INDIA: RNTCP
LOGISTICS AND DISTRIBUTION OF DRUGS

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Executive Summary

Tuberculosis, a completely curable communicable disease, is a major health hazard in several developing countries, particularly in India. Recognizing the grave consequences associated with the spread of TB, Government of India, in 1962 launched National Tuberculosis programme (NTP), to control the spread of TB in India.

After three decades of intervention through the NTP it was observed that the effectiveness of the NTP was moderate. According to an estimate India records approximately 500,000 deaths a year due to TB. Concerned with this situation, Government of India with the help of World Health Organization (WHO), using a team of experts conducted a review of the NTP in 1992. As a result, the Revised National Tuberculosis Control Project (RNTCP) has been launched.

The key characteristics of RNTCP include quality assured diagnosis, standardized short-course combination of drugs, categorization of patients with appropriate drugs regimen for different categories of patients, direct supervision of drug ingestion, examination of the patients during and at the end of the treatment period, uninterrupted drug supply and generation of political commitment to an effective TB control programme. RNTCP is being implemented by Ministry of Health and Family Welfare, Government of India, with technical advice from WHO, using the existing health care infrastructure.

This report is primarily concerned with the drugs supply system to support RNTCP. It is organized in two parts. The first part evaluates the capability of the existing drugs supply system, to meet the requirements of RNTCP. The second part proposes a revised drugs supply system to enable effective RNTCP implementation.

The existing drugs supply system is found to be functionally oriented (planning, stores and distribution) and not purpose oriented. Consequently, the existing system is characterized by long purchase lead time, price as an exclusive criterion for vendor selection, poor relationship with vendors, stock replenishment policies insensitive to variations in drugs consumption, ineffective quality control procedures, poor co-ordination among procurement, consumption and distribution, and excessive stock or frequent shortages of drugs. The supply system is managed by multiple government agencies using complicated and outdated general purpose procedures, which impedes effective implementation of RNTCP.

The revised drugs supply system is designed to provide 100% service level, reduce outdates and lower inventory of drugs in the system. In this report, a revised drugs supply system is proposed with simplified procedures. In the proposed system, procurement and distribution of drugs is more closely influenced by consumption at the primary health center or at the TB unit. The purchase relationship between vendor and the supply system is designed to support the objectives of RNTCP. In the process of selecting vendors, price is an important criterion, but not the only criterion; adequate weightage is given to drugs quality and supply schedule reliability. The vendor is an integral part of the supply system with the added responsibility of drugs distribution. The role of the medical stores department is eliminated. The material accounting and payment are managed by a lean structure supported by an effective information reporting system. The functional departments which traditionally managed the drugs supply system would be replaced by a third party vendor who would not only supply drugs but also help in distribution.
Revised National Tuberculosis Control Project
Logistics and Distribution of Drugs

1. Introduction

Government of India, as a part of its mission to control Tuberculosis in India, launched the National Tuberculosis programme in 1962. A review of the NTP was carried out in 1992, by a team of experts representing Government of India, World Health Organization and Swedish International Development Agency (SIDA). They found the impact of the NTP to be marginal. A number of recommendations relating to the design, content, organization, management of resources was made to increase the efficiency of the NTP. Based on these recommendations Government of India launched the Revised National Tuberculosis Control Project (RNTCP) with the support of WHO, in 1992.

The first phase (1992-94) of RNTCP covered 2 million people in three different project sites. The second phase (1994-96) covered 14 million people in 14 project sites at the rate of 1 million per site. The RNTCP implementation phase three was launched in the beginning of 1997.

The key characteristics of RNTCP include quality assured diagnosis, standardized short-course combination of drugs, categorization of patients with appropriate drugs regimen for different categories of patients, direct supervision of drug ingestion, examination of the patients during and at the end of the treatment period, uninterrupted drug supply and generation of political commitment to an effective TB control programme. RNTCP is being implemented by Ministry of Health and Family Welfare, Government of India, with technical advice from WHO, using the existing health care infrastructure.

The central theme of RNTCP is DOTS (Directly Observed Treatment, Short Term) strategy which requires direct supervision of drugs administration to the TB patient during the entire course of treatment. RNTCP classifies TB patients into three categories. Treatment for an individual TB patient is in two distinct consecutive phases known as intensive phase and continuation phase. The intensive phase cures the patient and the continuation phase prevents relapse. To ensure continuous availability of drugs during the treatment regime, combination of tablets for a dose is packed in a blister pack and a box containing adequate number of such blister packs is issued to the appropriate TB unit, to cover every new TB case detection.

RNTCP is implemented by using the existing health care infrastructure in India. The health care infrastructure consists of three different inter connected segments viz. the infrastructure facilities consisting of a string of health care facilities like the primary health care centres, district and state hospitals. These facilities are backed by a number of publicly funded research (medical) institutions and clinical laboratories to support programme implementation. A large pool of medical and para medical professionals, supporting staff, medical supplies and financial budget constitutes the second segment of this infrastructure. The information reporting system, project implementation team, Government policies and procedures, technical support by external agencies constitute the third component.
The smallest unit close to a patient is either a TB-unit or a paramedical outfit managed by a health worker or a Primary Health Center (PHC). These units are under the administrative control of the District Tuberculosis Center (DTC). The DTC is managed by a medical officer (DTO). Depending on the population of the district, the DTO may be supported by a X-ray technician, microscopy specialist, stores incharge and number of medical and paramedical staff.

The DTOs are under the overall supervision of State Tuberculosis Officer (STO), who jointly reports to the technical wing of the Ministry of Health, Government of India, headed by Deputy Director General of Health Services, DDGHS(TB), and the respective state health department. The STO is the overall incharge of monitoring RNTCP at the state level. Usually, a state owned and managed TB research cum demonstration center provides technical, scientific and operational support to STO.

At the national level DDGHS (TB) is the project incharge of RNTCP. The DDGHS (TB) is supported by a technical wing for programme design, implementation and monitoring. The WHO project team stationed at New Delhi works closely with the technical wing of DDGHS (TB) for RNTCP implementation. The medical supplies of RNTCP are provisioned by DGS&D, an independent procurement agency of Government of India. The drugs procured by DGS&D are delivered by vendors to one of the seven depots located across the country.

The RNTCP project implementation team recognizes the importance of adequate resources and expertise needed in managing such a comprehensive project. Several important attributes of RNTCP are appropriately designed to ensure its successful implementation. An extensive management control system in the form of quarterly reports, is designed for programme review at the TB Unit level, which is consolidated at the state and national level.

The drugs system is one of the critical support systems of RNTCP, which includes planning (forecasting quantity required), procurement, storage and distribution sub-systems. The DOTS strategy of RNTCP assumes a continuous trouble free supply of drugs to the system. Effective coordination between consumption, procurement, storage and distribution is absolutely necessary to meet this critical requirement. Any internal conflict among these functions would result in excess availability of drugs or non-availability (and consequent expiry) of drugs in the system. From the programme implementation point of view the timely availability of drugs is more important than the inventory cost associated in managing supply. This report reviews the existing drugs supply system to support RNTCP and suggests modifications that are necessary for effective RNTCP implementation.

The methodology adopted in the conduct of the study was to visit various agencies associated with RNTCP, viz. the technical wing in the Ministry of Health and Family Welfare, the DGS&D, medical stores organization, and project sites to get a first hand view on various aspects related to drugs supply. These visits were also used to understand and critically examine the systems and procedures related to drugs procurement, storage and distribution. The site visits provided a feel for RNTCP implementation. Discussion with the stores incharge in DTC as well as field level officials was used to understand the complications in drugs distribution and the expectations of these officials.
The locations visited include: WHO Office at New Delhi, Ministry of Health and Family Welfare, Nirman Bhavan, New Delhi; Directorate of General Supplies and Disposals, R.K. Puram, New Delhi; Government Medical Stores Department, Madras; Project locations Gulabi Bhag, New Delhi and Mehsana District in Gujarat; TRC at Madras; Institute of Thoracic Medicine, Madras; Department of Health, Tamil Nadu Government; Directorate of Public Health, Madras; Tamil Nadu Medical Supplies Corporation, Madras and its regional warehouse at Madras.

2. Existing Drugs Supply System

2.1 Description

The section describes the existing drugs supply system (procurement, storage and distribution) and evaluates its usage in the context of RNTCP. The national drugs supply system is being managed and controlled by sections and departments under DDGHS (TB) and DGS&D jointly. The basic reason for handling procurement and supply of drugs at the national level by DGS&D is to achieve economies of scale in buying and consequent reduction in purchase price. The planning section under the Deputy DGHS (TB) is in charge of determining the quantity required by consolidating indents received from state TB officers, obtaining financial approval for procurement action and allocation of procured drugs to project sites. The DGS&D is in charge of actual procurement, holding inventory and managing drugs distribution.

The preparatory work related to estimating the requirement of TB drugs is done at the DTC, where the requirement of TB drugs is forecasted twice a year. By considering the stock on hand, estimated detection of TB cases (135 out of 100,000 population), an estimate on drugs quantity needed is obtained. This projection is submitted to the state TB officer, who consolidates this on all TB care units under his supervision and transmits it to the planning wing of DDGHS (TB). The indents received from the states are consolidated at the planning wing and a final estimate on total drugs quantity is arrived at. The planning wing communicates the total quantity of drugs required (after obtaining financial sanction) to the DGS&D directorate, for initiating procurement action.

During the first year pilot project, RNTCP procurement was managed by the planning wing of DDGHS (TB). Subsequently, it was decided to transfer this responsibility to the DGS&D. The reasons that influenced this administrative change are (a) procurement is a specialised commercial function and hence best handled by an appropriate agency like DGS&D (b) the technical wing of DDGHS (TB) has limited exposure to commercial function and procedures and therefore is not well equipped to handle this responsibility and (c) DGS&D has vast experience and greater expertise in handling such activities.

When the procurement indent is received by DGS&D, based on purchase value of the total requirement, either a national or an international tendering procedure is initiated. Accordingly, the tender notice is issued and published in specified type of commercial and/or technical magazines. The commercial response to tenders from vendors is awaited until a pre-specified date. The tender documents and commercial offer are scrutinized (for technical and commercial validity) to select a set of vendors to place procurement orders. Operationally,
this would mean a sequence of meetings consisting of representatives from various wings in the ministry. The predominant criterion used in shortlisting vendors and awarding procurement contract is the quoted price. At the end of this process, a decision as how much of what drugs would be purchased from which vendor is made. Accordingly, purchase orders are released to vendors specifying item, quantity and delivery schedule.

The vendors are advised to deliver the drugs to one of the seven medical stores depots located in Bombay, Calcutta, Guwahati, Hyderabad, Karnal, Lucknow and Madras. Purchase order copies are communicated to treasury to facilitate payment and the planning wing of DDGHS (TB) for information and supply coordination. Vendors often request for changes in quantity of drugs to be delivered and delivery time period. After some administrative process, usually this deviation is granted.

When the drugs supply is received at (one of) the medical stores, samples (collected according to random sampling procedure) are sent for quality check to an independent certifying agency. On appropriate quality certification the material is taken into stock. A copy of the material receipt note along with inspection certificate is sent to DGS&D and planning wing of DDGHS (TB). DGS&D transmits these documents to treasury for payment. It also sends quarterly statements on stock on hand, despatches and receipt to the planning wing of DDGHS (TB) for drugs supply coordination and control.

The planning wing, based on stock statement from GMSD and original indent requirement by DTC, prepares and communicates an allocation instruction to the GMSD which forms the basis for drugs despatch to the DTC. On receipt of allocation information, the relevant medical store arranges to despatch the appropriate quantity (subject to stock availability) to DTC by authorized transporters. Usually the mode of transport is by road and transport charges are paid in advance. Accordingly, the stock register in GMSD is updated. Often, variations between DTC requirement and despatch quantity is reported. On such occasions, the concerned DTC refuses to accept drugs supply and returns the drugs to GMSD.

2.2 Observations

2.2.1 Organization

1. The planning wing of DDGHS (TB), and DGS&D operate more or less independently. Consequently, procurement follow up is seldom feasible; stock management is poor leading to excess stock or no stock at the DTC.

2. The focus and importance attached to drugs supply by technical wing of DDGHS (TB) and DGS&D are different. For technical wing, drugs procurement and supply is the only activity and is of prime importance to the success of RNTCP implementation. For the DGS&D, TB drugs procurement is one of the several routine purchase responsibilities at an all India level, and therefore has no special significance.

3. The planning wing 'lacks' the commercial knowledge related to drugs procurement. The purchase wing is seen as not technically equipped to decide on the drugs purchased. The obvious requirement is teamwork.
4. For the GMSD, managing tuberculosis drugs is one of the activities. Actually, in a typical GMSD there are several sub stores (and stores in charge) related to health care projects under implementation by GOI. Consequently, GMSD operates according to its own priority in receiving material, on quality certification, despatch management and stock reporting.

2.2.2 Practices

1. The entire purchase procedure is rule bound. This was perhaps designed to achieve transparency, ensure fair practices and accountability of public expenses. Over a period of time, it has led to increase of paperwork, evolution of complicated procedures, and performance of several non-value added activities.

2. The lowest price as a criterion to select a vendor for placing purchase order has resulted in unhealthy competition among vendors to quote unrealistic prices to secure an order. Often, because of unrealistic prices, vendors resort to contract manufacturing. Further, on such low prices vendors are unable to effect delivery. If they do, adherence to delivery schedule and drugs quality is (often) compromised.

3. The quality certification in the existing system is only a procedural formality. No deviations are reported. The tender evaluation procedure does not consider past quality performance in awarding a contract.

4. The likelihood of default in delivery schedule of supplies is not captured in the bid evaluation system. Often manufacturers who quote and win a contract at a very low price are unable to ensure reliable supply. Since variations in delivery schedule surface only at a later time, the supply system is put under severe strain.

5. The drugs allocation and distribution is managed by the planning wing of DDGHS (TB). The stock position (at DTC) at the time of allocation and despatches is often not known to this wing, due to time lag in stock reporting system.

2.2.3 Performance

1. Indenting, consolidation, order placement, material receipt, stock allocation activities are widely spread over the time horizon. The lead time to convert a purchase indent to purchase order is four months and it takes an additional three months for material to arrive to the system.

2. The procurement cycle time is too long. The cycle time should be shortened for effective functioning of material supply. Unless major changes are initiated in the existing systems and procedures, cycle time reduction is not feasible.

3. Due to long procurement lead time, the supply system is not capable of meeting any additional drugs requirement of DTC or State TB Officer without a reasonable time lag.
4. The DTC officials feedback indicate that either there is too much of drugs or too little. There is no balanced co-ordinated flow of drugs supply. On many occasions, drugs despatched is not needed at the DTC are returned to medical stores incurring avoidable transportation expense and paperwork.

5. The field TB units and DTCs suffer from either non-availability of drugs, or excessive stock of drugs with limited useful (remaining) life time.

6. Before the introduction of combination packs, certain drugs would be available while others may not be, resulting in limitations on dosages administered. Even after the introduction of combination packs, because of shortages or limited (remaining) useful life time of drugs, “breaking up” of patient specific boxes between several patients is often resorted to.

2.2.4 Related Issues

1. In view of (complex) procedural delays, unrealistic procurement prices, delayed payments and excessive paper work involved, several (pharma) manufacturers of repute are reluctant to participate in the Government bidding process.

2. There is no follow up either by planning wing or by DGS&D on pending purchase orders. The whole procurement delivery is left to the discretion of vendors, after a formal purchase order is released.

3. The management of drugs supply system, in its current form is not supported by an adequate reporting system. More fundamentally, performance measures like service level, stockouts, non-moving inventory are not even reported.

4. In reality, every step of the procurement system is followed for the purpose of completion of paper work. The need to comply with regulations takes precedence over value addition and purpose.

5. The motivational level of officials involved in procurement is an important factor which affects the effectiveness of the supply system. In our interactions, barring a few exceptions, we found the motivational level of officials to be low.

2.3 Suggested Modifications

To improve the performance and effectiveness of the drugs supply system as administered by DDGHS (TB), Government of India, several modifications in its present form and systemic changes are needed. These modifications with their associated potential benefits and limitations in implementing them are now discussed.

2.3.1 Structure

The planning, procurement and distribution of drugs should be brought under one single agency for better coordination and effective management control. Consequently, the planning department of DDGHS (TB) would have an operations cell in charge of the entire logistics
related to TB drugs supply. This unified structure would provide the much needed focus in meeting the requirements of the TB drugs system as envisaged in RNTCP. Supply coordination and quick response time would be consequences of such a revised organization. This suggestion is likely to be met with tremendous resistance in the present setup. The fact that technical wing was in charge of purchase for one year during RNTCP pilot implementation may be used to argue in favour of this suggestion and establish this practice as a regular feature. The fact that the DGS&D is an expert body in commercial aspects related to purchase would be an argument against this proposal. However, in our view, this expertise is not getting translated into tangible benefits (in terms of supply system) to RNTCP.

2.3.2 Stores

The GMSD and its stores should be made more responsive to the requirements of RNTCP. Currently, GMSD only plays the role of physical despatch of drugs under the overall guidance of the allocation plan of the technical wing of DDGHS (TB). The GMSD depots are plagued with non-moving stock, have difficulty in managing returned stock from DTC, and are unable to respond or initiate action related to stock out situation in their assigned region. We envisage a more collaborative and complementary role between GMSD and the technical wing of DDGHS (TB). Accordingly, the store supervisors at GMSD need to be trained as distribution managers. They would have the responsibility to allocate and despatch stocks based on updated requirement, usage and stocks at DTCs. They may also be able to bring pressure on the planning section to ensure adequate drugs supply to the system. Since these depots are regionally located the response time to send stocks would be shorter and despatch alternatives to DTCs can be tailor-made. The planning section of DDGHS (TB) would play an important, yet focussed role of managing drugs inventory at all India level by stock transfer across the depots, expediting procurement and follow up, monitoring material flow from GMSD to DTC.

2.3.3 Response Time

The drugs procurement indents are generated twice a year by DTC. The consolidation at the state level and a repeat consolidation at the national level leads to the first delay in initiating action on a purchase request. The decision to procure (the drugs) is further delayed by DGS&D’s systemic procedures. Then, there is a delay in supply commencement and a further delay due to allocation decision and despatch. Therefore, by the time material is delivered to DTC, it may be at least six months after indent placement. The stock, consumption, wastage during this time is not controlled. Therefore, when some drugs stock ultimately arrives at DTC, its utility and usefulness is either limited or marginal. Therefore, the indenting - consolidation - procurement - distribution cycle must be shortened. This can be achieved by switching over to an annual rate contract for longer time duration. Frequently updated stock statements would also help to manage the system better. Such an arrangement does require additional information infrastructure. The quarterly reports that are being generated by GMSD depots are inadequate for the purpose of updating the stock position.
2.3.4 Vendor Development

The procurement decision is essentially based on low cost. The desirability of purchasing drugs worth approximately Rs. 400 million on this criterion alone needs re-examination. The procurement wing needs to rethink whether in addition to cost, any other combination of attributes may be used. This would obviously require convincing various Government departments. Several reputed pharma companies do not wish to participate in the tendering process because of unrealistic prices and long delay in arriving at a procurement decision. Further, on a year to year basis the set (group) of pharma companies who respond to drugs purchase tender enquiry has very little or no overlap. The purchase contract is usually for one year. Consequently, there is no continuity or long term relationship with vendors. This manifests in terms of performance gap between what is promised and what is delivered to the system.

2.3.5 Non-Value Added Activities

Number of activities related to procurement like quality certification, inspection, technical and commercial evaluation of tenders, certification requirements of pharma companies to participate in bidding procedure are performed as rituals. In spite of all these checks and balances, a number of deviations are reported in practice. The possibility of eliminating some of the activities by introducing quality at source, selection of socially responsible and commercially stable vendors, for procurement, should be explored.

2.3.6 Management Information System

A plethora of reports are submitted to the state Government as well as to central Government RNTCP implementation team. These reports do not clearly bring out the supply system performance for its monitoring and control purposes. For example, service level (defined as the percentage of quantity available to quantity needed in a procurement cycle) stock outs, wastages, procurement lead time are neither reported nor monitored. In addition, the unreliable (drugs requirement) forecast at DTC further compounds the difficulty in performance monitoring.

2.3.7 People Involvement

Extensive interaction and detailed discussion with officials involved in the drugs supply system indicates, barring occasional deviations, wide variability in their involvement and responsibilities. These officials believe that the activities related to procurement, storage and distribution are to be performed without violating the established standard procedures. The urge to contribute to the success of RNTCP is at best latent. An awareness and role responsibility campaign may be useful. However, such a campaign alone would have limited impact if other related systemic issues are not dealt with.

To summarise, we are proposing a merger of functional sections to form a consolidated logistics unit to support RNTCP, greater decentralization of decision making in GMSD, streamlining purchase procedures, using a set of alternative indicators to select vendors, more frequent update on stock inventory, trust based long term vendor relationship and inculcating a service orientation in the attitude of the officials associated with RNTCP. While, these
attributes are absolutely necessary to deliver what is expected of RNTCP, this may be difficult
given the realities of Government working and the magnitude of changes required in its
present form. The need to treat RNTCP purchase as a project purchase with a welfare or
service orientation (which is different from routine Government buying) may be a difficult
concept to several concerned officials.

3. Tamil Nadu Government Model

Every State Government in India, has its own drugs procurement and distribution system for
medical supplies to the district and state hospitals owned by it. The broad features of the
system are similar to the Central Government system in terms of indenting, consolidation,
tendering, order placement, material receipt, quality certification and distribution to major
hospitals and consumption locations. The indenting procedure is usually twice a year. The
other systemic hurdles like long response time, procurement based on lowest cost, inadequacy
of quality control and certification, delayed feedback on stock availability, inappropriate
allocation of stock quantity, non-existence of good performance indicator reporting, are
common in state Government medical supplies procurement systems.

In addition, there are local complications as a consequence of state Government policy related
to the medical supply system. Some state Governments have difficulty in providing adequate
financial outlay in the budget for procurement of drugs; some Government programmes are
characterized by abnormal delay in implementing the purchase procedure. Often, the budget
allocated for drugs procurement is shifted to capital equipment purchase for health care
projects of the State Government. While some State Governments have a professional
approach to the drugs supply system, by and large the state Government supply model is a
replica of the central Government system and is characterized by irregularity in stock supply
and low service level. None of these systems are sensitive to the need and requirements of
the drugs supply system of a project like RNTCP. Therefore, there is very little that can be
emulated from such systems.

The Tamil Nadu State Government model seems to be an exception in handling the drugs
supply system. The state Government had formulated an autonomous corporation to handle
procurement, storage and distribution of drugs outside the purview of existing Government
departments. The procurement is through a transparent open tendering system. Supplies are
purchased only from reputed pharma companies (no negotiating intermediate agency) using
the generic name of drugs and not brand names. The purchase contract is usually for a year
and is awarded to a vendor whose quoted price is realistic. The vendor prices are compared
in relation to some standard internal price computation to examine the feasibility of quoted
prices. The quality control and inspection procedures are rigorous. Technical laboratories
of repute have been retained for quality certification based on random samples of incoming
material. The procurement budget is not a constraint, as sufficient allocation of funds are
made available by the state government. The demand forecasting of individual items, is based
on consumption data available for a short period of time. This data is being used by the
system to decide on order quantity.

The physical distribution of drugs is facilitated by half a dozen warehouses located all over
the state. Every user (in this case, a participating hospital or a peripheral health care unit)
is provided with a pass book and a notional financial budget. The user can draw any amount of medicine (at a pre-determined notified price) against the budget. The pass book is accordingly updated. When the original budget is exhausted, additional budgetary sanction is possible with ease. In addition, purchases upto 10% of the original budget can be made by user hospitals independent of the system. In this system, the entire process of indenting is dispensed with.

A computerized Management Information System (MIS) at a state level is used to monitor stock and stock management across warehouses. The only deficiency in the system is it assumes that what is issued to a consumption location through a pass book is actually consumed. The reality may be different. Further, stock accounting procedures are restricted to the warehouses owned by the corporation. However, in the last two years, consequent to the new system being operational the service level and availability of medicines at the user hospitals and health care units have dramatically improved.

In summary, Tamil Nadu state government model does not deal with indent, procurement, storage and distribution cycle. The distribution is directly related to consumption at the field hospitals. The tendering process is effective. Quality certification procedures are professionally managed. The distribution of drugs inventory is supported by a comprehensive information support system.

4. Revised Drugs Supply System

The following list of recommendations are necessary to enhance the capability of drugs supply system in RNTCP.

4.1 Structure

We propose a separate agency (central logistics group) comprising planning, purchase and distribution responsibilities, with a comprehensive mandate to meet all the needs of RNTCP drugs supply system. This new group can be located in either: (a) The technical wing in the DDGHS (TB), (b) the vendor chosen, with a representative to liaise closely with the DDGHS (TB).

4.2 Procurement Strategy

Since RNTCP uses combination of drugs in blister packs, the technical specification of drugs to be procured is well known. We recommend contracting a vendor who can supply and support the (logistics) drugs distribution for a period of two or three years on a projected volume and an accepted price. Consequently, the procurement process is simplified. The vendor to be associated with this project should be an organization of repute with adequate financial and organizational strength. The prime consideration for such a relationship should be willingness to be part of a project like RNTCP which enhances the quality of life by better health care and not based on commercial aspects. A list of attributes that may be used in selecting such a logistics partner is appended. We recommend the process of appointing/associating such a partner may be handled by an expert committee consisting of members from DGHS (TB), DGS&D, and the WHO implementation team. A committee
based decision would ensure appropriate vendor selection and transparency in decision making. When such a vendor is selected, adherence to contract terms would be based on commitment and not on commercial considerations like penalty or reward. Since a box of medicines sufficient for an entire treatment course is allocated to every new case detection, the system has inherent safety in dealing with unanticipated contingencies on demand and disruptions in supply.

4.3 Distribution

The GMSD can be eliminated in the revised distribution system. The vendor would supply an appropriate quantity of needed drugs on a monthly basis or on a quarterly basis directly to DTC under intimation to the central logistics group. The DTC would be the nodal redistribution agency. Quality certification is a consequence of vendor commitment to the project and his pride in associating himself with RNTCP. In the initial stages of implementing the system, random checks may be conducted by the State TB Officers in consultation with DTC stores. The feedback from the field may also be used for corrective action. No major discrepancies are expected, as the vendor (most probably a pharma company of repute) is expected to build this relationship on dignity and trust. As a reciprocation, the vendor may be allowed to use this relationship as national supplier for anti TB drugs, in his other product advertisements. We do not envisage any difficulty in enthusing the involvement of a vendor for this purpose.

4.4 Inventory Control

The main distribution of stock would take place according to a passbook given to each peripheral health institution participating in the RNTCP. It is recommended that one month of stock may be stored with these PHIs, to meet consumption due to variations in demand and supply. On a monthly basis, say the first week of every month, the front end TB care units may draw the requisite number of medicines from the DTC store depending on the new cases detected in the last month so as to maintain one month stock with them. The passbook would have a notional budget which would be updated after every withdrawal from the DTC. It is recommended that the DTC maintains a three months (consumption equivalent) stock. In the proposed system, at the end of the first week of every month the downstream consumption is known. Accordingly, the DTC can provision a requisite quantity (three months consumption - stock on hand) with the central coordination agency. The physical movement of the material could be either from the manufacturing facilities of the vendor or from the district stock keeping centers of the vendor. Information on quantity requisitioned may be communicated to the state TB officer, central logistics group and vendor so that payment process can be initiated. The actual payment may be made, after drugs receipt confirmation report is received.

4.5 Payment Procedures

Payment procedures should be centralized and made simple. It is recommended that payment may be made in advance (say 30% of procurement budget) to the vendor. Since the vendor provides distribution support an additional service charge of say 5% on the cost of drugs may be considered and be decided by negotiation. The advance amount with the vendor can be periodically updated based on actual drugs receipt information received from DTC. Once in
a quarter, there can be an accounting (financial) reconciliation between the logistics control
group and the vendor.

4.6 Redistribution of Inventories

The central logistics group would get monthly stock statements from State TB Officers. The State TB Officer would in turn get stock statements on a monthly basis from DTO. Any accumulation of inventory, abnormal consumption, perpetual shortage would get addressed within a span of one month. The inventory levels in the system would be managed in relation to the number of new cases detected. Based on the dynamics of the situation, stock transfers can be effected via the vendor. Periodical material accounting checks at the DTC by central logistics group as well as checks at the peripheral units by DTC would ensure adequate control on pilferage. Misappropriation of drugs in this system can still happen from boxes (consisting of dosage packs) that are allocated to TB patients who have discontinued their treatment. In our opinion, this can be monitored and controlled from the monthly returns submitted by the DTC.

4.7 Potential Benefits

The system ensures 100% service level. It avoids by definition, stock out situation as well as outdates. The pipeline inventory of drugs is moderate. The stock replenishment is directly related to consumption in terms of new cases reported. The actual consumption over a period of time would hinge on the effective implementation of DOTS. The overall operational cost of the system is measurable (equivalent to the service charge paid to the vendor) and would be less than current operational cost.

4.8 Limitations

The major strength and weakness of the system is the vendor. We expect the vendor to provide not only quality supply of drugs but also value added distribution service. This requirement is within the capability of reputed private pharma companies who distribute their products across the country. The selection of such a partner is an important decision. The DGS&D set up is probably not an appropriate agency to make this decision. The HIV control programme in India, already practices a similar arrangement for effective distribution of HIV test kits.

5. Other Options, Not Recommended

The other possible option to manage drugs distribution is to use a third party logistics support agency. This agency would supervise, for a pre-determined price, the information and materials flow in the system to ensure an effective service level. In India, such service outfits are increasingly available. Logically, this is a feasible option for drugs supply system implementation in the context of RNTCP. However, in this arrangement, the third party logistics agency needs to liaison with the vendor for procurement as well as the technical wing in DDGHS (TB) for distribution. The agency also has to respond to the needs of DTCs and State TB Officers. The weakness of such an arrangement would be higher cost of operation and grey areas related to service level, stock outs, outdates and quality certification.
The tracking of the causes for problems reported in the field and responsibility fixation would be difficult. Also, this option introduces one more agency with no clear responsibility and capability focus. For example, the third party logistics agency would not be able to deliver drugs on time if the vendor, for some reason is unable to ensure distribution of drugs. Hence, such an option is not recommended.

Alternatively, the WHO project office at Delhi can handle this responsibility. This may lead to a high degree of centralization at the WHO project office and require interfaces with several Government agencies. While the responsibility of drugs delivery system would rest with the central logistics group, it may not be able to influence and co-ordinate decisions of the agencies associated with RNTCP, like vendors, DTC, STO etc without appropriate expansion in the resources used. The cost of operating such a structure is likely to be very high. In view of such practical considerations, this option is not recommended.
**Appendix 1**

List of Abbreviations

<table>
<thead>
<tr>
<th>No.</th>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>CHC</td>
<td>Community Health Centre</td>
</tr>
<tr>
<td>2.</td>
<td>DDGHS</td>
<td>Deputy Director General of Health Services</td>
</tr>
<tr>
<td>3.</td>
<td>DGHS</td>
<td>Director General of Health Services</td>
</tr>
<tr>
<td>4.</td>
<td>DGS&amp;D</td>
<td>Director General of Supplies and Disposal</td>
</tr>
<tr>
<td>5.</td>
<td>DHO</td>
<td>District Health (Medical) Officer</td>
</tr>
<tr>
<td>6.</td>
<td>DOTS</td>
<td>The 5-point strategy for TB control promoted by WHO</td>
</tr>
<tr>
<td>7.</td>
<td>DTC</td>
<td>District Tuberculosis Center</td>
</tr>
<tr>
<td>8.</td>
<td>DTO</td>
<td>District Tuberculosis Officer</td>
</tr>
<tr>
<td>9.</td>
<td>GOI</td>
<td>Government of India</td>
</tr>
<tr>
<td>10.</td>
<td>GMSD</td>
<td>Government Medical Stores Depot</td>
</tr>
<tr>
<td>11.</td>
<td>MSO</td>
<td>Medical Stores Organization</td>
</tr>
<tr>
<td>12.</td>
<td>NGO</td>
<td>Non-Governmental Organization</td>
</tr>
<tr>
<td>13.</td>
<td>PHC</td>
<td>Primary Health Center</td>
</tr>
<tr>
<td>14.</td>
<td>STO</td>
<td>State Tuberculosis Officer</td>
</tr>
<tr>
<td>15.</td>
<td>TNMSC</td>
<td>Tamil Nadu Medical Supplies Corporation</td>
</tr>
<tr>
<td>16.</td>
<td>TNSG</td>
<td>Tamil Nadu State Government</td>
</tr>
<tr>
<td>17.</td>
<td>TRC</td>
<td>Tuberculosis Research Center</td>
</tr>
<tr>
<td>Appendix 2</td>
<td>Institutes Visited and Persons Interviewed</td>
<td></td>
</tr>
<tr>
<td>-----------</td>
<td>-------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>WHO, Delhi Office</td>
<td>Dr. Tom Frieden, Medical Officer, TB, WHO, Delhi</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dr. S. Radhakrishna, WHO, SEARO</td>
</tr>
<tr>
<td>2.</td>
<td>Ministry of Health and Family Welfare,</td>
<td>Dr. Khatri, Deputy DGHS (TB)</td>
</tr>
<tr>
<td></td>
<td>Nirman Bhavan, New Delhi</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>TB Project Site, Gulabhi Bhag, New Delhi</td>
<td>Dr. R.K. Mehra, Project Incharge, Delhi</td>
</tr>
<tr>
<td>4.</td>
<td>Directorate of General Supplies and</td>
<td>Dr. Biswas, Deputy Director General</td>
</tr>
<tr>
<td></td>
<td>Disposal, R.K. Puram, New Delhi</td>
<td>Mr. Murthy, Section Officer</td>
</tr>
<tr>
<td>5.</td>
<td>Government Medical Stores Depot, Madras</td>
<td>Dr. Ramana, Assistant Director General</td>
</tr>
<tr>
<td>6.</td>
<td>Mahavir Hospital, TB Clinic, Hyderabad</td>
<td>Dr. Murthy, Consultant Physician</td>
</tr>
<tr>
<td>7.</td>
<td>State Health Services, Hyderabad</td>
<td>Dr. Ishwariah, Joint Director</td>
</tr>
<tr>
<td>8.</td>
<td>Administrative Staff College of India,</td>
<td>Dr. G.N.V. Ramana, Faculty member, ASCI</td>
</tr>
<tr>
<td></td>
<td>Hyderabad</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Tuberculosis Research Center, Spurtank</td>
<td>Dr. P.R. Narayanan, Director</td>
</tr>
<tr>
<td></td>
<td>Road, Chetput, Madras</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Institute of Thoracic Medicine, Madras</td>
<td>Dr. Jaganath, Professor</td>
</tr>
<tr>
<td>11.</td>
<td>Tamil Nadu Government Health Services,</td>
<td>Mr. R. Poornalingam, IAS</td>
</tr>
<tr>
<td></td>
<td>Madras</td>
<td>Secretary, Department of Health</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dr. K. Bhaskaran, Additional Director of</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medical and Rural Health</td>
</tr>
<tr>
<td>12.</td>
<td>Tamil Nadu Medical Supplies Corporation,</td>
<td>Mr. Mohanthy, IAS, Managing Director</td>
</tr>
<tr>
<td></td>
<td>Madras</td>
<td>Mr. T.T. Guhan, Senior Regional Manager,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mr. Suresh, Quality Control Incharge,</td>
</tr>
<tr>
<td>13.</td>
<td>Gujarat State Health Department,</td>
<td>Dr. B.M. Soni, Assistant Director (TB)</td>
</tr>
<tr>
<td></td>
<td>Gandhinagar</td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>Gujarat State TB Project, Mehsana</td>
<td>Dr. Jadhav, DTO, Mehsana District</td>
</tr>
</tbody>
</table>
Appendix 3

Procurement Process

Case 1

Nov. 4, 1996 - Purchase intimation (Value Rs. 14 million) from TB Division
Nov. 5, 1996 - The concerned section in DGS&D records this intimation
Nov. 6, 1996 - Departmental approval sought by the concerned section of DGS&D
Nov. 7, 1996 - Departmental approval obtained
Nov. 11, 1996 - Bidding documents released
Dec. 6, 1996 - Tender document opened

(86 firms were approached, 24 companies responded, 8 bids were actually received)

Dec. 12, 1996 - Summary of bids (eligibility) presented
Dec. 20, 1996 - Technical committee was not finalized on intervention by superiors, committee was formulated
Jan. 6, 1997 - Technical committee was announced: gets to work
Jan. 13 & 28, 1997 - Meetings of the technical committee: No final decision. The tenders were referred to yet another committee
Feb. 4 & 5, 1997 - Technical committee recommendation finalized
Feb. 11, 1997 - Purchase Advisory Committee meeting held

In view of time delay, a quantity equivalent to 4 month consumption was ordered based on the lowest bid. Fresh tender was to be called for the remaining order or seek ministry’s permission for modifications.

April 1997, the purchase request is still pending.
Appendix 3: Procurement Process (contd.)

Case 2

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan. 22, 1997</td>
<td>Indent received on 22.1.97 for a requirement before April 1997.</td>
</tr>
<tr>
<td>Jan. 24, 1997</td>
<td>Purchase proposal put up for departmental approval</td>
</tr>
<tr>
<td>Jan. 28, 1997</td>
<td>Departmental approval received</td>
</tr>
<tr>
<td>Jan. 30, 1997</td>
<td>Tender document released</td>
</tr>
<tr>
<td>Feb. 17, 1997</td>
<td>Tender opening date</td>
</tr>
<tr>
<td>Feb. 19, 1997</td>
<td>Shortlist prepared for purchase Advisory Committee</td>
</tr>
<tr>
<td>Feb. 20, 1997</td>
<td>Proposal to Purchase Advisory Committee</td>
</tr>
<tr>
<td>Feb. 21, 1997</td>
<td>Purchase committee approval</td>
</tr>
<tr>
<td>Feb. 26, 1997</td>
<td>Order placed on vendor with scheduled delivery on 15.3.97</td>
</tr>
</tbody>
</table>

As of end April 1993, material not received. Status unknown.
### Attributes That May be Considered in Selecting a Vendor/Distributor

<table>
<thead>
<tr>
<th>Attributes</th>
<th>Desirable Level</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Organisation</strong></td>
<td></td>
</tr>
<tr>
<td>Reputation</td>
<td>Excellent image</td>
</tr>
<tr>
<td>Years of existence</td>
<td>At least 5 years</td>
</tr>
<tr>
<td>Growth in Sales Turnover,</td>
<td>Consistent Growth; at least 5% more than inflation rate</td>
</tr>
<tr>
<td>Profitability and Gross Margins</td>
<td></td>
</tr>
<tr>
<td><strong>2. Facilities</strong></td>
<td></td>
</tr>
<tr>
<td>Manufacturing location</td>
<td>Multiple locations</td>
</tr>
<tr>
<td>Plant capacity</td>
<td>At most 10% for TB drugs</td>
</tr>
<tr>
<td>Technology and Choice of Equipment</td>
<td>Established and/or state of art.</td>
</tr>
<tr>
<td><strong>3. Operations</strong></td>
<td></td>
</tr>
<tr>
<td>Adherence to Good Manufacturing practices</td>
<td>High</td>
</tr>
<tr>
<td>Manufacturing Cycle time</td>
<td>Shorter (About 3 weeks)</td>
</tr>
<tr>
<td>Inventory turns</td>
<td>At least 15</td>
</tr>
<tr>
<td>Quality Assurance System</td>
<td>Excellent</td>
</tr>
<tr>
<td>Product costing</td>
<td>Activity based costing</td>
</tr>
<tr>
<td>Vendor rating system</td>
<td>Relevant</td>
</tr>
<tr>
<td><strong>4. Sourcing</strong></td>
<td></td>
</tr>
<tr>
<td>Vendor base</td>
<td>Moderate volume</td>
</tr>
<tr>
<td>Operational flexibility</td>
<td>Medium to High</td>
</tr>
<tr>
<td>Financial stability</td>
<td>High</td>
</tr>
<tr>
<td>Quality Assurance Systems</td>
<td>Excellent</td>
</tr>
<tr>
<td>Technology used</td>
<td>Appropriate state of art</td>
</tr>
<tr>
<td><strong>5. Distribution</strong></td>
<td></td>
</tr>
<tr>
<td>Spread</td>
<td>High</td>
</tr>
<tr>
<td>Reach</td>
<td>95% of Indian population</td>
</tr>
<tr>
<td>Location of Warehouses</td>
<td>Fairly spread</td>
</tr>
<tr>
<td>Response time</td>
<td>At most 15 days</td>
</tr>
<tr>
<td>Service level</td>
<td>At least 95%</td>
</tr>
</tbody>
</table>
Appendix 5

Extracts from the World Bank’s Staff Appraisal Report on the Indian RNTCP

RNTCP Project Implementation

The project would be implemented in a decentralized fashion through the structure of the National Tuberculosis control Program, the existing health system at the state level and below, and NGOs experienced with community participation and health sector activities.

Role of the Central TB Division: Project implementation would be coordinated by the Central Tuberculosis Division under the director General for Health Services in the MOHFW with the support of the Central Training and Research Institutes. From the administrative side of the Ministry, the project would be coordinated by an official at the level of Joint Secretary. The Division would be responsible for the management of the proposed project. This would include: coordinating the program with the states, ensuring flow of funds to States and District Societies, overseeing the implementation of the technical and operational policies, guidelines and procedures through frequent field visits and data analysis, coordinating the procurement and distribution of drugs, vehicles and selected equipment, reviewing media services and program evaluation proposals. It would also oversee implementation of training, IEC and outreach, monitoring and evaluation, MIS system, and operations research. A full-time Program Director dedicated solely to the management of the NTP has been appointed by the MOHFW and would be the primary manager of project implementation.

Role of the National Tuberculosis Control Board. This advisory Board would be chaired by the Union Health Secretary with the Director General of Health Services as the vice-chair. It would act as an apex body and would be responsible for policy formulation, approval of annual implementation plans, approval of budgets and allocation of resources, coordination with other GOI departments, and evaluation of program objectives and achievements. The purpose of this body would be to promote an integrated approach to TB control nationwide. The Board would include staff from the main TB Research and Training institutes, the private and NGO sectors and representatives of donor organizations as members.

Role of the State Tuberculosis Control Cell. The State Cell would be responsible for the implementation of the project at the state level and for ensuring coordination and integration of the program with relevant institutions, including medical colleges. The State TB Cell would be supported by a Tuberculosis Coordinating Committee responsible for periodic program reviewers.

Role of the District Tuberculosis Center (DTC). The District Tuberculosis Centre (DTC) is the most important implementation unit at the District level and is responsible for the overall success of the project in the district, including: (a) training and direct supervision of the staff of the sub-district Tuberculosis Units; (b) consolidating and maintaining patient records by cohorts; (c) providing technical assistance to all health facilities offering TB services; and (d) coordinating TB activities with NGOs and the private sector, maintaining quality control, and reporting project outcomes to the state cell.
Role of the District Societies. The District Tuberculosis Society would be responsible for ensuring availability of funds for payment of honoraria, contractual services, laboratory supplies, selected IEC activities and maintenance expenses, including petrol, oil and lubricants (POL) for vehicles. It has been agreed that in those districts where a District Leprosy Society or other Health Society is in operation, the charter could be modified to expand its activities to include TB control. Alternatively, a new District TB Society would be formed. As already established, the Societies would be chaired by the District Collector and the District TB Officer (DTO), assigned to the District TB Center would act as Secretary for the Society. Half of the Society's membership would be comprised of representatives from NGOs and the private sector. Both as Secretary of the Society and as the main officer for TB control, the DTO, under the District Chief Medical Officer, would be responsible for the appropriate implementation of the project at the district and sub-district levels and for integrating the TB activities in the district with general health services, including the involvement of the NGOs and the private sector. Annex 8 provides details on the District TB Societies.

Role of the Tuberculosis Units (TUs). The TB Units at the sub-district level comprised of a Senior TB Laboratory Supervisor (STLS) and a Senior TB Supervisor (STS), would play a critical role in ensuring project success as their key responsibility is to ensure quality control for laboratory work, case management, and patient registration and reporting at the peripheral level where treatment services would be provided.

Role of the City Corporation. In the City Corporations, project implementation would be the responsibility of the TB Officer of the Corporation with the technical support from the District TB Officer. They would have joint responsibility for the implementation of the project, with the MO providing the managerial supervision of the staff and the DTO providing the technical supervision and advice on the program.

Role of WHO in the Project. Starting with the 1992 Program Review, WHO has collaborated with the Government of India and with the IDA project team, having played a pivotal role in the design and preparation of the project. As a co-financer of technical assistance under the project, WHO's important role would continue during implementation. Specifically, WHO would assist the National Program by: (a) providing TB technical assistance through a TB Advisor stationed in Delhi; (b) facilitating the implementation of drug quality control; and (c) providing technical support and advice to IDA, GOI and the state governments in project management and evaluation.
Proposed Drug Supply System

- Payment
- Logistics Center
- Treasury
- Contract
- QC Reports
- Requisition
- STO
- MIS
- TB Unit
- DTC
- Vendors
- Drugs
- Labs

Flowchart showing the processes and connections between different departments and systems in the proposed drug supply system.