observation by health staff on a daily basis during the intensive phase (hospitalised or ambulatory). The remaining patients in the intensive phase receive a one-week supply and swallow their daily dose self-administered or occasionally under observation of a guardian at home.

<sup>21</sup> NGOs, faith-based and community-base organizations, population size of district e.t.c

	DOTS centres (patients pay up-front). Case detection remains low, however, in the first six months in 2003, a total of 8791 TB patients (sm +ve/-ve ratio 1.1) were diagnosed, which is a 20% increment compared to last year.
6. National AIDS & STIs Control Programme (NAS COP) and the NLTP should collaborate closely in addressing the dual epidemics of TB and HIV.	Although progress is still slow, the appointment of a national TB-HIV co-ordinator has initiated several activities in the field of TB-HIV collaboration. Further implementation is expected to begin with the release of GFATM funds. A first draft of the national TB-HIV guidelines has been produced.
7. The NLTP should urgently identify and address the causes of the reportedly low proportions of diagnostic confirmations with smear examination, low case detection of symptomatic in general health facilities and poor provision of smear microscopy services.	The CRL has started culture and sensitivity testing and is now also involved in NLTP training and supervision activities. The appointment of a laboratory technician within the CU of the NLTP has improved communication dramatically. Routine supervision to the provinces and districts by a team of the CU has now been initiated with the arrival of three new staff members at the CU. In Nairobi the problem of starting treatment of patients without sputum examination continues, mainly at KNH and IDH.

**19. Please review the recommendations made during the pre-delivery country visit using the country visit attachment to this checklist; write below the recommendations and the progress/expectations made by the NLTP/government for fulfilling them.**

**Table 9: 1<sup>st</sup> Monitoring mission recommendations and action taken**

<b>Recommendation to MoH:</b>	<b>Action Taken &amp; Results</b>
<i>NLTP should develop and implement a specific plan of action for Nairobi addressing key areas such as decentralisation of diagnostic and treatment services, supervision and monitoring, private sector involvement, integration of joint HIV-TB activities and re-establishment of supervised treatment.</i>	<i>Recommendation 5 of TRC, Table 8, p. 15, similar. See action taken previous page of this report.</i>
<i>NLTP should develop uniform guidelines on monitoring patient compliance during the intensive phase of treatment.</i>	<i>Recommendation 4 of TRC, Table 8, p. 15, similar. See action taken previous page of this report.</i>
<i>NLTP should develop mechanisms to monitor the quality of the quarterly reports of District TB and Leprosy Co-ordinators (DTLC) and Provincial TB &amp; Leprosy Co-ordinators (PTLC) E.g. PTLCs should verify quarterly reports with data from the district registers routinely during their quarterly meetings.</i>	A joint meeting of CU, PTLCs and DTLCs is planned for March 2004 to address this issue (this is the first time DTLCs will be involved in these joint meetings).
NLTP should develop tools to verify drug distribution with expected drug consumption based on patient data at the district level.	<i>A computerized inventory control management system is due to be completed at central level in Feb. 04, after which training of provincial staff will begin to allow installation of computers at provincial level that are linked to the central database. In addition, new commodities data collection forms are due to be introduced at the provincial and district levels allowing PTLCs and DTLS to “pull” drug needs from central level. Training will begin in Feb. 04 and be phased in by province.</i>
<i>The NLTP should finalise the current MDR surveillance</i>	<i>The drug-resistance survey was completed in September 2002. The</i>

<b>Recommendation to MoH:</b>	<b>Action Taken &amp; Results</b>
<i>exercise. An additional analysis of the extent of a possible “MDR problem” in Nairobi, through verifying re-treatment classification and the presence of MDR proof, could be useful.</i>	<i>results have not been published. A joint effort of NLTP, KEMRI and CDC, partly funded by CIDA, resulted in the collection of 1088 samples, reading of 2199 smears and preparations of 2109 cultures. The first cultures have been tested for drug sensitivity but the final results are still not available. Internal prioritisation has shifted attention from finalising this survey to other activities at KEMRI. The survey data form an important basis of the planned reapplication to the GLC.</i>
<i>The NLTP should develop a Quality Assessment system for sputum smear examination in collaboration with the newly established reference laboratory.</i>	<i>The CRL was renovated with FHI/USAID funds and started functioning again in April 2003 after almost 6 years of inactivity. The CRL is now equipped with a BACTEC machine and two technologists have been trained to use it. The laboratory cultured 800 sputum samples from Nairobi, 120 samples from Coast province and 80 from North Rift Valley April-May 2003 but the results have not yet been analysed. Other provinces have now also been requested to submit sputum samples of all re-treatment and failure cases to utilise the CRL maximum capacity. The CRL has also established contact with the Supra-national Reference Laboratory in Brisbane, Australia and are eagerly awaiting the results of the first batch of cultures (both Bactec and LG) that were sent for quality control.</i> <i>The KNCV monitoring mission of Sept. 2003 has recommended that an annual plan of supervision and training of peripheral laboratories is developed together with a supervision/monitoring tool, which should assist NLTP/CRL to make an inventory of available services and quality. It was also recommended that NLTP use the WHO guidelines on laboratory services and the WHO checklist for the assessment of laboratory services as a basis.</i>
<i>PTLCs should verify the actual physical stock in provincial stores with the stock recorded in the store registers prior to submitting their bi-annual stock reports to the central level.</i>	<i>This issue will be addressed again at the joint CU, PTLC, DTLC meeting in March 2004.</i>
<i>GOK/MOH should establish a separate, realistic, budget line for TB drugs.</i>	<i>Recommendation 3 of TRC, Table 8, p. 15, similar. See action taken previous page of this report.</i>

## 21. GDF request for next year

Year: 2004/2005

Date drugs required:

July 2004

**Table 10:** Estimates of patients to be treated with GDF drugs

(a) Non-Nomadic

Category	Regimen	Total estimated cases to be treated with DOTS <sup>22</sup>	Estimated cases to be treated with GDF drugs
1	2(RHZE)/6(EH)	43919	0

<sup>22</sup> Based on 2002 case-finding reports.

<b>2</b>	2S(RHZE)/1(RHZE)/5(RH)E	7686	7686
<b>3 &gt; 15yrs</b>	2(RHZ)/6(EH)	48300	48300*
<b>3 &lt; 15yrs</b>	2(RHZ)/4(RH)	9893	9893*
<b>TOTAL</b>		<b>109798</b>	<b>65879</b>

\*GDF supplies of EH and RH provided in 2002 will contribute to treatment in the continuation phase of Cat. III for adults and children. Once the GoK procured Cat. III kits are phased in, GDF supplies will no longer be required for Cat. III adults.

(b) Nomadic (Manyatta)

Category	Regimen	Total estimated cases to be treated with DOTS <sup>23</sup>	Estimated cases to be treated with GDF drugs**
<b>1</b>	2(RHZE)/2(RHZ)/3(EH)	4880	4880
<b>2</b>	2S(RHZE)/4(RHZE)	854	854
<b>3 &gt; 15yrs</b>	2(RHZE)/3(EH)/3(EH)	4656	4656
<b>3 &lt; 15yrs</b>	2(RHZ)/2(RH)/2(RH)	1810	1810
<b>TOTAL</b>		<b>12200</b>	<b>12200</b>

\*\*GDF will supply some of the TB drugs required for all these regimens in 2004/2005 i.e.: (RHZE), Streptomycin, and R150/H75

Plan for use of existing drug stocks/pending drug deliveries:

From July 2004 GoK procured patient kits will be used entirely for Cat. I.

Existing stocks of RHZ and EH will be used for treatment of:

- Nomadic Cat. I & III (<15yrs.)
- Non-nomadic Cat. III

The stocks will first be assigned to Nomadics and <15yrs Non-nomadics, with the remaining difference assigned to Non-nomadics (covering approx. ¼ of annual need in case of RHZ). The ¾ proportion of Cat. III Non-nomadic patients not treated with (RHZ) and (EH) will be covered by the GoK-procured Cat. III patients kits.

The above plan of action will allow use of existing stocks with minimum wastage, although large stocks of (EH) will still remain due to non-usage of EH procured for non-nomadic cases 2003/2004: approx. 25% (See Annex 8 for details).

*22. Calculation of drug needs - GDF Supply*

At the time of writing there is an emergency need of approx. 70,000 vials of Streptomycin 1g, occasioned by the use of x2 vials of 0.75g for the majority of retreatment cases whereas drug orders for 2003/2004 anticipated use of x1 vial<sup>24</sup>. The GDF secretariat together with the GoK are

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<sup>23</sup> Based on 2002 case-finding reports.

<sup>24</sup> According to J. Mansoer the weight of most patients is above 70kg, which requires more than one 750mg vial of streptomycin. The rest of the second vial is usually discarded.

jointly taking action to meet this immediate shortfall in order to avoid treatment interruption of Cat. II patients.

**Table 11:** *Expected drug stocks as of July 2004* (Source: Data provided by NTP/CDC)

<b>Product</b>	<b>Quantity (tablets/vials/kits)</b>
Streptomycin 0.75g	0
R120/H50/Z300	13,200,000 (existing stock)
R150/H75	0
E400/H150	26,700,000 (existing stock)
E400	0
Cat. I Patient Kit	79,000 (ETA July 04)
Cat. III Patient Kits	40,000 (ETA July 04)

Cat. I Non Nomadic Cases (GoK Supply and GFATM)

The delivery of 79,000 Cat. I kits in July 2004 will see all 43,919 estimated Cat. I patients started on the new kits, leaving a buffer of approx. 50% at this time.

Cat. III Non Nomadic Cases (GoK Supply & Existing stocks)

Once the above (RHZ) and (EH) stocks have been assigned to cover the needs of nomadic cases, where applicable, and <15yrs non-nomadic Cat. III cases (both categories of which cannot use the Patient Kits), the remaining (RHZ) and (EH) will be assigned to non-nomadic Cat. III cases covering approx. 38,500 out of 48,300 patients. This means that approx. 10,000 Cat. III cases will be started on the new Cat. III kits in July 2004. A buffer of approx. 60% for Cat. III non-nomadic adult patients will exist at this time.

**GDF Supply 2004/2005**

- Cat. II Non nomadic cases (GDF supply)
- Part of ALL Cats. of Nomadic cases (GDF supply & Existing Stocks)
- Continuation phase of <15yrs Non-nomadic cases (GDF supply)

The above plan requires, therefore, that GDF supplies for 2004/2005 (starting July 04) in the third and final year of the current grant will be to cover all Cat. II non-nomadic cases (plus 100% buffer), part of the drug needs of all categories of nomadic cases not covered by existing stocks and the continuation phase of <15yrs non-nomadic cases, meaning the following order requirements:

**Table 12:** *Cat. II Non Nomadic Cases*

<b>Product (Blister)</b>	<b>Quantity (tablets/vials) including 100% buffer</b>
Streptomycin 1g	860,832
Water for Injection, 5ml	860,832
R150/H75	6,456,240
R150/H75/Z400/E275	3,873,744
E400	4,304,160

**Table 13:** *Part of all Cats. of Nomadic Cases*

<b>Product (Blister)</b>	<b>Quantity (tablets/vials)</b>
Streptomycin 1g	51,240
R150/H75	325,800
R150/H75/Z400/E275	2,903,520

**Table 14:** *Continuation Phase <15yrs Non-nomadic Cases*

<b>Product (Blister)</b>	<b>Quantity (tablets/vials)</b>
R150/H75	1,780,740

### ***Annex 1: Mission Recommendations***

#### To NLTP and GoK

##### *General*

- National and international GoK tenders for procuring TB drugs should be restricted to manufacturers who comply with WHO standards of quality and manufacturing procedures, as assessed by The Procurement, Quality and Sourcing Project: Access to Anti-Tuberculosis Drugs of Acceptable Quality, which was initiated in 2002 by the GDF in conjunction with WHO Department for Essential Drugs and Medicines Policy/Quality Assurance and Safety: Medicines (EDM/QSM). Local pharmaceutical manufacturers should be encouraged to participate in the WHO Pre-qualification Project.
- The unprecedented budget commitment for TB drugs established by GOK for 2004-2006 should be safe guarded and fulfilled.
- GoK/MoH should arrange for immediate emergency procurement of 100,000 vials of Streptomycin.
- NTLP should follow up on the important technical recommendations of the KNCV monitoring mission of September 2003, a number of which have not yet been addressed (See Annex 2)

##### *Drug Management*

- Accurate and timely recording of TB drug shipments and deliveries should be applied consistently across the country. The development of a computerised stock tracking system should be expanded to replace manual entry and accounting in the central KEMSA stock ledger .
- A comprehensive plan for introducing Stop TB patient kits should be completed and adopted by end April 2004.
- CU staff should be trained in quantification and supply chain management logistics to allow for a smooth transition to local capacity in these areas once CDC and JSI-DELIVER support comes to an end.<sup>25</sup>
- Security stocks should be established at each level of the distribution chain (central, provincial, and district). Currently the system works without a real buffer stock but the increased fiscal budget for drugs and forthcoming grants will allow its creation. The number of drug units (or Kits) below which

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<sup>25</sup> The quantification of drug requirements is elaborated by a CDC consultant. The transportation of TB drugs and commodities to provincial stores and the inventory control system is supported by JSI. The technical cooperation of both agencies will end during the following two years. Local staff should be trained to take full responsibility of these activities before the end of these projects. The systematization of accumulated knowledge (in the form of manuals of procedures, and practical guides to use the spreadsheets) may be an immediate activity to make a smooth phase-out of the projects.

an immediate order must be placed (security stock) should be established for each warehouse and service, depending on the consumption and lead-time.

- Inventory control at KEMSA should be improved. JSI is already supporting a logistic unit in KEMSA. Technical support should include the inventory control for TB Drugs.<sup>26</sup>

***Annex 2: Technical Recommendations*** (As excerpted from **Progress Report 31 on the KNCV evaluation mission to Kenya, September 2003**)

- It is recommended to develop and implement a more regular HIV surveillance among TB patients. The development of TB-HIV collaboration activities, which will be supported by a national TB-HIV strategy with guidelines, is a good opportunity to include detailed TB-HIV surveillance plan and activities. Part of the surveillance should now come from routine HIV testing of TB patients. Another part can still come from period anonymous testing of particular groups of TB patients.
- It is recommended to review the WHO/CDC guidelines on surveillance of HIV among TB patients by Erica Duffel et al.
- CRL should finally agree with KEMRI and NLTP on specific role of CRL and means of collaboration and reporting. It is advised to keep research and routine operational activities (supervision, MDR surveillance, and training) separated which doesn't mean that CRL laboratory staff can't be engaged in research activities of KEMRI. KEMRI on the other hand should be able to access staff and equipment of CTR to be used in research activities.
- CRL should distribute universal bottles to all provinces. PTLC are requested to encourage sputum collection of all re-treatment and failure cases to be send to CRL.
- CRL should establish a continual supra national quality control with Mycobacterial Reference laboratory, Prince Charles Hospital, Brisbane in Australia.
- CRL should analyse the results of the first culture and DST of samples of Nairobi, Mombassa and Rift Valley North. Reveal the number of samples received, number of samples cultured (per method), contamination rate per method, positivity rate per method and detailed drug resistance pattern of all DR cases
- NLTP should develop an annual plan of supervision and training of peripheral laboratories and develop a supervision/monitoring tool, which should assist NLTP/CRL to make an inventory of available services and quality. It is recommended to use the WHO guidelines on laboratory services and the WHO checklist for the assessment of laboratory services as a basis.
- NLTP should analyse the treatment results of the different categories of re-treatment (relapse, return after default, failure, other) cases over the last two years to support the overall analysis of the drug-resistance situation as apart of the preparation of a new GLC proposal.
- NTLTP should continue to emphasise DOT in the intensive phase.
- KEMRI should finalise the testing of drug sensitivity of the remaining cultures and should than produce and distribute the detailed results of analysis of the drug-resistance survey before the end of this year.
- The TB-HIV co-ordinator should finalise the TB-HIV proposal on the pilot in Nakuru and put a request forward to WHO for funding as soon as possible. The Nakuru project should get going as it will otherwise loose its role as a pilot, since the GFATM plan of NLTP which includes the introduction of joint TB-HIV activities in 10 districts will also commence.

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<sup>26</sup> The mission established the accuracy of the inventory control system by comparing the bin cards with the results of a physical countdown in KEMSA, two provincial stores and 2 district stores. Only the inventory control system at KEMSA was not updated and showed discrepancies. The inaccuracies in KEMSA inventory control may have important repercussions in the whole system, leading eventually, to stock outs. The same observation was made by CDC recently (see table section 13).

- The TB-HIV working group should adopt the national TB-HIV Guidelines to the interim WHO policy document which will be published in December 2003 and finalise the national document as soon as possible.
- NLTP should develop a supervision schedule for 2004 and to communicate this with the provinces. They are also advised to produce action point lists for every province that has been visited and provide regular feedback.
- The CU should make an inventory of the current fleet of motorcycles and submit a request for new motorcycles to USAID and KNCV.
- NLTP data should be made available on a central server, which can be accessed by more computers at once.
- PTLCS are encouraged to prepare annual training needs and prepare a plan utilising all available funding for 2004.
- NLTP should urgently discuss the regulations concerning Global Fund support to the NLTP with the CCM. PM should carefully monitor the correct use of the funds and ensure strict adherence to the approved plan of action for the GFATM.

***Annex 3: Programme of mission***

<b>DAY</b>	<b>AGENDA</b>
January 17 <sup>th</sup>	GDF Team arrives in Nairobi
January 19 <sup>th</sup>	Briefing of WHO Representative and staff; Meeting with JSI-DELIVER; Meeting with Director KEMSA; Inspection of KEMSA stores; Discussions with NLTP
January 20 <sup>th</sup>	Meeting with donors/Partners; Discussions with NLTP
January 21 <sup>st</sup>	Field visit to North Rift Province: Provincial KEMSA store, Eldoret; District hospital, Trans Nzoia, Kitale; Peripheral Health facilities x2: Tom Mboya Health Centre & Kiminini Cottage Hospital
January 22 <sup>nd</sup>	Field visit to Western Province: Provincial KEMSA store, Busia; District Hospital, Busia; Peripheral Health Centre, Nambale; Matayos Peripheral Health Centre, Busia.
January 23 <sup>rd</sup>	Executive Debriefing: Minister of Health, PS, DMS, WHO Representative. Final discussions with NLTP; GDF Team leaves Nairobi

***Annex 4: List of people met***

1. Hon. Charity Ngilu, Minister of Health, Kenya
2. Mr. W. Godo, Permanent Secretary, MoH
3. Dr. Nyikal, Director of Medical Services (DMS), MoH
4. Dr. Kimani, Deputy DMS, MoH
5. Dr. Jeremiah Chakaya, NLTP Manager
6. Dr. John Mansoer, CDC/NLTP
7. Dr. Kalu, Acting WHO Representative – Kenya
8. Dr. Joyce Onsongo, Communicable Diseases Control Officer, WHO
9. Dr. Kangangi, NPO-TB, WHO
10. Mr. S. Kinzett, JSI-DELIVER
11. Mr. D. Karuti, JSI-DELIVER
12. Mr. Njiri, JSI-DELIVER
13. Ms. J. Waweru, JSI-DELIVER
14. Dr. Mtana Lewa, Deputy Director, KEMSA
15. Mr. E. Kyalo, Senior Store Keeper, KEMSA
16. Ms. C. Mugane, Clerk, KEMSA
17. Ms. Susanne Schmitt, Malteser
18. Mr. Bedan Gichanga, USAID
19. Mr. Martin Mudambo, CDC
20. Mr. Joseph Odiambho, CDC
21. Mr. Franz Freidrichs, GTZ
22. Mr. John McWilliam, FHI
23. Mr. Julius Tome, AMREF
24. Ms. Christa Cepuch, MSF
25. Ms. Bibiana Njue, MoH
26. Dr Sitienei, PTLC, North Rift Province
27. Mr. J. Chebon, Head KEMSA depot, North Rift Province
28. Dr. Alfred Kivisha, DTLC, Trans Nzoia District
29. Dr. Langat, DMOH, Trans Nzoia District
30. Mr. Charles Onger, District Store Keeper, Trans Nzoia, Kitale
31. Ms. Ketray Ayamba, Nurse, District Hospital, Trans Nzoia, Kitale
32. Ms. Florida Siti, Nurse-in-charge, Tom Mboya Peripheral Health Centre
33. Ms. Jane Alenga, Nurse, Kiminini Cottage Hospital, Peripheral Health Centre
34. Dr. S.O. Adallah, PTLC, Western Province
35. Mr. Musera, Senior Store Keeper, KEMSA depot, Western Province
36. Dr. Mukabi, DMOH, Busia District Hospital
37. Mr. F. Ohia, Chest Clinic, Busia District Hospital
38. Mr. S. Lokemer, Peripheral Health Centre, Nambale
39. Medical Officer in Charge, Matayos Peripheral Health Centre, Busia

### ***Annex 5: Preliminary Planning for Implementation of Patient Kit system***

Approximately 100,000 kits for Category I and III patients will be delivered to the central store before July 2004. The use of kits is recommended by GDF/WHO and their pending introduction, was received with enthusiasm by the MoH personnel interviewed during the field trip, indicating primary that a kit system will potentially reduce their workload. The implementation of the patient kit system requires, however, taking into consideration the following recommendations:

- **Improve conditions and storage capacity of central warehouse (KEMSA):** The ground space KEMSA assigned to TB medicines was, at the time of the visit, close to its full capacity. There is, however, enough overhead space to accommodate the kits, provided that the warehouse is conditioned with high shelving and lift trucks. It was reported that these improvements are already programmed for the following week. The preparation of the warehouse should start immediately.
- **Negotiate with the supplier of the kits, the time and conditions of the delivery, and details regarding packing, labelling and insert information:** The GoK is still able to negotiate the conditions for the delivery of the kits. The kits should be delivered in more than one consignment, each one compatible with the storage capacity of the central and peripheral stores. The size of the shipping containers and blisters is critical to optimize the storage space needed; the adequate supply of labels will allow the re-use of the packing material (cardboard boxes). GDF will send a sample pack to NTP to be used as the gold standard for negotiation with the supplier. In any case, medicines should be ordered as pre-packed kits rather than loose drugs to be packed in the MoH stores.
- **Communication to provinces /districts about the need to work on optimizing the space in the stores:** There should be an early communication to the provinces and districts about the implementation of the patient kits system. Based on the information provided by the NTP, the peripheral stores should optimize the warehousing space to accommodate the patient kits. The NTP should explore if some donors could provide technical and financial assistance for preparing the storage spaces throughout the supply system.
- **Elaboration of plan for the management of TB Kits:** A comprehensive plan for the management of the TB Kits should be prepared. It must include, at least the following sections:
  - *Distribution strategy:* The frequency of the deliveries should be consistent with the storage capacity, i.e. the lower the storage capacity the more deliveries within a period. A push system may be gradually substituted by a pull system once the pipeline is full and the ordering process is in place.
  - *Forms/formularies to be completed:* Forms and formularies must be adapted / created, so that the inventory control system reflects the simplicity of distribution and consumption of the kits. The inventory control of the kits is easier for all the levels of the supply chain since kits contain all drugs as a single inventory unit as opposed to the current system where 4 or 5 separate drugs must be handled. Recording of individual drugs may still be needed for the remaining drugs at the end of the distribution chain (in the case of default patients and deaths), and when returning drugs to the provincial or central level where the reconstitution of patient kits will take place. The procedures, regulations, norms and forms should be compiled in a manual of procedures.

- *Training and communication strategy:* When the manual of procedures is completed the details of the implementation should be shared with all the personnel involved in the process. The participants in the workshops should be trained, at least, in the following aspects: quantification, reception and storage of the kits, completion of registration and inventory forms, communication with the patient, re-packing of partially used kits.
- **Monitoring and evaluation:** Kenya is pioneering the implementation of a patient kit system, therefore the process must be monitored and evaluated. The use of process indicators (stock outs, availability, inventory control), and outcome indicators (defaults, treatments completed, cured patients, etc) will provide solid ground to introduce any change during the implementation phase. The monitoring /supervision visits to stores and services should include the review of reporting forms, interviews with the personnel and patients, the observations of the storage conditions, the repacking process, and the collection of excess drugs that will not be needed to reconstitute new patient kits in health facilities.
- **Continuous supply of spare drugs:** Even after a successful implementation of the patient kit system, a limited supply of separate drugs will still be needed to complete partially used kits, and for the treatment of patients with allergies or adverse reactions to one or more of the drugs in fixed dose combination products.
- **Create a buffer stock for kits:** The number of kits purchased for Categories I and III may not be enough to treat the new cases and *fill the pipeline* with a reasonable buffer stock. To minimize losses due to expiration and create a buffer stock of patient kits, all the remaining loose drugs should be used to treat patients before the kits are initiated. This may mean transferring all remaining loose drugs for use in on district or region to minimize the confusion during the transition to patient kits. The 2004/2005 tender should be programmed on time taking into account the lead-time of the present tender (2003/2004). The use of loose drugs – while waiting for the products of the 2004/ 2005 tender- is not recommended.
- **Human resources administration:** The mission team found highly motivated and efficient personnel in the provincial and district levels. Procedures and routines were strictly followed and the technical expertise of the personnel was close to optimal. The workload, however, may be near the limit of their capacities. The number of human resources assigned to the program has not changed even though there has been an increase in the financial resources to be executed<sup>27</sup> and the number of cases diagnosed each year (increasing steadily at a rate of 14-20%/ year).

In the following years the financial situation of the MoH may not allow an increase in the number of personnel for the NLTP, therefore the following strategies may be considered to optimize the performance of the human resources already available:

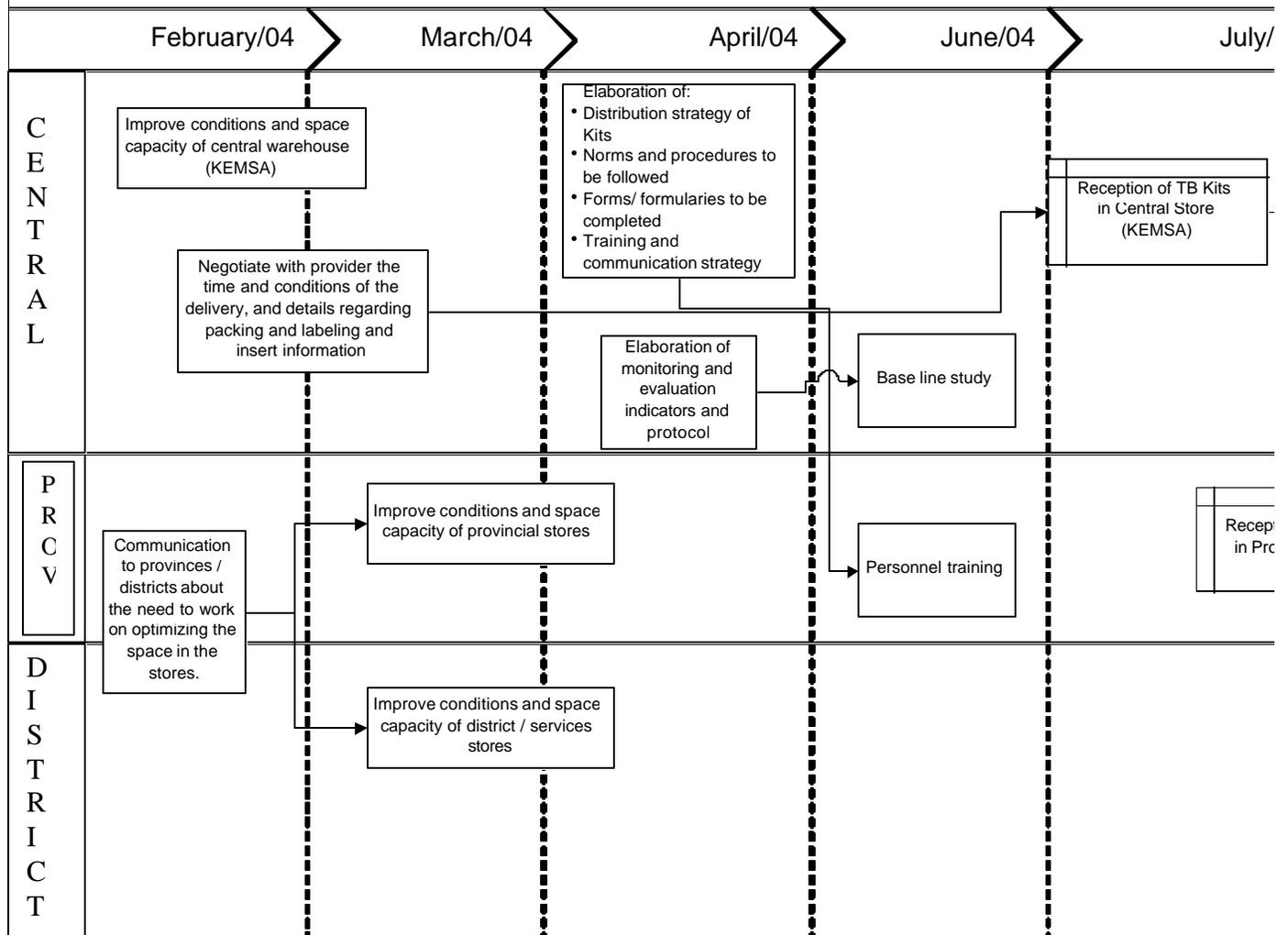
- Use the patient kit system as a strategy to reduce the workload: One of the benefits of the kits is to make the quantification, procurement and supply processes easier. The forms required for delivery, receipt and inventory control, for instance, should be simpler and less time consuming since a patient kit is one inventory item versus the 5 or 6 drug items under the current system.

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<sup>27</sup> Besides resources from the GDF, Kenya was recently awarded with a grant from the Global Drug Fund for AIDS, Tuberculosis and Malaria.

- Introduce a computerized inventory control system: The introduction of a computerized system will simplify the inventory control management in central and provincial levels. During the introductory period, however the BIN card system must be used simultaneously, until the computerized system is tested and full functional.

# Strategy for the implementation of the Kits system



**Annex 6: Detailed Drug Management Report on Site Visits – Provincial level**

1. *KEMSA Central Medical Stores, Nairobi 19<sup>th</sup> January 2004*

**Stock management:** The BIN cards were not updated in correspondence with the issue and receipt forms; therefore they did not match the physical count conducted by the team. There is no defined security stock for each of the TB drugs.

**Store inspection:** TB drugs are stored in a separate cage. The cage is securely locked and no pilferage was reported during the past year. The space available is not optimized due to the lack of elevated shelving. The aeration and humidity are not a problem due to the weather conditions of Nairobi. The store is clean. The practice of spilling water in the floor to prevent dust accumulation must be avoided because there is a risk of wetting the medicine containers.

The TB drugs are placed on pallets and shelves. Due to the absence of high shelves most of the shipping containers are accommodated on pallets. In some cases, the pallets are put on top of the medicine containers to accommodate an additional layer, pressing (and potentially damaging) all the boxes underneath.

**Issues / recommendations:**

*Optimize use of space:* The plan to increase the available space in KEMSA store by placing higher shelves should be implemented immediately, in preparation for the delivery of the TB patient kits before July/04.

*Computerize the inventory control system:* The manual inventory control system is outdated and inaccurate. The miscalculations the mission found may have an important impact on the availability of TB drugs. The NLTP should consider obtaining partner support to computerize the inventory control system of KEMSA and train the personnel.

2. *North Rift Valley Provincial Store, 21<sup>st</sup> January 2004*

**Stock management:**

JSI transports the drugs from KEMSA every 3 months. Drugs are then collected by the districts according to the plan of the coordinator, which takes into account the districts quarterly reports and their requests. The inventory is controlled manually on bin cards. Records matched 100% against the physical count performed by the team. No stock outs of TB drugs were reported in the last two years. No pilferage was reported. There is no defined security stock for TB drugs.

**Store inspection:**

Store conditions were good. The store was clean and the temperature and aeration was acceptable at the time of the visit. However, it was indicated that the temperature may reach 30 Degrees Celsius during summer. The TB drugs are located in a cage, properly classified and ordered. There is no area for handling and packing and the space available may not be enough for the accommodation of the kits.

**Issues / recommendations :**

*Optimize use of space:* Extra space should be available for the accommodation of the TB kits. A TB partner may provide technical assistance to optimize the use of the warehouse capacity.

*Introduce overhead fans:* Overhead fans should be installed to assist with keeping the store temperature below 30 Degrees Celsius during the hot, dry months.

3. *Western Province Provincial store, Busia, 22<sup>nd</sup> January 2004*

**Stock management:** JSI delivers the TB drugs regularly. Drugs are usually collected by the districts. The inventory is controlled manually using bin cards. Records matched 100% against the physical count done by the team. No stock outs of TB drugs were reported in the last 2 years. No pilferage was reported. There is no defined security stock for TB drugs.

**Store inspection:**

Store conditions were reasonable. The store was clean and the temperature and aeration was acceptable at the time of the visit. There is a dedicated area for TB drugs. There is no area for handling and re-packing the kits and the space available may not be enough for to accommodate the kits.

**Issues / recommendations :**

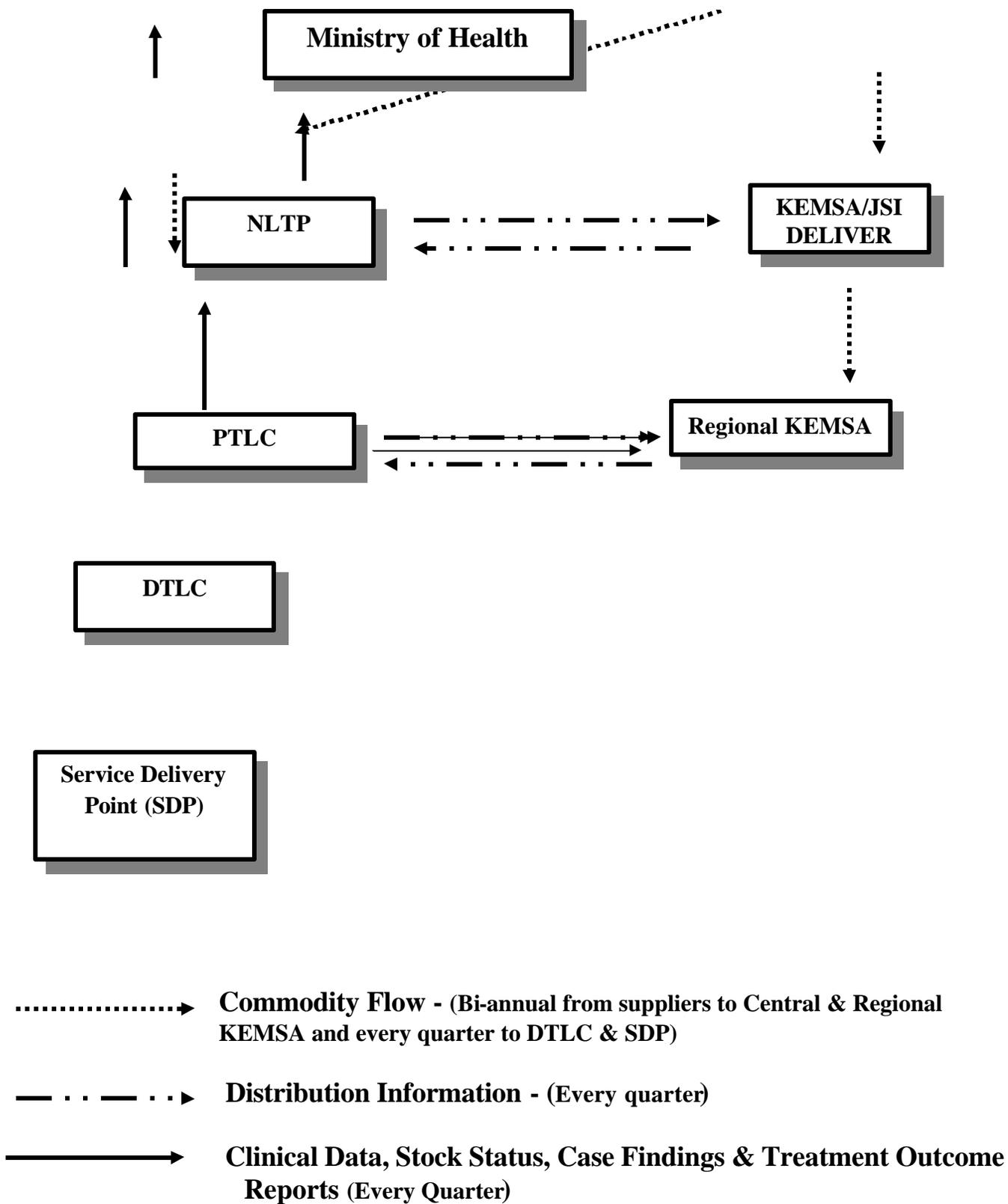
*Optimize use of space:* Extra space should be available for the accommodation of the TB kits. JSI may provide technical assistance to optimize the use of the warehouse capacity.

*Annex 7: Drug Management and Distribution Organogram*

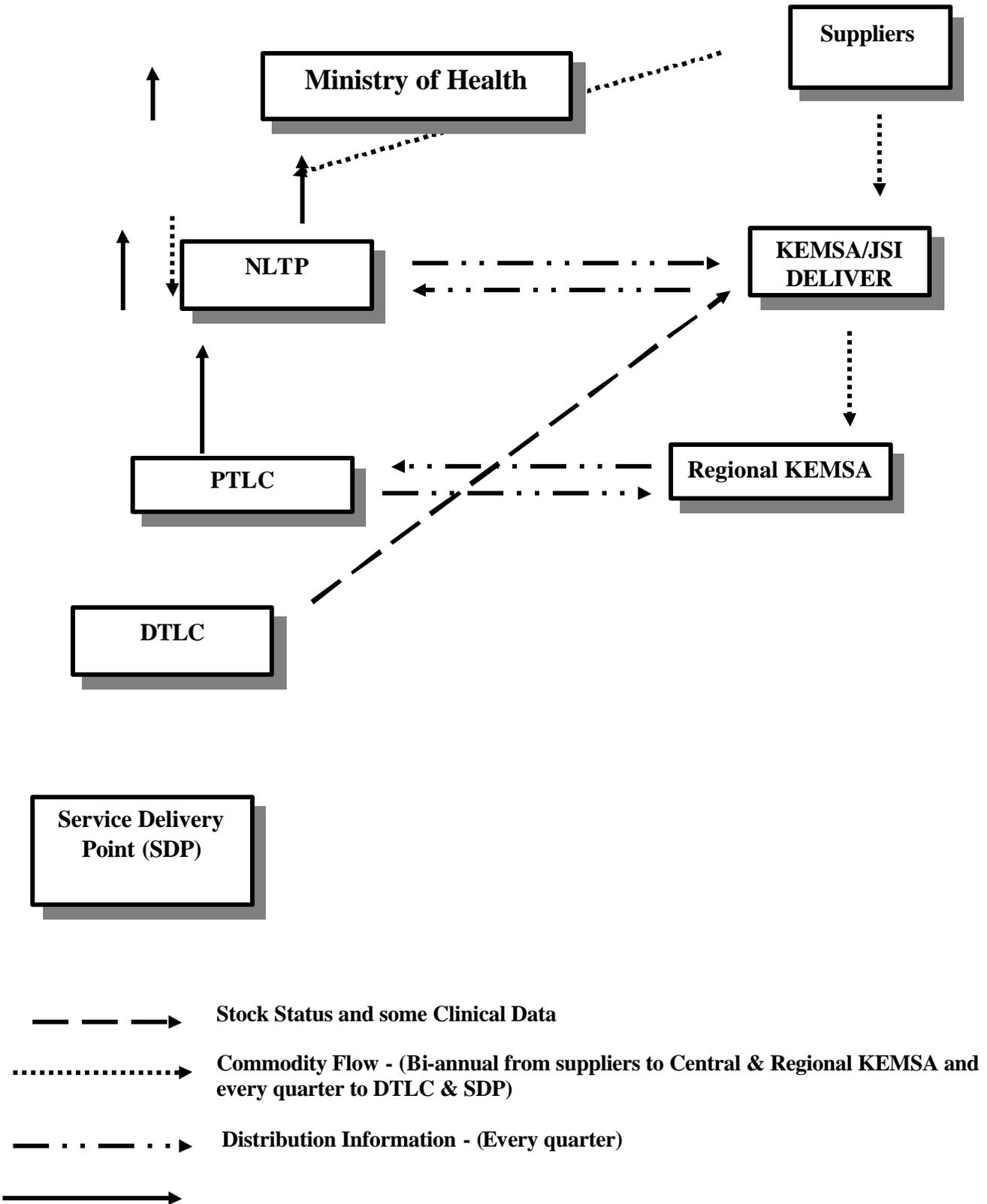
**TUBERCULOSIS/ LEPROSY COMMODITIES SUPPLY CHAIN &  
REPORTING SYSTEM (CURRENT)**



**Suppliers**



### TUBERCULOSIS/ LEPROSY COMMODITIES SUPPLY CHAIN & REPORTING SYSTEM (PROPOSED)



**Clinical Data, Stock Status, Case Findings & Treatment Outcome Reports (Every Quarter)**

**Annex 8: Tuberculosis Case Finding Report & Estimates 2003**

Qrt.	Type of Regimen	New smear positive	Retreatment					New smear -negative			New extra-pulmonary		
			Sm.pos. Relapse	Other Relapse	Failure	R.A.D.	Total	<15 yrs	15+ yrs	Total	<15 yrs	15+ yrs	Total
I	SCC	8723	580	370	19	208	1177	1206	6807	8013	466	2428	2894
	Manyatta	876	59	58	0	27	144	218	739	957	132	211	343
	Total	9599	639	428	19	235	1321	1424	7546	8970	598	2639	3237
II	SCC	8341	585	667	22	247	1521	1418	6860	8278	468	2462	2930
	Manyatta	925	73	77	3	24	177	245	617	862	133	195	328
	Total	9266	658	744	25	271	1698	1663	7477	9140	601	2657	3258
III	SCC	9037	757	720	40	236	1753	1432	7546	8978	467	2585	3052
	Manyatta	901	74	91	1	28	194	190	666	856	123	181	304
	Total	9938	831	811	41	264	1947	1622	8212	9834	590	2766	3356
IV	SCC	8985	757	720	40	236	1753	1431	7423	8854	467	2526	2993
	Manyatta	901	74	91	1	28	194	190	666	856	123	181	304
	Total	9886	831	811	41	264	1947	1621	8089	9710	590	2707	3297
Yr	SCC	35086	2679	2477	121	927	6204	5487	28636	34123	1868	10001	11869
	Manyatta	3603	280	317	5	107	709	843	2688	3531	511	768	1279
	Total	38689	2959	2794	126	1034	6913	6330	31324	37654	2379	10769	13148
	%	40	7					39			14		

Not added to this numbers are the, on average 750 TB cases reported and treated by the Refugee who also receive drugs through the NLTP.

**Non-nomadic numbers & % of <15 years PTB- /EPTB:** 7,355 = 17% of all PTB- + EPTB case

**Nomadic numbers & % of <15 years PTB- /EPTB:** 1,354 = 28% of all PTB- + EPTB case

**Total numbers & % of <15 years PTB- /EPTB:** 8,709 = 17% of all PTB- + EPTB case

**Proportion < 15 years amongst PTB+ cases:** 774 2% of all PTB+ cases

**TB case finding Kenya, all cases/year/quarter and expected cases 2003-2004-2005**

	Q1	Q2	Q3	Q4	Total	Ann. increase	Q1/Tot%
1995	6,954	6,814	7,396	6,978	28,142		25
1996	8,090	8,283	9,517	9,090	34,980	24%	23
1997	9,677	10,285	11,503	8,580	40,045	14%	24
1998	10,757	12,233	13,199	13,224	49,413	23%	22
1999	13,631	14,223	15,436	14,396	57,686	17%	24
2000	16,102	15,240	16,671	15,962	63,975	11%	25
2001	17,637	18,213	18,919	18,248	73,017	14%	24
2002	19,145	19,810	21,903	21,256	82,114	12%	23
2003	23,127	23,362	25,075	24,840	96,404	17%	24
	24%	24%	26%	26%			
2004	27,070	27,070	29,326	29,326	112,793		

<b>2005</b>	31,672	31,672	34,312	34,312	131,967	17%
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<b>Expected first half 2004:</b>		54,140				
<b>Expected second half 2004:</b>		58,652				
<b>Expected first half 2005:</b>		63,344				
		<b>Total</b>	<b>PTB+</b>	<b>Retreatm.</b>	<b>PTB-</b>	<b>EPTB</b>
	2003 %		40	7	39	14
<b>Expected July 2004 - June 2005:</b>		121,997	48,799	8,540	47,579	17,080

<b>Percentages and numbers on Non-nomadic &amp; Nomadic regimens July 2004 - June 2005</b>						
		<b>Total</b>	<b>PTB+</b>	<b>Retreatm.</b>	<b>PTB-</b>	<b>EPTB</b>
<b>90%</b>	<b>Non-nomadic</b>	109,797	43,919	7,686	42,821	15,372
	%		40%	7%	39%	14%
<b>10%</b>	<b>Nomadic</b>	12,200	4,880	854	4,758	1,708
	%		40%	7%	39%	14%

**Annex 9: Treatment Outcome and Drug Consumption of Non-nomadic cases**

<b>PTB+</b>										
<b>Kenya</b>	month	Smear negative		Smear not done		Smear positive		Died		
	n	n	%	n	%	n	%	n	%	n
<b>Total</b>	<b>2</b>	17,371	78	2,159	10	299	1.3	545	2	1,033
<b>Country</b>	<b>5</b>	14,206	64	4,155	19	102	0.5	900	4	1,583
	<b>8</b>	14,392	65	3,254	15	106	0.5	1,119	5	1,847

**at 2 months**

Already a 12% drop-out. Information from the field shows that the majority of drop-outs occur during the first 2 weeks of treatment. Very few after the 1-st month of treatment. We can assume that in this category of patients 6% of the initial phase drugs (RHZE) is not consumed.

It also means that, at this phase of treatment, we can predict that already 12% of the continuation phase drugs (EH) will not be cons

**at 5 months**

A total drop-out of 17%, meaning an additional drop out of 5%. It is not clear when the majority takes place. Let us assume that all drop-out at the 4-th month of treatment. This will result in an additional 5% of patients not consuming a 4 months supply of EH

**at 8 months**

A total drop-out of 20%, meaning an additional drop out of 3%. Let us assume that all drop-out at the 6-th month of treatment. This will result in an additional 3% of patients not consuming a 2 months supply of EH

<b>Calculations:</b>									
Assume 100 PTB+ cases									
Normally ordered:				36,000					
12% not using 6 months of EH:				4,320					
5% not using 4 months of EH:				1,200					
3% not using 2 months of EH:				360					
Total not used:				5,880	this is equal to:16%of the ordered EH for this group				

**PTB-**

<b>Kenya</b>	month	Completed 2/8 months treatment		Died		Absconded		Transfer
	n	n	%	n	%	n	%	n
<b>Total</b>	<b>2</b>	16,902	85	774	4	1,234	6	957
<b>Country</b>	<b>8</b>	14,986	75	1,372	7	2,057	10	1,452

<b>EPTB</b>								
<b>Kenya</b>	month	Completed 2/8 months treatment		Died		Absconded		Transfer
	n	n	%	n	%	n	%	n
<b>Total</b>	<b>2</b>	5,634	84	319	5	418	6	351

<b>Country</b>	<b>8</b>	4,993	74	495	7	722	11	512
<b>PTB- + EPTB</b>								
<b>Kenya</b>	month	Completed 2/8 months treatment		Died		Absconded		Transfer
	n	n	%	n	%	n	%	n
<b>Total</b>	<b>2</b>	22,536	85	1,093	4	1,652	6	1,308
<b>Country</b>	<b>8</b>	19,979	75	1,867	7	2,779	10	1,964

**at 2 months**

These data show that already at 2 months of treatment there is a drop-out of 15%, meaning that 15% won't use the 6-month EH cor

**at 8 months**

There is an additional drop-out of 10% of cases by the end of treatment. If we assume that they on average drop-out at 5 months of it will mean that that 10% of the patients will not use a 3 month quantity of EH

**<15 years of treatment**

17% of the PTB-/EPTB cases is <15 years of age. This implies that they won't use EH at all but RH in the continuation phase of treatment. Never been made while ordering drugs for this type of patient.

**Calculation:** assume 100 PTB-/EPTB cases

Normally ordered:

36,000 EH

17% <15 yrs. not using 6 months EH:	6,120						
15% >15 yrs. not using 6 months EH:	4,482						
10% >15 yrs. not using 3 months EH:	1,566						
Total not used:	12,168	this is equal to: 34% of the ordered EH for this group of patients					