

Global Drug
Facility
Monitoring
Mission to Kenya,
and Technical
Assistance for the
Implementation of
the TB Patient
Packs Trip Report:

*Kenya, April 25 –
May 6, 2005*

Management Sciences for Health
is a nonprofit organization
strengthening health programs worldwide.



This report was made possible through support provided by the U.S. Agency for International Development, under the terms of Cooperative Agreement Number HRN-A-00-00-00016-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

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May 2005

**Rational Pharmaceutical Management Plus
Global Drug Facility Monitoring Mission to Kenya, and
Technical Assistance for the Implementation of the TB Patient Packs
Trip Report: Kenya, April 25– May 6, 2005**

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May 10, 2005

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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, family planning, HIV/AIDS, Tuberculosis, Malaria and other infectious diseases, and in promoting the appropriate use of health commodities in the public and private sectors.

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Abstract

After three years of support from the GDF, the Government of Kenya is interested in applying for a second term grant. The approval of the application will depend partly on the results of a monitoring mission undertaken by GDF with the collaboration of MSH/RPM Plus. The recent introduction of TB patient packs imposes additional challenges to the pharmaceutical management of the TB program. This report includes a synthesis of the results of the GDF/RPM Plus monitoring visit, and the most relevant findings and recommendations regarding the implementation of the TB patient packs.

Recommended Citation

Barillas, Edgar 2005. *Global Drug Facility Monitoring Mission to Kenya and Technical Assistance for the Implementation of the TB Patient Kits: Trip Report. Kenya, April 25th – May 6th, 20*. Submitted to the U.S. Agency for International Development, by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

Key Words

Tuberculosis, TB Patient Packs, pharmaceutical management, TB-Global Drug Facility

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Acronyms

CDC	Center for Disease Control
DOTS	Directly Observed Treatment – Short Course
GDF	Global Drug Facility
GFATM	Global Fund for AIDS, Tuberculosis and Malaria
GLC	Green Light Committee
GMP	Good Manufacturing Practices
GoK	Government of Kenya
JSI	John Snow Incorporation
KAPTLD	Kenya Association for the Prevention of TB and Lung Disease
KEMSA	Kenya Medical Supplies Agency
MDR-TB	Multi-drug-resistant TB
MoH	Ministry of Health
MSH	Management Sciences for Health
NLTP	National Leprosy and Tuberculosis Program
PPB	Pharmacy and Poison Board
RPM Plus	Rational Pharmaceutical Management Plus
SPSS	Statistical Package for the Social Sciences
TRC	Technical Review Committee
TB	Tuberculosis
USAID	United States Agency for International Development
WHO	World Health Organization
E	Ethambutol
H	Isoniazid
R	Rifampicin
S	Streptomycin
Z	Pyrazinamide

Background

The Global 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.

The Technical Review Committee (TRC) of the GDF is the organism responsible for reviewing grant applications to the GDF. The GDF TRC makes recommendations to the WHO of the necessary steps for Programs to meet conditions for GDF support. One component of this review and recommendation process is a country visit. The scope of such a visit is outlined below.

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 GDF has supported the Government of Kenya (GoK) for three years (2002 – 2004). Provision of a grant for TB drugs for a second term is dependent partly on a monitoring visit that was coordinated with the National Leprosy and Tuberculosis Program (NLTP) for April 25-29, 2005. The monitoring team consisted of Robert Matiru, GDF Technical Officer, and Edgar Barillas, MSH/ RPM Plus Senior Program Associate.

RPM Plus, with support from USAID/Africa Bureau, is also providing technical assistance to the NLTP for monitoring the implementation of TB patient packs¹. Part of the technical assistance includes a survey of the implementation process. The data collection in health facilities will start in May 2005. RPM Plus will provide technical support for the processing and analysis of the information. The Kenya experience in the implementation of the patient pack system will be shared with other countries planning to implement a similar system.

Purpose of Proposed Visit

The purpose of the GDF monitoring visit (April 25-29) was to assess:

- Adherence to GDF terms and conditions of support
- Program management (including case treatment outcomes), financial management and drug management.
- Estimate the quantity of medicines needed for a GDF second term grant.
- Evaluate the issues raised by the GDF TRC or during previous GDF visits.

The purpose of the technical assistance for the TB patient pack implementation (May 2-6) was to:

¹ A TB patient pack or kit is a box containing the complete TB treatment for one patient. The box is prepared by the supplier according to the technical specifications provided by the TB Program. For procurement and inventory control purposes the “pack” (and not the loose medicines) is the accounting unit.

- Analyze, with local counterparts, the plan and organization for the first phase of the survey and adjust as necessary for subsequent phases.
- Determine the best options for data analysis and presentation of the findings in the partial and final reports.
- Analyze the dissemination strategies of the survey final report.

Scope of the Work

As a member of the RPM Plus GDF TB team, Dr. Barillas will:

- Confirm fulfillment of the conditions for support from the GDF by accessing specific information included in the GDF monitoring tool.
- Establish the numbers of patients to treat, quantities and specifications of drugs required (for a possible 2nd term grant).
- Discuss with Kenya official the next steps for the eventual provision of a GDF grant.
- Brief senior government officials and other stakeholders on the role of the GDF
- Brief USAID/Kenya officials as requested

For the monitoring of the implementation of TB patient packs, Dr. Barillas will:

- Collect data in the central and local level to review the current situation of the pharmaceutical supply management.
- Analyze and discuss with local counterparts the processing and analysis of data that will be collected in the field.
- Discuss with local counterparts the outline for the partial and final reports.
- Discuss with local counterparts the dissemination strategies of the survey findings within the country and in international symposia.

Activities

GDF Monitoring Mission

1. Confirm fulfillment of the conditions for support from the GDF by accessing specific information included in the GDF monitoring tool

Interview with national health authorities: The following information was obtained through interviews with the WHO representative in Kenya, the NLTP Manager, the Director of Medical Services (DMS), representatives of donor agencies, coordinators of TB programs in private clinics, the Director of the Pharmacy and Poison Board (PPB) and the procurement officer of the Ministry of Health (MoH).

- The NLTP has complied with the recommendations of previous GDF monitoring missions. The political commitment has been expressed in a budget line for TB medicines during the previous three years, and the recommendation of including WHO pre-qualified providers was addressed in the tender floated by the end 2004 and in a recent tender to procure medicines using Global Fund (GFATM) resources.
- The 2003 tender was awarded to a non WHO pre-qualified local manufacturer who delivered 88,000 packs (53,000 Category I and 35,000 Category II) in June 2004. The prices were very much competitive, even in international markets: US\$ 13.85 for a Category I pack, and US\$11.04 for a Category III pack.
- The reliance on pre-qualified providers according to international standards is particularly important since the national capabilities to assure the quality of the medicines is limited. Officers of the PPB reported that limited financial resources and inappropriate technical capacity prevents them from performing an appropriate GMP inspection, marketing surveillance and quality control of products from donors.
- The GDF shipments were cleared from the port in less than four days. All importation taxes and duties were paid by the GoK. A John Snow Inc. (JSI) officer informed that, in at least in one case, these minor delays were caused by the fact that the GDF did not provide the necessary documentation (way bill and invoice) in advance for the release of the Streptomycin. Once the required documents were faxed, the shipment was immediately released. The details are included in the following table:

Medicine	Quantity	Date of arrival	Date released from port
HRZE	8,243,000	Sept/13/04	Sept/17/04
S 1grm	963,500	Sept/14/04	Sept/17/04
E 400 mg	3,710,112	Sept/13/04	Sept/17/04
RH	10,671,360	Sept/13/04	Sept/17/04

- During the last year the NLTP has implemented the following important steps to

- improve pharmaceutical management:
- A single regimen was established for Category I and III patients, simplifying the procurement process and the inventory control.
 - No stock outs were registered at Kenya Medical Supplies Agency (KEMSA) since the previous monitoring visit (January 2004).
 - A computerized system has improved inventory control at KEMSA. There was a total correspondence between the manual ledgers and the electronic inventory program. The mission's findings last year were discouraging in this particular aspect. There are still separate systems in KEMSA for the inventory control registry and consumption data, processed and analyzed by a Center for Disease Control (CDC) consultant at the NLTP central unit. The NLTP with the support of JSI is already working on a single pharmaceutical management information system.
 - The NLTP is mobilizing GFATM resources to improve the distribution system and to procure TB medicines, including 2nd line medicines, through the Green Light Committee (GLC). The DOTS Plus pilot project was recently approved by the GLC. Due to the late approval, the resources from GFATM may need to be reprogrammed.
- The proposed budget line of K\$135 million for 2004-2005 (to procure approximately 120,000 complete treatments) was reduced to K\$ 100 million at the final approbation of the budget. Based on this budget, an international tender for the procurement of 100,000 TB patient packs was awarded to Lupin Pharmaceuticals by the end of 2004².
 - On the visit to the KEMSA warehouse, the mission realized that the purchase order to Lupin was not placed at that moment. The procurement officer explained that the reason for the delay was a legislation recently issued by the GoK taxing all pharmaceutical importations. The purchase order wasn't issued because the Procurement Office was expecting assignment of additional resources, or revision of the ruling. Since neither of these took place, the procurement office will pay the 10% importation tax out of the same resource line assigned to TB medicines. Unfortunately, this solution implies that only 70,000 packs (out of the 120,000 originally required by the GoK) will be bought. At the moment of the monitoring visit, no cooperating agency was expected to fill that gap.
 - The supply of TB medicines may eventually be reduced to critical levels during the following months. At the moment of the visit, the number of Category I packs in KEMSA was only enough to cover 2 months of consumption, and there was a similar amount in provincial and district stores and health facilities (about four months in all the store chain). Even if the purchase order is issued immediately the lead time for the supply of Lupin drugs may be 4-5 months. According to the mission estimates the program may start to experience medicine stock outs by that time.
 - In a second visit to KEMSA, the mission found that the area of the warehouse where the TB medicines are stored was flooded. There was not apparent damage to the medicines at that moment, since they were properly placed on pallets. The

² A WHO pre-qualified manufacturer

flooding was due to obstructed rain holes in the nearby streets.

Field visit to private providers and public health facilities in the Central Province:

- The NLTP and the Kenya Association for the Prevention of TB and Lung Disease (KAPTLTD) started a collaborative program three years ago. Under the terms of the memorandum of agreement, private clinics will comply with NLTP treatment protocols and report the cases and treatment outcomes. Sanofi Aventis ® will supply the medicines at low prices to these clinics. Currently the cost of a complete Category I treatment is K\$ 5,000.00³. Patients pay in advance for their medicines, but receive the supplies periodically to improve compliance and proper administration of the medicines. Currently there are 44 hospitals and clinics working under the terms of this agreement, treating around 1,000 patients per year. These private facilities are monitored every month by the KAPTLTD supervisor⁴ (a former staff of the NLTP). Three of these facilities were visited by the mission: The Nairobi Equator Hospital treated 119 patients in 2004. The Menelik Medical Center treated 77 patients, and 22 patients have been diagnosed so far this year (as of April 2005). In the Nairobi private hospital there were approximately 20 patients under treatment at the moment of the visit.



- After treatment is started the patients are expected to visit the clinic every 20 days for the first 3 months and then every month during the continuation phase. There are charges for each visit⁵. The TB patient packs provided by Sanofi Aventis ® are, in fact, a combination of loose drugs and blisters organized as a “pack” in a paper bag labeled with the name of the patient and date (see picture). These private facilities are reconstituting the packs using remaining medicines left over by defaulters or deceased. Because treatments are usually interrupted late in the intensive phase, or during the continuation phase, some private clinics are facing an excess of drugs used in the continuation phase (EH).
- The mission visited the provincial stores, district stores and health facilities in the Nyeri province. The NLTP provincial coordinator and two sub-coordinators

³ The medical authorities at the Menelik Medical Center mentioned that after the agreement the prices of Aventis TB Drugs have come down from K\$ 40,000 to K\$ 5,000 per treatment (exchange rate: K\$ 75.00 x US\$ 1.00).

⁴ Matron F.K. Leli. KATLD project manager.

⁵ The Nairobi Hospital, for instance, is charging K\$ 100 per visit.

facilitated the field work. As explained by provincial coordinators, JSI delivers the medicines to the provincial warehouse, and then the provincial NLTP delivers to all the districts. The medicines are either transported to the health facilities by the districts, or picked up by the responsible of the program in health facilities. The mission found no evidence of stock outs in any of the stores and facilities visited, but the available stock is usually limited to 2 or 3 months of consumption. The mission identified that there was not a clear procedure for the collection of the *supply boxes*⁶ and the reconstitution of the patient packs. Whether the packs will be reconstituted in the district or provincial level, was still not clear to the provincial coordinators. Overall, however, the introduction of the TB patient packs was well accepted by the personnel and patients.

- At the moment of the visit to the provincial store, the space was enough to store the packs and loose medicines available⁷, but the room may be limited for an increased amount of safety stock (as recommended in this document) and for the repacking TB patient packs. The physical count of loose TB drugs and patient packs matched the records in the ledgers. There were no labels in the shelves indicating the name of the medicines in the boxes and the expiry date, but the rest of the storage conditions and practices of the provincial store were acceptable.
- The Chest Clinic at the Nyeri Hospital evaluates an average of 30 TB patients per day. Due to lack of space, the chest clinic is storing district medicines without a proper registration in the bin cards. There was no available record of the medicines deposited in the supply boxes, and the mission found minor discrepancies between the physical count and the ledger register. The reasons for the discrepancies, as expressed by the district and provincial coordinators, were that some packs were used for training and not discharged from the bin cards, and that excess medicines collected from health facilities were not always included in the district bin cards.

The interview to a patient attending the chest clinic revealed that the patient knew about the disease, its transmission, the eventual side effects of the medicines, and the importance of completing the treatment. The patient was able to identify her “box” easily among the others and she knew that in order to be cured she must finish all the tablets in it. The treatment was only strictly supervised every 10 days when the provider evaluates the patient and provides a new 10-day supply of medicines.

- In the Othaya District Hospital the mission found acceptable storage conditions, no stock outs during the previous months, a safety stock equivalent to three months of consumption and no discrepancies between the physical count of the TB patient packs and the ledgers.
- In the Karatina District Hospital the mission found that the district store (within the same building) was storing a small amount of TB patient packs because of the lack of space in the TB clinic. The bin cards were properly filled and matched the physical count, but the storage conditions of the district store were poor: the

⁶ These are the boxes where the health providers deposit the blisters extracted from the TB patient pack after their adjustment according to the body weight.

⁷ At the moment of the visit there were only 190 Category I packs in the regional store.

warehouse was storing all kind of items and even obsolete equipment; the medicines were not properly ordered and labeled. The working space in the chest clinic, which is also the storage room for TB medicines, is extremely limited⁸. Some boxes with loose TB medicines were hidden behind others in the shelves. The mission identified important discrepancies between the physical count of medicines and the ledgers. The mission also found that the person responsible for TB was registering the delivery and consumption of the patient packs as loose medicines which imposed an unnecessary workload.

- The overall impression of health care providers and logistic managers in the provincial and district warehouses is that the TB patient pack system has been easy to implement and has reduced the burden of inventory control.

2. Establish the numbers of patients to treat, quantities and specifications of drugs required (for a possible 2nd term grant):

Originally the NLTP expressed interest in a GDF grant to cover Category II patients and medicines required (including buffet stocks) for the treatment of nomadic patients. Since the approved NLTP budget is only enough to procure 70,000 packs (for category I and III), the GDF may be required to supply the complementary packs for the treatment of the new patients expected for the following year plus the buffer stock. The details of the calculation (using the GDF template) are included in the following table:

⁸ Funds have already been requested to the NLTP to expand the working space.

Global Drug Facility Monitoring Mission to Kenya and Technical Assistance for the Implementation of the TB Patient Packs

Drug	Description	Annual Drug needs	% Buffer Stock	# Months before normal delivery****	Needs until next regular delivery	Current stock (at the time of visit)	# Months' stock on-hand	Expected deliveries outside of this grant*	Required Advance Order	Type of Packaging Advance Order	Regular GDF order	Total Required Order**
RHZE150/75/400/275	Rifampicin 150 mg / Isoniazid 75 mg / Pyrazinamide 400 mg / Ethambutol 275 mg film coated tablets	4,312,000	100%	8	2,874,667	2,874,667	8	0	1,078,000	Blister	7,546,000	8,624,000
CAT. I & III KIT	Category I & III Patient Kit	100,000	100%	8	66,667	28,900	3.5	91,500	62,767	Blister	83,500	146,267
RH150/75	Rifampicin 150 mg / Isoniazid 75 mg, film coated tablets	0	100%	8	0		NA		0	Blister	0	0
Z400	Pyrazinamide 400 mg tablet	0	100%	8	0		NA		0	Blister	0	0
E400***	Ethambutol HCl 400 mg film coated tablets	0	100%	8	0		NA		560,000	Blister	0	560,000
EH400/150	Ethambutol 400 mg + Isoniazid 150 mg film coated tablets	0	100%	8	0		NA		0	Blister	0	0
RH150/150	Rifampicin 150 mg / Isoniazid 150 mg, film coated tablets	0	100%	8	0		NA		0	Blister	0	0
RHE 150/75/275	Rifampicin 150 mg / Isoniazid 75 mg/ Ethambutol 275 mg., film coated tablets	5,544,000	100%	8	0	0	0	0	0	Blister	11,088,000	11,088,000
H300	Isoniazid 300 mg tablet, 1000 tablets/unit	0	100%	8	0		NA		0	Blister	0	0
S 1 g	Streptomycin (as sulphate) powder for injection 1 g.	616,000	100%	8	410,667	646,500	13	0	0	Vial	996,167	996,167
Solvent	Water for injection, 5 ml vial, 100 vials/unit	0	100%	8	0		NA		0	Vial	0	0
Disposable Syringe	5ml disposable syringe	0	100%	8	0		NA		0	Box	0	0

*Refers to the deliveries outside of this grant, from the time of the visit until 12 months after the next regular GDF delivery

** As can be seen from the table, Total Required Order (column M) has 2 components: Regular GDF order (column L) and Required Advance order (column J). The GDF can normally guarantee the provision of drug from the day of placing the order only for the Regular Order part. If approved, the Required Advance Order will be provided, but only if there are sufficient amount of drugs in the GDF stockpiles.

***Programme switching to RHE for 2nd term. RH stocks as of end April enough for 8.8 months and E400 for 7 months, therefore advance stock of 2 months of E400 needed as inputted manually above

**** Indicated as 8 months since this second term application needs to go to desk audit and TRC Review therefore Grant Agreement/Order Placement unlikely to be until early to mid June 2005

Even with the contribution of the GDF, the supply of TB medicines may turn critical since, according to the estimates of the GDF mission, the available stock in the entire storage chain was just enough to cover four months of consumption. The delivery of the TB patient packs from Lupin may take 4-5 months after issuing the purchase order. The delivery of medicines from the GDF (if the application is approved) may take 6 months. The only palliative to an eventual stock out may be the immediate awarding of a recent tender for TB medicines (20,000 Category I packs) with GFATM resources, and only if the tender favours a local provider, reducing the lead time⁹.

3. Brief senior government officials and other stakeholders on the role of the GDF and discuss with Kenya officials the next steps for the eventual provision of a GDF grant:

The mission explained to government officials the GDF requirements for a 2nd term grant, and provided the necessary documents and information to apply. The mission expressed that there are good chances for the approval, since the GoK has complied with most of the recommendations of previous monitoring missions.

4. Brief USAID/Kenya officials as requested:

USAID / Kenya officials were briefed during the donors meeting on April/25/05.

Monitoring of implementation of TB patient pack system

1. Collect data at central and local levels to review the current situation of supply management, and monitoring of the patient pack implementation:

The Nakuru province was visited May 04, 2005. The situation with TB patient packs management was similar to the one described in the previous sections. As in the Central Province, the overall impression is that there has been a successful implementation of the patient pack system, and both MoH staff and patients are pleased with this innovation. Some relevant observations that complement the ones made for the Central Province are:

- Because of its location near a main road, the Nakuru hospital reports an important amount of patients in transit. Most of the medicines of the supply boxes are used for their treatment. They even had to open a pack to dispense loose medicines for patients in transit and to supplement the dose of a few overweight patients.
- Only the provincial and district coordinators received training in the use of the TB patient packs. To prevent the mishandling of the packs, the district is centralizing the treatment of patient using TB packs, imposing a huge workload to the staff, and congestion in the already small district store (see picture).
- Since no training on the use of packs has been provided, the Nakuru West Dispensary is currently opening the packs to pull out loose medicines.

⁹ This may be unlikely since the tender requires WHO pre-qualification which is not met by local providers.

- In the Naivasha sub-district hospital the inventory control of the packs is still based on the loose drugs in it, imposing an unnecessary workload for the program coordinator who is currently treating 263 patients.

Regarding the monitoring of the implementation of the patient packs, Dr. Samuel Gitau (NLTP coordinator of the project) informed that the training of 18 supervisors and data collectors (district and provincial coordinators) on the completion of the monitoring tool was carried out on March 29-30. The data collection had not yet started because final agreements between the MSH local office and Dr. Samuel Gitau were still pending.



In a meeting with Michael Thuo (MSH/RPM Plus Coordinator in Kenya) and Alix Kihara (Office Manager) on May 3, 2005, the following agreements were reached:

- Allowances for full time public employees are not permitted. A public employee should be on temporal leave from his/her post in order to be contracted or receive an allowance from MSH/RPM Plus.
- Dr. Gitau should complete the *request for expense reimbursement* before requesting an advance to initiate the data collection.
- Receipts are needed for hotel accommodations but not for meals and incidentals.
- The per diem rate will not exceed the MSH approved rates for the region.

With this explanation Dr. Gitau will initiate the data collection in the next two weeks.

2. Analyze and discuss with local counterparts the processing and analysis of data collected in the field:

The procedures for data collection, validation of data, data entry and analysis of the information were discussed with Dr. Samuel Gitau. The data will be included in a SPSS® data base, which will be tested before the data entry. An agreement was reached on the frequency tables and indicators that will support the analysis of the information. A data analyst will be contracted to work on the elaboration of the data base.

3. Discuss with local counterparts the outline for the partial and final reports:

RPM Plus consultant and Dr. Gitau discussed and agreed on a tentative outline and contents for the partial and final reports. The reports will include, at least, the following sections: executive summary, background information (including the situation before the

introduction of the packs), the methods used, the results of the monitoring visit, the discussion of the results and recommendations.

4. Discuss with local counterparts the dissemination strategies of the survey findings within the country and in international symposia:

The results will be used to introduce adjustments in the implementation phase and reinforce weak areas in the trainings to come. Data collection will likely begin before the third week of May 2005. The conditions that lead to the decision to implement a patient pack system and preliminary results from the first round of monitoring visits may be presented at the SEAM conference in Ghana (June 20-22 2005) and at the UNION meeting in Paris (October 18-22 2005).

Collaborators and Partners

Robert Matiru, GDF Technical Officer

Jeremiah Chakaya, NTP Director

Michael Thuo, RPM Plus/Kenya

Samuel Gitau Kinyanjui, Coordinator of the TB patient pack study

Next Steps

To avoid stock-outs of TB medicines in coming months:

As previously mentioned, even with the contribution of the GDF, the supply of TB medicines may turn critical since, according to the estimates of the GDF mission, the available stock in the entire storage chain was just enough to cover four months of consumption. The delivery of the TB patient packs from Lupin may take 4-5 months after issuing the purchase order. The delivery of medicines from the GDF (if the application is approved) may take 6 months. The NLTP may consider the following options to avoid stock outs in the following months:

- The immediate awarding of a recent tender for TB medicines (20,000 Category I packs) with GFATM resources to a local manufacturer in conditions to provide high quality products at the shortest time possible.
- The mobilization of national and/or international financial resources for the direct procurement in international markets. A meeting should be organized to address the situation and agree on the financial sources and emergency procurement mechanisms.

For the application to a second term grant:

- The GDF support ended December 2004. The NLTP has the opportunity to apply for a second term grant if certain conditions are met. The details of the recommendations will be included in the GDF monitoring mission report. The most relevant suggestion is that a budget line for the procurement of TB medicines must be kept in the MoH budget. The resources should be enough, at least, to cover all the expected cases. Therefore, the amount of resources required for 2005-2006 must be around K\$140 million. In correspondence with an increased rate of detection, a 20% raise for the following years should be contemplated. Since this amount is the minimum required to treat all the new cases, this budget line should be “secured” to prevent any cut that is usual in the public administration before the final approval of the budget. The resources for 1st line medicines should be budgeted independently from other medicines and supplies. Resources for 2nd line medicines (for the treatment of MDR-TB) should be programmed on top of the financial requirements for 1st line medicines, to prevent that high priced 2nd line drugs end up consuming the resources allocated for 1st line medicines¹⁰.

For the improvement of TB pharmaceutical management:

- The NLTP should appoint a logistics manager to assume full responsibility of the medicines and commodities supply management. Currently these activities are

¹⁰ The DOTS Plus pilot project will start with GFATM resources to procure 2nd line medicines through the GLC mechanism.

carried out by the NLTP manager and by JSI and CDC consultants. These activities are particularly critical because of the new challenges (increase rate in case detection, the introduction of the TB patient pack system and the initiation of a DOTS plus project), and because the JSI project will eventually finish on September 2006.

- It is necessary to enforce a close communication between the NLTP, the procurement officer and KEMSA. Coordinated activities should lead to:
 - Continuous information on consumption, availability and forecasting of pharmaceutical requirements to keep a security stock and prevent stock-outs.
 - Elaboration of a standardized tender document for the procurement of TB medicines that must be used for all bids, not considering the financial source.
- The tender document should address all the conditions to guarantee the quality of the medicines. WHO prequalification must be a requirement for all manufacturers, since local regulations and laboratory resources are not sufficient to assure the quality of the products. The tender document may also include a clause indicating that providers should pay the costs of laboratory analysis so that the MoH lack of financial resources does not constitute an obstacle to perform these studies.
- Due to unsteady conditions of the procurement mechanisms and availability of public resources, it is recommended to hold a security stock equivalent to at least one year's worth of consumption. Three months' worth can be held in health facilities, three months in distinct/ provincial stores, and 6 months in the KEMSA store. The amount of the security stock and its distribution in the store chain may be modified according to the space availability, lead times and frequency of deliveries.
- The results of the collaboration with the private sector are encouraging. In the coming years it will be progressively difficult for the MoH to confront on its own the constant increase in the number of new TB patients. The collaboration with the private sector should therefore, be expanded and improved.
- The introduction of patient packs was originally planned as a pilot project, but the implementation was rapidly scaled up to the rest of the country without the proper training of all the health providers. Since most provincial and district coordinators are already trained, the rest of the NLTP staff may be trained during the regular supervision visits. The elaboration and distribution of posters, including the guidelines for the adjustment of the packs according to the body weight, may be a valuable aid for the trainees.

Reconstitution of packs:

- Proper storage conditions have to be implemented for the storage and reconstitution of TB packs. If the conditions of the provincial and district stores in the rest of the country are similar to the ones found in Nyeri and Nakuru, a better utilization of the space and the addition of some shelves may create the space needed to hold an increased security stock.

- During the supervision visits to the health facilities and district stores, NLTP coordinators should count the loose medicines available; including the ones not used from the TB patient packs (deposited in the supply boxes). The coordinators should estimate the monthly consumption of loose drugs in that particular facility and leave the equivalent of three months of consumption as a security stock. The rest of the medicines should be collected and transferred to the provincial store.
- The pharmaceutical inventory system developed by JSI and currently used in the central KEMSA store should be expanded with the incorporation of consumption data in health facilities. Even if the default and death rate is kept low, some facilities may eventually experience an excess of EH use in the continuation phase, while a few others, particularly those with a high proportion of patients in transit, may experience shortages. This stresses the importance of reporting on the consumption of loose medicines. The procurement of loose HRZE should be considered to balance the excess of EH.
- The NLTP needs to update the guidelines for the use of TB patient packs. The personnel interviewed in health facilities suggested a friendlier format and a bigger font. The new version should include the instructions for the reconstitution of the packs. The instructions may take into consideration the following issues:
 - The medicines to include in the pack should have at least 6 months of shelf life.
 - The physical conditions should be adequate (no change of color in the tables or tear blisters).
 - The box should be relabeled with a standard and pre-printed label. The NLTP may consider including an inscription as the following:

<i>This TB patient Pack has been reconstituted by the NLTP(with the authorization of the original manufacturer) using the following medicines</i>				
Medicine	Manufacturer	Batch	Expiry Date	Quantity

- A blank sticker to include the patient personal data should also be included.
 - The guidelines for the use of TB patient packs should warn the health providers about the use of reconstituted packs and packs coming from different providers. Some questions that the personnel may have should be anticipated and answered in advance (How should the pack be adjusted if there are 28 tablets per blister?)
 - There should be single criteria regarding the number of treatment days per month: while the central unit is recommending 28, the health facilities are using 30.
- The provincial store seems to be the best level to reconstitute the patient packs, since the stocks outs and surpluses can be better balanced at that level. The

provincial store should keep the equivalent of three months of consumption (of patient packs and loose drugs). All the patients' packs and loose drugs in excess should be transferred to KEMSA.

- For a proper inventory control:
 - Health facilities and districts should withdraw from inventory all medicines collected by the provincial store.
 - The provincial stores should:
 - Include all drugs collected from the district stores in the inventory
 - Withdraw all the drugs needed for the reconstitution of the packs from the inventory
 - Include the reconstituted packs as a “single” unit in the inventory
 - Withdraw all loose drugs and packs transferred to KEMSA and the districts from the inventory
 - Similar procedures should be followed by KEMSA.
- It is necessary to standardize the technical specifications of the patient's packs, so that all the providers comply: size of the box, color of the tablets, inscriptions in labels and inserts, etc. Ideally, the design and labeling of the boxes should allow the transportation and re-use of the empty ones. According to the Pharmacy and Poison Board, there seems to be no legal impediments for the reconstitution of the packs with medicines from different sources in the box from the original provider, but this has to be discussed with all interested parties.

Annex 1: Agenda

Day	Time	Meeting/ Activity
April/26/05	9:00	WHO Representative
	11:00	Director of Medical Services
	12:00	Pharmacy and poison board
	14:30	Donors meeting
April/27/05	9:00	Nairobi Equator Hospital
	10:00	Nairobi Private Hospital
	11:00	Menelik Medical Center
	14:00	NLTP in Nyeri Province (Provincial health officers, Provincial coordinators of NLTP and regional store)
April/28/05	8:30	Chest Clinic Nyeri Hospital
	10:00	Othaya District Hospital
	13:00	Karatina Regional Hospital
	16:00	Procurement Officer Ministry of Health
	17:00	Director of Medical Services
April/29/05	9:00	Estimation of medicines required from the TB-GDF
	14:00	Debriefing session with NLTP manager
May/3/05	9:00	Working session Dr. Samuel Gitau
	12:00	JSI (Jane Waweru)
	14:00	KEMSA store
	16:00	Office Manager (MSH/RPM Plus Alix Kihara)
	17:00	MSH/ RPM Plus (Coordinator Michel Thuo)
May/4/05	9:00	Provincial Hospital Nakuru
	11:00	Regional KEMSA store, Nakuru
	12:00	Nakuru West Dispensary
	15:00	Naivasha Subdistric Hospital
May/5/05	9:00	Discussion of data processing and analysis
	10:00	Meeting with electronic data programmer to analyze the design of the data base
	14:00	Debriefing session with Dr. Chakaya
May/06/05	10:00	Meeting for agreements and follow (Dr. Gitau)

Annex 2: Contacts

	Name	Institution/title
1.	Salme Keriuki	Nurse, the Nairobi Hospital
2.	Mr. Mashera	Depot manager, provincial store, Nyeri
3.	Alix Kihara,	Office manager MSH/RPM Plus
4.	Michel Thuo,	MSH/ RPM Plus Coordinator
5.	Jane Waweru	JSI
6.	Zack Bolo Awino	Senior Principal Procurement Officer MoH
7.	James W. Nyikal	Director of Medical Services
8.	Sarah A. Chuchu	Executive Officer, Pharmacy and Poisons Board Ministry of Health, Kenya
9.	Dr. Jeremiah Chakaya	NLTP Manager
10.	Dr. John Mansoer,	CDC/NLTP
11.	Mr. Bedan Gichanga,	USAID
12.	Mr. Franz Freidrichs,	GTZ
13.	Haron Njiru	Data Analyst