STANDARD OPERATING PROCEDURES MANUAL FOR STATE DRUG STORES

UPDATED

October- 2012

Central TB Division, Directorate General of Health Services
Ministry of Health and Family Welfare, Nirman Bhawan,
New Delhi 110108

FOREWORD

It gives me immense pleasure to present the Revised Standard Operating Procedures Manual for State & District Drug Stores. As you are all aware, the DOTS Programme is being implemented in the entire country since March 2006 and has become the second largest Programme in the world. It is the endeavor of Govt. of India to now continue the efforts to sustain this vast programme.

One of the most important components out of the five components of RNTCP is the uninterrupted supply of drugs. To ensure this, the National Programme has established a monitoring system which needs to be continuously monitored, reviewed and further improved. A good system is extremely important, allowing for rapid assessment of progress and problems so that timely corrective actions can be taken immediately.

With all States now having established fully operational State Drug Stores in their States, the total number of State Drug Stores now stands at 39. The mammoth task of ensuring uninterrupted supply of drugs in the whole country is now being decentralized to the States with the help of various training activities conducted by officials of Central TB Division and from M/s. Strategic Alliance Management Services Pvt Ltd., an Agency appointed by WHO to assist Central TB Division in management of drugs and other logistics.. A vast improvement in drug management at the State levels has since been noticed but with Pediatric & MDR Drugs also becoming an integral part of RNTCP, the drug management activity has become slightly more complex, necessitating the need to revise the Drug Stores Manuals.

I would like to express my sincere thanks to M/s. Strategic Alliance Management Services Private Ltd. who have developed & revised this manual in collaboration with the Programme Officials working in the field & to WHO for their continuing assistance.

DDG (TB)

CONTENTS

APPENDICES

ABBREVIATIONS

ACI	Advanced Consignment Intimation
ADR	Additional Drug Request
ADS	Adequacy of Drug Stocks
BC	Bin Card
CIT	Communication & Information Technology
CMO (TB)	Chief Medical Officer (TB)
CP	Continuation Phase
CTD	Central TB Division
CTD-RO	Central TB Division-Release Order
DANIDA	Danish International Development Agency
DDG (TB)	Deputy Director General (TB)
DFID	Department for International Development
DIV	District Issue Voucher
DLS	Drug Logistics Supply
DOE	Date of Expiry
DOTS	Directly Observed Treatment, Short course
DTA	Drugs Transfer Advice
DTC	District TB Centre
DTO	District TB Officer
FEFO	First Expiry First Out
GDF	Global Drug Facility
GFATM	The Global Fund to fight AIDS, Tuberculosis and Malaria
GMSD	Government Medical Store Depot
GRAN	Goods Receipt Acknowledgement Note
IM	Inventory Management
IAP	Indian Association of Pediatricians
IP	Intensive Phase
MC	Microscopy Centre
MDR	Multi Drug Resistant

MO	Medical Officer
MSS	Monthly Stock Statement
Na-PAS	Sodium PAS
PHI	Peripheral Health Institute
POD	Proof of Delivery
PVS	Physical Verification Sheet
PWB	Patient Wise Box
QRPML	Quarterly Report on Programme Management & Logistics
RNTCP	Revised National Tuberculosis Programme
RR	Reconstitution Register
SDS	State Drug Store
SIV	State Issue Voucher
SN	Stocking Norms
SO	Supply Order
SR	Stock Register
SSU	Sub-Stocking Unit
STO	State TB Officer
TU	Tuberculosis Unit
UOM	Unit of measurement
USAID	United States Agency for International Development
WRDR	Worksheet for Reporting Drug Requirement

INTRODUCTION

The Revised National Tuberculosis Control Programme (RNTCP) comprises an application of DOTS principles in the Indian context. The programme was started in the country in 1997 and the entire country implemented the programme by March 2006 with assistance from World Bank. Ensuring continuous availability of good quality anti-TB drugs is an essential feature of RNTCP.

The Pediatric Patient-Wise Boxes (PWBs) have been introduced for the first time for treatment of pediatric patients under the programme. The Country is also rapidly expanding availability of MDR Drugs/ 2nd Line drugs for patients who may have already taken treatment in the past but have developed resistance towards one or more Anti-TB drugs. These developments in the programme necessitated revision in SOPs and accordingly guidelines on treatment of pediatric patients and management activity for such drugs has also been included. This Revised Manual also includes information on the procedures for procurement and management of the second-line drugs used in the treatment of multi drug-resistant TB. *(**Note**: Unless otherwise stated in this manual, Anti-TB drugs shall be referred to only 1st line drugs for adult patients under the programme)*

Under the programme, drugs are administered to patients under direct observation, through an extensive network of more than 400,000 DOTS centres, in 35 states & UTs across the country. Ensuring drug adequacy and smooth management of the supply chain in a programme of this magnitude has been a Herculean task, hitherto managed by the Central TB Division (CTD) at the central level. It is now the endeavor of CTD to decentralize this aspect of drugs logistics to the respective states.

The drug management function encompasses the activities of procurement, distribution, usage, monitoring and reporting.

Procurement

Procurement, Supply & Logistics Unit has been established in Central TB Division (CTD) for procurement and logistics functions at the Central level. The unit is under the supervision of a Chief Medical Officer and is supported by a Procurement & Supply Management Consultant. The procurement is done through a Procurement Agency hired by MoHFW, based on requirement calculations and Technical specifications formulated by CTD, pursuant to their approval by a Technical Committee. An agency, outsourced with the support of WHO is performing Drug Logistics functions at CTD.

The procurement (both for World Bank and GFATM funded states) is done at the level of Ministry of Health & Family Welfare (MoHFW), Govt. of India from only Suppliers who can supply “WHO Pre-qualified products” defined as manufacturers complying WHO-Good Manufacturing Practices (GMP) as assessed by WHO Pre-qualification Programme.

The procurement of 2nd Line Anti TB Drugs for the World Bank funded states is done through International Competitive Bidding (ICB) by the procurement agency of MoHFW. For the states funded by GFATM, these drugs are procured through Global Drug Facility (GDF) of Stop TB Partnership.

Distribution & Monitoring

Distribution of drugs to the range of service delivery outlets under the programme has to be carefully monitored, so as to ensure uninterrupted availability of quality drugs. Requirements at drug stocking points are worked out on the basis of current utilization patterns and expected stocks at the time of delivery. The drug distribution process of 1st line drug is depicted in Table 1 on next page and summarized below:

(1) Distribution of drug supplies is primarily effected from the manufacturer to the Government Medical Stores Depots (GMSDs) at Karnal, Mumbai, Kolkata, Chennai, Guwahati and Hyderabad

(2) Monitoring of drug supplies with regard to requirement and consumption is done through a system of Quarterly Reports, tracking the drug stock position at each district by providing details of the following:

(a) Patients put on treatment during the quarter

(b) Quantities of different drug items consumed

(c) Stock of different drug items received during the quarter

(d) Closing stock of drug items

(e) Drug requirements of the districts.

In case of 2nd line drugs, the suppliers are required to deliver drugs directly to the consignees which are the State Drug Stores of the implementing State.

State Drug Stores

For the long-term sustainability of the programme, as well as to facilitate its fast expansion, it has become necessary to decentralize aspects of drug management to the states. An important initiative in the context of the above has been the establishment of State Drug Stores (SDS) in implementing states.

SDS' facilitate the distribution of anti-TB drugs within the State by sharply reducing lead-times for fulfilling drug requests, thereby helping ensure uninterrupted supply of anti-TB drugs. There is obvious need for all states to have at least one SDS and some of the larger states may need more than one. Based on this need, RNTCP has desired norms for establishment of SDS in a State. As per RNTCP, 1 SDS may be established for each

50 million population. For hilly & difficult States, at least one SDS is required to be established.

Advantages of establishing SDS' include the following:

1. Reduced complexity of logistics management for CTD and GMSDs, as intra-State, district level drug requirements, shall be fulfilled directly by the SDS'

2. Significantly improved response times for fulfilling the emergency drug requirements of DTCs, as these shall be serviced from geographically proximate SDS

3. Sharply improved management of drug inventory at DTCs through the STOs' ability to micro-manage and access more current information on drug availability and requirements, etc.

Standard Operating Procedures for State Drug Stores (SDS)

This manual documents standard operating procedures recommended for SDS', covering interalia, the following activities:

1. Receipt of Drugs at State Drug Stores

Procedures to be followed for the receipt of drugs at the SDS and the subsequent updation of stock records.

2. Issues/ Dispatches by State Drug Stores

Procedures to be followed for the issue and dispatch of drugs by the SDS.

3. Inventory Management

Procedures for tracking and replenishment of drug inventory at the SDS and subordinate stocking points within the state.

4. Expiry Management

Procedures to be followed for management of short-expiry drugs and other items at the State, district & sub-district levels.

5. Physical Verification & Reconciliation of Drug Stocks

Procedures to be followed for the periodic physical verification and reconciliation of drug stocks at the SDS.

6. Communication & Information Technology Infrastructure (CIT)

Communication and Information Technology infrastructure required by the SDS.

7. **Staffing Requirements**

   Staffing requirements for the efficient discharge of stores and logistics functions.

8. **Location, Space & Storage Arrangements**

   Location, space and storage arrangements to be created at the time of establishing/upgrading the SDS.

9. **Secure Custody of Drugs**

   Measures to be taken to ensure the secure custody of drugs at the SDS.

10. **Guidelines on Treatment of Pediatric Dugs**

    Detailed guidelines on treatment of pediatric patients with pediatric patient-wise boxes.

11. **Guidelines on Management of drug Logistics for PMDT/2nd Line Drugs**

    Detailed guidelines required to be adhered to for treatment of Multi Drug Resistant (MDR) patients under RNTCP.

12. **Arrangements for Transportation of Drugs**

    Arrangements required to be made for the transportation of drugs from the SDS to various stocking units in the State.

13. **Reconstitution**

    Recommended procedures required to be employed when reconstitution of drugs is necessitate.

14. **Quality Assurance**

    Procedures instituted by CTD to maintain the quality of drugs, throughout their shelf life.

The manual documents detailed procedures to be followed for the above activities by concerned RNTCP functionaries. Additionally, operational forms for reports, records and registers to be maintained, as well as MIS reports, helping designated officers to oversee drug logistics, have also been provided.

Role of State TB Officer

The State TB Officer (STO) plays a vital role in implementing SDS procedures described in this manual and ensuring the institution of effective drug management systems in the state. Key responsibilities of the STO include the following:

1. Overall supervision of SDS operations and Inventory Management of drugs.

2. Review of drug stock adequacy at all levels, ensuring their uninterrupted supply.

3. Timely submission of the quarterly report for the state and monthly report for the SDS.

4. Timely corrective action to prevent drug expiry.

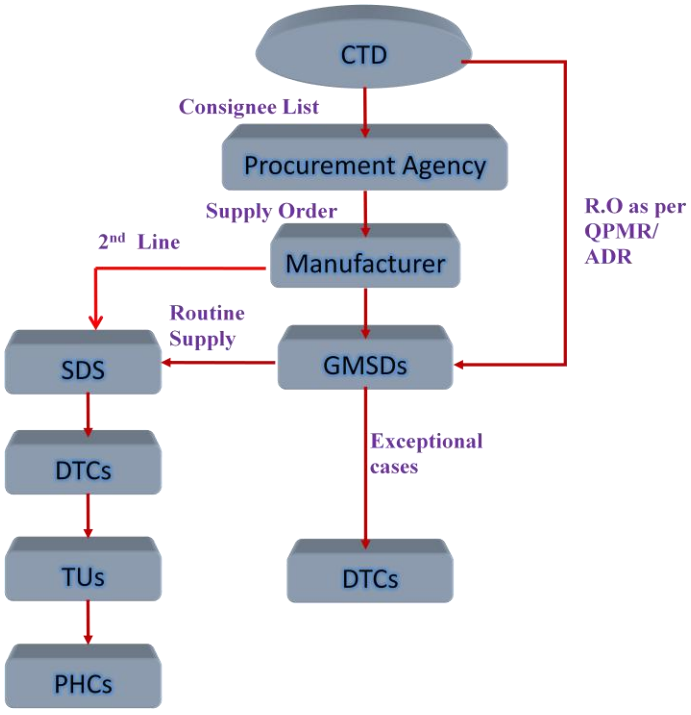
5. Timely action to redistribute drugs to prevent local shortages.

Quality Assurance

Maintaining quality control of drugs is a critical programme requirement. This is enabled through pre-dispatch testing of drugs. In addition, CTD has hired an independent quality control laboratory, which regularly tests samples, both 1st & 2nd line drugs, lifted on a random basis from District Tuberculosis Centre's (DTCs), SDSs and GMSDs. An overview of the Quality Assurance Scheme established by CTD has been provided in Appendix III to this manual.

A system is also in-place for the quality assurance of drugs through random sampling by GMSDs as well as sampling on the basis of specific complaints by State and Central Drug Inspectors.

DEPICTION OF DRUG DISTRIBUTION PROCESS



RECEIPT OF DRUGS AT STATE DRUG STORES

This section deals with procedures to be followed for the receipt of drugs at the State Drug Stores (SDS) and immediate next steps for the updation of stock records and storage/ stacking of materials.

Overview

SDS' may receive 1st line drugs from multiple sources including:

1. Government Medical Store Depots (GMSDs)

2. SDSs of other states

3. DTCs/ SDSs of the same state

GMSDs shall be the primary stocking points, for receipt of anti-TB drugs from the manufacturers and distribution to SDSs across the Country.

Receipts from GMSDs/ SDSs (in other states) are coordinated by Central TB Division (CTD) and are usually in response to quarterly reports/ additional stock requests made by State TB Officers (STO) and/or District TB Officers (DTO). (Note: Receipts from SDSs in other states may in some cases comprise transfers authorized by CTD, to adjust excessive drug stocks accumulating with the concerned SDS).

Returns/ transfers from districts/ other SDSs (in the same state) are usually a direct consequence of instructions issued by the STO to correct stock imbalances observed within the state.

Procedures recommended for the above transactions are described below.

Receipt of Drugs From GMSDs

The Pharmacist shall perform the following functions on receipt of drugs from the GMSD(s):

1. Ensure that an approved copy of the CTD- Release Order (CTD-RO), issued by the Central TB Division, is received either before or along with the consignment. The CTD-RO serves as an authorization document, enabling the SDS to receive the consignment of drugs.

2. Additionally ensure that a complete set of transmission documents (including the Issue Voucher of the GMSD, Delivery Challan, Consignee Copy of Lorry/ Courier Receipt etc.) describing the contents of the shipment, is handed over by the transporter, along with the incoming shipment of drugs.

3. Check the contents of the incoming consignment to ensure conformity with CTD-RO and specifications as per the GMSD's transmission documents, as above.

   (***Notes:***

i. The check shall be limited to visual inspection and count of the number of cartons received and matching the same with the Issue Voucher and Challan of the GMSD. The Storekeeper will not ordinarily open sealed cartons unless:

   a. The seal and/or exterior suggest damage or shortage.

   b. Shortages have been frequently observed in the recent past, suggesting that it would be prudent to verify contents. In such cases, verification may be carried out for a period of time or in respect of a specific GMSD or transporter.

ii. There could also be instances where the GMSD has opted to make part shipments. In such cases, the Storekeeper shall flag the CTD-ROs in question and record details of drugs received and the balance quantity pending supply. The Storekeeper shall follow-up closely with the supplier in respect of all flagged CTD-ROs, ensuring that balance supply is made at the earliest).

4. In case of shortages and/ or transit damages determined through visual inspection, the same should be brought to the attention of the transporter. Details of the shortage/ damage should be noted on the GMSD Issue Voucher / Delivery Challan/ Lorry Receipt and the transporter's attestation thereof obtained by means of signature.

   *(**Notes:***

i. In the case of shortage/ damage determined by the Storekeeper through visual inspection s/he shall take the precaution of opening the seals of all cartons received and carefully checking their contents down to the lowest packaging unit (PWB).

ii. Ideally, SDS should take custody only of undamaged stock from the perspective of the drugs in question being in a good enough condition to be administered to patients. SDS storekeeper shall segregate and preserve damaged stocks till further instructions are received).

5. After visual inspection, acknowledge drugs received in GMSD Issue Voucher/ Challan/Lorry Receipt and return it to the transporter. The Storekeeper shall retain a copy of the above document in the **Stores Receipts File**.

6. In the exceptional cases, where shortages/ transit damages are noticed, the Storekeeper shall forward a photocopy of the transporter attested GMSD Issue Voucher/ Challan to the STO within 15 days of receipt, retaining a copy of the same

in the stores receipts file. The copy of such Issue Voucher & Challan should be sent to the GMSD & CTD for necessary action at their end.

7. Record complete details of the drug consignment actually received (viz. GMSD Issue Voucher Particulars, Batch Reference, Date of Expiry, etc.) in the Bin Card (BC: Form Reference 1- A) & in the relevant folio of the Stock Register (SR: Form Reference 1–B).

   *(**Note:***

   a) In the case of shortage/ damage/ discrepancy in the quantity of drugs actually received vis-à-vis that indicated as per the transmission/ authorization document, record complete details of the same in the 'Remarks' column of the SR and highlight the same.

   b) In case transmission documents are received prior to receipt of drugs, entry shall not be made in the SR on the basis of such documents viz. CTD-RO, GMSD Issue Voucher / Challan.

   c) Alternatively, if drugs are received prior to receipt of transmission documents, entry in SR shall be made only after their receipt and confirmation as to the quantity supplied by GMSD or the respective sending unit.)

Receipt of Drugs from State Drug Stores of other States

Pursuant to the quarterly review, CTD may periodically authorize transfer of drugs from one state to another state, to adjust stock imbalances and/or ensure the timely utilization of close to expiry drugs. A formal Drug Transfer Advice (DTA: Form Reference I–D), shall be prepared at CTD & e-mailed/ faxed to both the transferor/ sending unit and the transferee/ recipient unit. Following this, the Storekeeper of the transferor/sending unit shall generate a State Issue Voucher (SIV: Form Reference I–C).

On receipt of the transferred drugs, the Storekeeper of the recipient unit shall repeat steps (1) to (7) detailed at above paras on receipt of drugs transferred from other SDSs, with the exception that the authorization document in this case shall be the DTA and acknowledgement of the drugs received should be made by signing the SIV. Acknowledged copies of the SIV should be sent to the STO, transferring SDS & to CTD.

Intra-State Return/ Returns of Drugs from districts

In the normal course, the SDS shall receive drugs from the GMSDs. However, pursuant to the quarterly review, the STO may authorize returns/ transfers from DTCs or multiple SDSs within the state, to adjust stock imbalances and/or ensure the timely utilization of

close to expiry drugs. Once again, a formal DTA should be generated by the STO for the purpose and e-mailed/ faxed to the transferor/ sending unit and the transferee/ recipient unit. In the same manner as stated above, the Storekeeper of the transferor/ sending unit shall generate a SIV/DIV and arrange for the dispatch of drugs as requested.

The Storekeeper of the recipient unit shall repeat steps (1) to (7) detailed at previous pages on the receipt of drugs transferred from other SDSs or DTCs within the state, with the exception that the authorization document in this case shall be the DTA. Acknowledgement of drugs received should be made by signing the SIV or DIV, as the case may be. Acknowledged copies of the SIV/ DIV should be sent to the STO, as well as the transferring SDS/ DTC.

Advance Intimation

Receipts at the SDS should ideally be preceded by advance intimation; CTD-RO shall serve this purpose, as the copy is simultaneously sent to GMSDs & SDS. The advance intimation shall enable the Storekeeper to make space and other arrangements for receiving the drugs.

The Storekeeper shall track receipt of drug supplies within the timelines indicated by the advance intimation. In case supplies are delayed over & above the timelines indicated, s/he must bring the delay to the attention of the GMSD by fax/ e-mail, marking a copy of the same to the concerned Officer-in-charge of drug logistics, to appropriately escalate attention.

In some cases, the SDS may not receive advance intimation. In such situations, the Storekeeper should accept the drugs, provided that the shipment is accompanied by necessary documents. The Storekeeper should immediately inform the STO/ CTD of the receipt of drug supplies for further necessary action.

Road Permits

Local taxes are levied by some states and payable at border entry/ check-posts, as the drug supplies enter the state. In the case of such states, availability of a ‘Road Permit’ along with the drug supplies ensure that levies as above are not attracted, as the drugs are meant for free distribution to patients and supplied under a National Health Programme. Accordingly, GMSDs shall request ‘Road Permits’ from consignees in states attracting local taxes in advance, giving complete details of the drugs being dispatched by them.

*(**Note:** Road Permits may be obtained from the Sales Tax Office. Four copies of the same are to be filled-up by the consignee, giving complete details of the name of the GMSD, description of drugs and their quantities, their value etc. as per information provided in advance by the GMSD. Three copies of the road permit shall be forwarded to the GMSD and the fourth retained by the consignee for record. Drugs should not be*

dispatched, without the Road Permit, by the GMSD. One copy of the Road Permit shall accompany the drugs to the consignee, one copy shall be retained by the GMSD and one copy submitted to the Sales Tax authorities, by the GMSD).

Forms referred to in this section of the manual

Title	**Reference**
GMSD Issue Voucher	External Document
Bin Card (BC)	I-A
Stock Register (SR)	I–B
State / District Issue Voucher (SIV / DIV)	I–C
Drugs Transfer Advice (DTA)	I–D

ISSUES / DISPATCHES BY STATE DRUG STORES

This section deals with procedures to be followed for the issue and dispatch of drugs by State Drug Stores (SDS)

Overview

SDSs shall issue and dispatch drugs under the following circumstances:

1. Routine quarterly supplies to District Tuberculosis Centers (DTCs)
2. Supplies to DTCs against Additional Drug Requests (ADR)
3. Transfers to other SDS(s) in the same state
4. Transfers to SDS(s) in other states

Issues for the purpose of routine quarterly and additional/ supplementary supplies to DTCs or transfers to other SDSs in the same state, shall be determined by the STO or officer in-charge (authorized by the STO for the purpose), on the basis of analysis of Quarterly Report on Programme Management & Logistics (QRPML) and/ or ADRs. Transfers to SDSs in other states, if any, shall be made on the basis of instructions from CTD.

Implementing DTCs shall be linked to the most convenient SDS (in terms of proximity and transportation arrangements), in the case of states having more than one SDS. Ideally DTCs shall only receive supplies from the associated SDS, identified through the above process.

Procedures recommended for the above transactions, are detailed in the paragraphs that follow.

Routine Quarterly Supplies To DTCs

Quarterly replenishment of drug stocks with districts shall be based on the QRPMLs submitted by them, providing complete details of opening and closing stocks, receipts, consumption and anticipated requirement.

Information provided in the QRPML, (derived in turn from detailed TU-wise drug stock statements), shall be incorporated in the Worksheet for Reporting Drug Requirement (WRDR-DTC: Form Reference I–E) to help determine the drug requirement of districts for the next quarter, considering drug stocks availability, utilization/ consumption of drugs during the quarter, stocking norms, etc.

WRDRs shall be discussed and approved by the concerned officer-in-charge and followed by the release of quarterly supplies to DTCs by the Pharmacist, as per the

workings therein and/or the generation of Drug Transfer Advice (DTA) in the case of drug stock imbalances at districts requiring adjustment.

*(**Note:** WRDR shall be used for authorizing issue/ supply of drugs from SDS. Drug transfers across DTCs to adjust stock imbalances and/or to ensure the timely utilization of close to expiry drugs shall be effected on the basis of DTA).*

The SDS Storekeeper shall perform the following activities on receipt of WRDR:

1. Ensure proper authorization of WRDR

2. Prepare three copies of the State Issue Vouchers (SIV) for the purposes of recording issue of drugs from stores

3. Identify and segregate drugs to be issued as per the WRDR, ensuring strict application of FEFO principles

4. Hand-over drugs to transporter for onward dispatch, along with first and second copies of SIV

5. Update the Bin Card & the Stock Register for issues made

6. On delivery of the consignment, obtain Consignor's copy of Lorry Receipt and acknowledgement from transporter on third copy of SIV, retaining and filing the same for store records

7. Receive back and file the second copy of SIV (consignee copy), duly acknowledged by the concerned DTC.

(***NOTE***: *While Storekeeper shall strictly follow FEFO principles, it is also expected of him to exercise due prudence in case of short expiry drugs. The distribution should be on a rational basis keeping in view the utilization pattern of each district with instructions to ensure timely consumption of such close to expiry drugs).*

Supplies to DTCs against Additional Drug Requests (ADRs)

There are likely to be occasions when the quarterly supply of drugs to DTCs as above, is insufficient to meet the needs of the district and additional drugs are required in advance of the next quarterly shipment. In such cases, the concerned DTC is required to prepare and submit an Additional Drug Request (ADR: Form Reference 1–G) to the STO, providing details in support of the supplementary requirement.

The ADR shall be carefully reviewed and validated by the concerned officer-in-charge, prior to approval. The approved ADR shall become the authorization document for supplementary issue/ supply of drugs from SDS.

The SDS Storekeeper shall repeat steps (1) to (7) described as above for the purposes of issuing additional drugs to DTCs, with the exception that the authorization document for this transaction shall be the ADR, instead of the WRDR.

In the normal course, DTCs shall make their own arrangements to collect drugs authorized for issue to them under the ADR mechanism. In case the DTC is not able to make arrangements for lifting, the SDS Storekeeper may alternatively dispatch drugs using the designated transporter, under freight 'to pay' arrangement (viz. payment for freight shall be made by the concerned DTC) or whatever mode of payment is convenient.

Transfer to other State Drug Stores in the same State

The quarterly review cycle by concerned officer-in-charge (please refer to the above paras), may suggest benefit from the transfer of temporarily excess drugs stocks available at any one SDS to the other(s), within the same state. Transfer as above shall be done through the means of DTA, generated by the STO.

The Storekeeper shall repeat steps (1) to (7) detailed as above, with the exception that the authorization document for this transaction shall be the DTA.

Transfers to State Drug Stores in other States

Similarly, the quarterly review of state level QRPMLs carried out by CTD may suggest benefit from the transfer of drugs across SDS in different states to adjust stock imbalances and/or to ensure the timely utilization of close to expiry drugs. Transfer as above shall be done through the means of DTA generated by CTD.

The Storekeeper shall repeat steps (1) to (7) detailed as above, with the exception that the authorization document for this transaction shall be the DTA.

Monthly Stock Statement

The SDS Pharmacist shall prepare a Monthly Stock Statement (MSS: Form Reference I–H) providing details of receipts, issues, and opening/ closing balance of drug items, as at the last day of each calendar month. The MSS should include the details of all issues made to the districts in the given format. The issues made by the SDS should ideally co-relate with the receipts as shown by the districts in their QRPMLs. MSS shall be submitted to the STO by the 5th of every subsequent month, by all the SDSs, in the state. The statement shall facilitate determination of drug stocks available with SDS(s) within the state.

MSS shall thereafter be forwarded to CTD through the STO, by the 10th of every month.

Forms referred to in this section of the manual:

Title	Reference
Bin Card	I-A
Stock Register (SR)	I–B
State Issue Vouchers (SIV)	I–C
Drugs Transfer Advice (DTA)	I–D
Worksheet for Reporting Drug Requirement-DTC (WRDR-DTC)	I–E
Worksheet for Reporting Drug Requirement-DTC (WRDR-TU)	I–F
Additional Drug Request (ADR)	I–G
Monthly Stock Statement (MSS)	I–H

INVENTORY MANAGEMENT

This section of the manual suggests procedures for on-going tracking and replenishment of the inventory of anti-TB drugs including pediatric drug boxes at the State Drug Store (SDS) and all subordinate stocking points, ensuring that these are maintained at or close to the stocking norms suggested by Central TB Division (CTD).

Inventory management (IM) practices described in this section, have been developed for the SDS, but can equally be applied to subordinate stocking points.

Overview

IM refers to the series of activities to be carried out by the concerned officer-in-charge at the STO's Office including:

1. Determination of drug stock status at the SDS and DTCs/ subordinate stocking points.

2. Review of adequacy of drug stocks at the above.

3. Correction of imbalances through transfers.

4. Replenishment of stock at DTCs to recommended levels.

5. Requisitioning for the replenishment of SDS stocks.

The above elements of IM are discussed in the paragraphs that follow.

Determination of drug stock status

The Quarterly/ Monthly Report on Programme Management & Logistics (QRPML: Form Reference I – I) is to be filled and submitted by all drug-stocking points and comprises the most important report for the purposes of Inventory Management.

The QRPML incorporates drug stocks and consumption reported by all subordinate units. Additionally, detailed information on stock transferred in/ out and reconstitution of PWBs (if any), is also provided. In case the reporting unit has close to expiry drugs, details thereof should be reported in the QRPML.

The managerial challenge for the concerned officer-in-charge at the STO's Office shall be to ensure that QRPMLs are filled and submitted on a timely basis by DTCs and TUs, after compiling the reports of subordinate stocking units upto PHI level. The reports of the stocking units need to be submitted by the following dates:

Report of Stocking unit	Date of submission of report
PHI to TU	1st week of each subsequent month
TU to DTC	10th of the subsequent month at the end of the qtr
DTC to State & CTD	15th of the subsequent month at the end of the qtr

An additional challenge shall be to ensure that the QRPMLs provide correct information on drug stock status, corresponding with stocks physically available in the concerned store. This shall require significant investment in the training of Pharmacists/ storekeepers across the state.

QRPMLs shall be validated by the designated officer, on receipt, at the STOs Office. The designated officer shall confirm the following:

1. Closing stock reported in the previous QRPML has been correctly carried forward as opening stock in the current QRPML.

2. Dispatches authorized by the STO in the previous quarter have been executed and the correct quantities reflected in the quarterly report.

3. Intra-district transfers are properly reflected in the QRPMLs.

Stocking Norms

A key deliverable for RNTCP is to ensure uninterrupted supply of drugs, and stocking norms have been developed by CTD, with a view to meeting this end-objective. It is currently planned that drug stocks equivalent to ten months consumption, shall be maintained with implementing states, which will include one quarter consumption.

Pediatric Drugs: Drug stocks equivalent to ten months consumption for pediatric drugs shall be maintained as in case of adult patients though pediatric boxes are not expected to be kept at the PHI levels.

SDS(s) and DTCs, comprising the principal stock points of the state, shall each maintain buffer stocks equivalent to three months consumption. These stocks shall be utilized for replenishing supplies from SDS to DTCs and from DTCs to TUs/ PHIs, after validating consumption indicated in the quarterly reports of the latter.

PHIs are consumption points and should maintain adequate quantities of drugs for the ongoing administration of DOTS to patients, and also a buffer to cater to fresh patient arrivals. It is planned that drug stocks for adult patients equivalent to two months shall be maintained at the beginning of the month of which one month stock shall be kept as

buffer. Stocks at PHIs and TUs shall be closely monitored, to ensure drug adequacy. Stocking norms for adult drug boxes may be depicted as follows:

State Level (10 months)

(Comprising 3 months buffer at SDS,
6 months buffer at Districts/ TUs/ PHIs and 1 month for utilization with PHIs)

District Level (7 months)

(Comprising 3 months buffer at DTC;
2 months buffer with TU; 1 month buffer with PHIs and 1 month for utilization)

Tuberculosis Units (4 months)

(Comprising 2 months buffer at TU; 1 month buffer with PHIs and 1 month for utilization)

Peripheral Health Units (2 months)

(Comprising 1 month buffer and 1 month utilization)

The above stocking pattern may be denoted as the 3-3-2-2 (SDS-District-TU-PHI) inventory-stocking norm, aggregating 10 months inventory on a state level.

However, in case of Pediatric Drug boxes, the stocking pattern is slightly modified keeping with the guidelines that pediatric boxes shall not be stocked at the PHI levels. This was necessitated as the pediatric boxes designed are primarily for only new cases of pediatric patients. For re-treatment cases of pediatric patients, the boxes shall need to be modified accordingly. As this is a complex mechanism & in depth knowledge of the programme guidelines would be required for conversion of new cases boxes into re-treatment cases boxes, compounded by possible absence of medical officers at the PHCs, stocking of pediatric boxes has been limited to the TU level only.

Stocking norms for pediatric drug boxes may hence be depicted as follows:

State Level (10 months)

(Comprising 3 months buffer at SDS, 3 months buffer with DTC, 3 months buffer with TU and 1 month for utilization)

↓

District Level (7 months)

(Comprising 3 months buffer at DTC; 3 month buffer at TU and 1 month for utilization)

↓

Tuberculosis Units (4 months)

(Comprising 3 month buffer and 1 month for utilization)

The above stocking pattern may be denoted as the 3-3-4 (SDS-District-TU) inventory-stocking norm, aggregating 10 months inventory on a state level.

Adequacy of Drug Stocks

Adequacy of Drug Stocks (Form Reference II–A) with DTCs is to be reviewed on a quarterly basis by the officer designated in charge of drug logistics at the STO's Office.

This shall be done by comparing drug stocks reported in the QRPML of the DTC with the stocking norm suggested by CTD, for the same.

Based on the above, the concerned officer-in-charge should flag all DTCs that are significantly under/ over stocked.

DTCs with severe drug shortages, which shall not be able to continue treatment of patients, without interim replenishment before the end of the quarter, shall obviously need to be attended to right away. Needs as above are typically addressed through the Additional Drug Request (ADR) or Drug Transfer Advice (DTA) mechanism.

Conversely the Review of Drug Adequacy may also indicate excessive stocks of 'close to expiry' drugs, which may not be fully utilizable at their current stocking units and run the risk of expiry. Such situations shall also be corrected by the use of DTAs.

Correction of Imbalances through Transfers

Drug stock imbalances (viz. significantly under/ over stocking situations and/or 'close to expiry drug stock balances evidently facing the risk of expiry) are usually corrected through the transfer mechanism.

However, there is a cost for executing transfers and this must be carefully evaluated by the concerned officer-in-charge, who shall decide whether incurring the expense is justifiable and preferable to correcting the imbalance in the normal course, by adjusting the next quarterly replenishment.

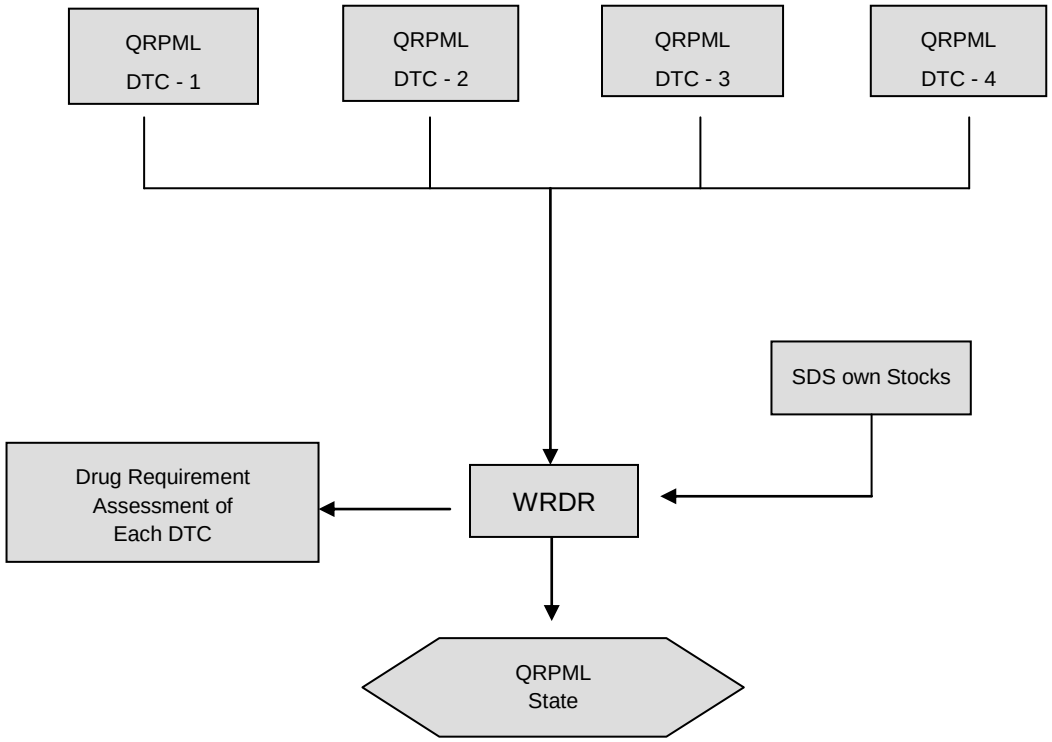
It should be noted that transfers shall only be authorized by the STO. The intention is to discourage the indiscriminate use of the transfer mechanism and the consequent costs incurred. Additionally, transfer of drugs needs to be carefully documented by both the transferor and the transferee DTC, to ensure proper reporting of drug stock balances. This end-objective is best served by restricting the number of agencies who can authorize the DTA.

Replenishment of DTC Stocks

Inventories of DTCs are routinely replenished on a quarterly basis, pursuant to the review and validation of the QRMPL submitted by them to the STO's Office.

Since replenishment as above addresses the need of the DTC and all its subordinate units for the quarter, it is important that the QRPML submitted for the purpose is based on the careful consolidation of QRPMLs received from subordinate units.

Actual requirement of drugs is thus worked out by the input of information reported in QRPMLs into the Worksheet for Reporting Drug Requirement (WRDR). This process has been depicted below.



Multiple factors are automatically considered while filling the WRDR including stocks available, stocking norms, pending/ pipeline supplies from multiple sources, reconstitution, number of patients put on treatment during the previous quarter and/or adjustments thereto, etc.

The WRDR is carefully reviewed by the concerned officer-in-charge and subsequent to his/ her sign-off, progressed with the preparation of the State Issue Voucher (SIV) for the release of drugs for the quarter.

Information pertaining to drug stock status of all SDSs within the state shall be incorporated in the WRDR, for working out total drug availability and estimating the requirement of drugs for the next quarter, for the entire state.

Replenishment of SDS Stocks

WRDR shall be progressed by preparation of QRPML for the State and requisitioning CTD for the replenishment of SDS(s) stocks.

This is done on the basis of the consolidated QRPML prepared by the STO's office, providing details of drug stocks and other information relating to the SDS(s) and DTCs.

The above document is carefully validated and reviewed by CTD, culminating in the preparation of CTD-RO for the replenishment of SDS(s) stocks for the next quarter.

Flow of Drugs

The flow of drugs is the direct reverse of the flow of reports. Drug requirements, consumption and stock positions, both at State and district levels are monitored at the Central TB Division through the quarterly reports submitted by the districts. Regular, accurate monthly PHI Reports as well as their correct consolidation at the TUs & District levels are hence, essential for correct monitoring of the stock position at various levels.

Supply of drugs by Central TB Division from the GMSD to the SDS is communicated to the State through a Release Order. Based on the district quarter report, stock is supplied from SDS to the district drug store to its TUs and then to the PHIs.

Hence, at the beginning, the PHIs are supplied with a stock of two months (i.e. stock for utilization in the first month along with a buffer of one month). Then, every month, as per the monthly PHI report, they are supplied with stock from the TU which helps to maintain the buffer stock for a month at the PHI. This buffer stock helps the PHI to provide drugs if more patients are put on treatment in a particular month and to provide cover for delay in supplies from TU. Thus no patient is sent back due to lack of drugs even on a single occasion.
For the TU level to ensure that the PHIs have a month's utilization stock plus a buffer stock of one month, it needs to have a buffer stock of two months at the beginning of the quarter. This will ensure a continuous supply of drugs.

The regular process of supply of fresh stock of drugs from the GMSD to the SDS/districts begins only when the districts submit their QRPML reports to the State/CTD (Epi-centre).

Once the QRPMLs are received by Central TB Division, it takes around 15-20 days for CTD to process the requirement (from all districts of all states). The district should have at least a utilization stock of 4 months at the beginning of the quarter. Similarly the State Drug Stores should have at least a reserve stock of 3 months of consumption of the state.

Reconstitution of Boxes

A key information element for working out drug requirement comprises the quantity of patient-wise category boxes recovered during the period through the mechanism of reconstitution.

*(**Note:** Reconstitution comprises the process of recovering and recycling partially unused category boxes from defaulting and/or deceased patients. CTD guidelines require that all such boxes be repossessed by the STS and forwarded to the DTC where they are periodically re-assembled/ reconstituted into full Patient Wise Boxes).*

The process of reconstitution is a technical one and covered by separate guidelines issued by CTD for the purpose (please refer to Appendix IV). From the view point of IM, the key aspect comprises the Reconstitution Register (RR: Form Reference I–J), which provides authentic information on the number of category boxes recovered through the process and taken into stores.

Forms referred to in this section of the manual

Title	Reference
Quarterly Report on Programme Management & Logistics (QRPML)	I–I
Adequacy of Drug Stocks (ADS)	II–A
Additional Drug Request (ADR)	I–G
Drug Transfer Advice (DTA)	I–D
State Issue Voucher (SIV)	I–C
Worksheet for Reporting Drug Requirement (WRDR)	I–F
Reconstitution Register (RR)	I–J

EXPIRY MANAGEMENT

This section of the manual deals with procedures to be followed for the management of short expiry drugs and immediate steps in dealing with the same so as to ensure their utilization within their shelf-life. The procedures recommended are generic and can be extended to all locations maintaining significant inventories of anti-TB drugs.

Short Expiry Drugs, as the name suggests, are drugs which are left with a short shelf-life & need to be utilized immediately to avoid their expiry. Shelf-life of drug is defined as a period during which the drug will last without deterioration, provided all precautions for good storage practices have been taken.

Overview

The storekeeper is expected to install appropriate tools to periodically monitor controls over the expiry position of drugs held in stocks mainly through storage of drugs of a particular description at one place, expiry-wise stacking and marking expiry dates on cartons/drug boxes with marker pens.

The storekeeper shall strictly follow FEFO (First-Expiry-First-Out) principles. However it is also expected of him to exercise due prudence in case of short expiry drugs, wherein the distribution shall be on a rational basis keeping in view the utilization pattern of each district to ensure timely consumption of such close to expiry drugs.

Divergence from FEFO principles, at times is necessitated primarily to ensure consumption within the shelf life and accordingly it shall not be taken adversely. The **s**helf- life of drugs, accordingly becomes a critical component of inventory management.

Shelf-life of Anti-TB Drugs

The table below gives details of shelf life of anti-TB drugs procured centrally under RNTCP

Expiry Details of Anti-TB Drugs procured under RNTCP		
Name of Drug	**Individual Drug**	**Expiry (No. of Years)**
Patient Wise Boxes	Rifampicin-450 mg	3 Years
(PC-1 & PC-2)/ PPs / Loose Drugs	Pyrazinamide-750 mg	5 Years
	Ethambutol-600 mg	5 Years
	Isoniazid-300 mg	5 Years
Inj. Streptomycin-0.75 g		3 Years
Pediatric PWBs / PPs / Loose Drugs	Rifampicin-75 & 150 mg	3 Years
	Pyrazinamide-250 & 500 mg	5 Years
	Ethambutol-200 & 400 mg	5 Years
	Isoniazid-75 & 150 mg	5 Years

As is seen from the above table, the shelf-life of Anti-TB drugs range from 3-5 years after which the chances of losing efficacy and side-effects thereof increase rapidly. Hence, it is important to ensure that appropriate steps are taken as soon as the drugs reach the critical stage, as indicated in the table above to ensure their usage well within their shelf-life.

Criteria for identification of short expiry Patient Wise Boxes (PWBs)

There may be instances when the stores may have some short-expiry drugs. It is important that proactive measures be taken to ensure transfer of such drugs to other districts/states to ensure no expiry. The DTO shall inform the State requesting for an approval for transfer to other districts. The table below explains how to identify short-expiry drugs in the stores.

Category	Months				
	Duration	Extension in IP	Possible Interruption	Max transit time for shifting of box	At risk of expiry, if less than *
PC-1 (New Cases)	6	1	2	3	12
PC-2 (Re-treatment Cases)	8	1	2	3	14

*** At the district level**

Note: Loose drugs can be used till the last date of expiry ie. Drugs with DOE of Dec-12 can be used till 31st Dec-12.

Issue of short-expiry drugs to districts

As soon as a decision has been arrived at by the State as regards the quantity of drugs to be issued & diverted, immediate steps for preparation of Drug Transfer Advice shall be taken. Necessary transportation & logistics arrangements shall be made for diversion from one DTC to other DTC or State Drug Stores. Once the DTA is finalized, based upon requirement & utilization assessment of each district, the DTOs need to accept these drugs. Ideally **at least six months shelf life in case of loose drugs** should remain before the drugs are diverted from one district to another district. In case of Patient Wise Boxes, a decision to divert drugs must be taken if these cannot be used with reference to the available shelf-life as per table given above.

The DIVs prepared for such drugs should clearly state in the 'Remarks' column that these are short-expiry drugs and should be used within their shelf-life. The transferee District TB Officer (DTO) shall also be impressed upon to make necessary arrangements to ensure utilization of such short expiry drugs within the given shelf life.

Diversion of short-expiry drugs from the State

The States shall frequently assess the availability of anti TB drugs vis-à-vis the utilization across the State. In case the drugs are in excess far beyond its utilization within the available shelf-life, such drugs shall necessarily be required to be diverted to other States.

However, it may not be always logistically convenient & feasible to divert drugs from one state to other and ensure utilization in that state. In case the drugs to be diverted are scattered across the state, it becomes all the more difficult and information pertaining to such drugs may not be fully reliable. The drugs to be diverted would need to be transported back to State Drugs Stores from all the DTCs. States shall need to gather accurate inventory & available shelf life of such drugs and make reasonable assessment of transportation time from District TB Centres to State Drug Stores. Ideally, **at least six-nine months shelf life** in case of loose drugs should be available when such drugs reach the other State so as to ensure their utilization before expiry.

Considering that transportation from District to State Drug Stores and onward transportation to other State may involve at least three to four months, the process of diversion between states shall be initiated in a fairly reasonable time. Accordingly, the States are expected to regularly assess the status of drug availability and consumption thereof especially after taking cognizance of available shelf life of the drugs.

Information in respect of excess drug availability with available shelf-life shall be provided to Central TB Division, with a request to divert such drugs to other States. On receipt of requests for diversion, CTD shall identify the States which can utilize these drugs within the given shelf-life. Both states, transferor as well as transferee shall work in close co-ordination to sort out all transportation & logistics issues after getting the go ahead from CTD. Drug Transfer Advice (DTA) shall be sent by CTD to both the States for diversion of drugs, and the states shall put all their efforts together so as to ensure utilization before expiry.

Shelf Life Analysis of Drug Stocks

Detailed analysis of the shelf-life of inventory of anti-TB drugs should be done regularly at the time of preparing drug stock reports with a view to identify short expiry drugs which may not be used within their shelf-life and run the risk of getting expired.

This analysis shall also be extended to drugs available at various District TB Centres to assess consumption of drug stocks within available shelf life.

Expiry Age Analysis of Drug Stocks (EAADS: Form Reference II-B) shall be prepared at STO's Office to help achieve the following objectives:

1) Identification of 'close to expiry' drugs stocks and conversely stocks with close to 'full term' life.

2) Determination of balances at risk requiring early corrective action.

3) Utilization assessment of such drugs across various DTCs.

4) Preparation of Diversion Plan to address the problem of short shelf life drugs, requiring approval by the STO.

The analysis shall be done under close supervision of concerned officer-in-charge, such that immediate steps for diversion of drugs prone to expiry may be taken to ensure their utilization within shelf life.

Physical Verification and Reconciliation of Drug Stocks

This section of the manual deals with procedures to be followed for the physical verification and reconciliation of anti-TB drug stocks at the State Drug Store (SDS) and immediate next steps for dealing with discrepancies determined, if any. The procedures recommended are generic and can be extended to all locations maintaining significant inventories of anti-TB drugs.

Overview

Physical verification of the inventory of anti-TB drugs and reconciliation thereof with store records shall be carried out under the supervision of the concerned officer-in-charge at the State, DTC, TU & PHI drug stores at the following times:

1. Regularly at the end of each month
2. Surprise checks during the year
3. At the year-end

Procedures recommended for the above are detailed in the paragraphs that follow:

Monthly Verification and Reconciliation

The SDS Storekeeper shall perform the following activities under the supervision of the concerned officer-in-charge on the last working day of every month:

1. Count and determine the number of Cartons / Boxes / Strips physically available at the store, for each of the drugs dealt with by the programme and record details thereof in the Physical Verification Sheet (PVS: Form Reference I–K).
2. Also record the number of Cartons/ Boxes/ Strips that should be available at the SDS as per the Stock Register (SR), for all drugs as above.
3. Determine and record discrepancies between stocks as per physical count and the SR, in the PVS.
4. Attempt to eliminate discrepancies between stocks as per physical count and the SR through a process of reconciliation. The following common causes for discrepancies should be checked/ considered during the reconciliation process:
    a. Confirm that all transactions have been properly incorporated in the SR viz.:
        i. Determine all transaction documents for the specified period on the basis of first and last pre-numbered authorized documents. For example,

consider all Issue Vouchers pertaining to the SDS for the particular month, etc.

*(**Note:** The above steps would readily apply only to issues, where SDS Issue Vouchers are consecutively numbered. In the case of receipts- there are multiple source documents e.g. GMSD Issue Voucher, CTD-RO, SIV of transferor stocking unit, etc. and these are not consecutively numbered for the SDS. For such cases, SDS shall have to request each consignor to list all transaction documents raised by them during the period, so that these can be traced into the SR.)*

ii. Transaction documents in respect of receipt have not been posted to the SR.

b. Confirm that all pre-numbered documents for receipts and issues for the period have been posted to the SR.

c. Check totals of all receipts and issues, ensuring that there are no arithmetical inaccuracies.

5. The concerned officer-in-charge shall review and sign-off the PVS after thorough verification, comprising the following steps:

   a. Validate that all receipts & issues have been recorded in the SR, based on first and last and/or discrete numbers of related documents confirmed by the suppliers.

   b. Compare transaction entries in the SR with related documents such as the set of documents received along with/ after the receipt of drug consignment, etc.

   c. Verify that details of Batch numbers, Date of Manufacture and Date of Expiry of drugs are consistently recorded in the SR at the time of receipt of each consignment. Also that the SR indicates expiry details in respect of drugs available in inventory.

   d. Confirm evidence of periodic, independent checking of the SR through the recording of observations/ comments and signatures of concerned programme officers.

   e. Compliance with key best practices such as First Expiry First Out (FEFO).

6. Un-reconciled discrepancies determined through the above process should be reported to the STO and CTD.

   *(**Note:** In the case of shortages, steps must be initiated for recovery of the cost of discrepant drugs from the person responsible. If the STO assesses there is genuine reason for the discrepancy, he may recommend waiver of recovery to the Competent Authority. Only the Competent Authority for the State should authorize waiver of recovery. This should be allowed in exceptional cases only).*

Pursuant to review as above, the PVS shall be forwarded to the CTD in the first week (i.e. by the 7th day) of the next month.

Surprise Checks during the Year

The concerned officer-in-charge & any other Senior official may conduct surprise verification of drug stocks at each of the State Drug Stores in the state.

Procedures to be followed for surprise verification shall be on similar lines described above for monthly verification.

PVS documenting outcomes of physical verification and reconciliation should be immediately sent to CTD, in case of unexplained discrepancies.

Year-end Verification and Reconciliation

Procedures described in above paragraphs for monthly verification are also to be repeated on the last working day (i.e. March 31) of every financial year.

The PVS documenting outcomes of this exercise shall be sent to CTD in the first week (i.e. by the 7th day) of April.

*(**Note:** Cases of shortage or damage to drugs, due to rodents/ pests/ fire/ seepage/ pilferage or expiry of drugs found during physical verification, shall be fully investigated by the STO's Office and reasons for the same incorporated in the year-end PVS, prior to forwarding to Central TB Division.*

Copy of PVS prepared at the time of monthly/ surprise check/ annual physical verification of drug stocks should be filed securely/ hard bound periodically and available with the SDS at all times).

Forms referred to in this section of the manual

Title	Reference
Physical Verification Sheet (PVS)	I–K
Stock Register (SR)	I–B

COMMUNICATION AND INFORMATION TECHNOLOGY INFRASTRUCTURE

Overview

CIT infrastructure comprises the backbone for the efficient functioning of the programme and its importance cannot be overemphasized.

The following CIT infrastructure facilities are anticipated for the smooth functioning of the SDS(s) and DTCs:

1. Telephone
2. Computer
3. Internet

Facilities at SDS

CIT infrastructure needs for SDS(s) are discussed in more detail in the paragraphs that follows:

Telephone

Each SDS should have an independent telephone connection. The telephone facility is essential for coordination and follow-up with CTD, GMSD(s) and/or other SDS(s), to ensure the timely receipt of drugs. Conversely, the direct phone line shall enable DTCs and subordinate units to contact the SDS for the purposes of requisitioning and following-up for the timely dispatch of drugs. The dedicated telephone line shall also facilitate monitoring of the drug situation at DTCs and various units by the SDS Storekeeper and making arrangements for the emergency supply of drugs to units, as necessary.

Direct phone access is assessed to be critical for the SDS and an independent telephone line is recommended, even where the store is a part of the STO's Office or a Hospital or a Health Center, having existing telephone facilities.

The telephone number of the Pharmacist should be circulated to DTCs and subordinate units for easy, immediate access & in case of emergency requirements.

Computer

Each SDS should preferably have an independent computer*. The computer shall be required to enable the functions of Inventory Tracking, Reporting, Analysis and Demand Forecasting to be carried out by the SDS. The computer shall also facilitate the

exchange of correspondence by the SDS through e-mail, regarding the receipt/ issue of drugs, sending/ receiving inventory reports and related matters.

(The term computer includes Internal/ External Modem, Printer, UPS and Computer Table)*

In cases where the SDS is located at and is part of the STO's Office and it is not possible to provide the store with an independent computer, the computer may be made available at the STO's Office.

Internet Connectivity

Internet connectivity shall be required by the SDS for receiving and sending reports on drug logistics and e-mail communication with various entities. The SDS computer would have to be e-mail enabled for the purpose (viz. fitted with an internal/ external modem and wired accordingly). Additionally, the SDS and/or the Storekeeper would require an e-mail address, as well as a dial-up account or equivalent facility, to connect with the Internet.

Direct internet connectivity is assessed to be critical for the SDS and an independent internet connection is recommended, even where it is a part of a Hospital or a Health Center, with existing internet facilities.

The SDS shall share internet facilities available at the STO's Office where it does not have a direct computer. An independent E-mail ID for the SDS and/or storekeeper shall be made available by CTD.

Forms referred to in this section of the manual

Title	Reference
-	NA

STAFFING REQUIREMENTS

This section of the manual deals with staffing and reporting requirements for the efficient discharge of the stores and logistics function at the State Drug Store (SDS) and other stocking units of the programme.

Overview

SDSs and other stocking units shall generally need the following staff to deal with the stores and logistics function:

1. Pharmacist
2. Store Assistant
3. Helper(s)

Staffing and reporting requirements in respect of the above resources at the SDS and other stocking units are summarized in the matrix given below:

Staff/ Reporting	SDS	DTC	TU	PHI
1. Staffing Requirement:				
a) Pharmacist	Required	Required*	Required*	Not Required
b) Store Assistant	Required	Required*	Required*	Not Required
c) Watchman/ Helper(s)	Required	Not Required	Not Required	Not Required
2. Reporting by above Drug Stores Staff:	Deputy STO/ Second Medical Officer	DTO/ MO In-charge	MO In-charge	MO In-charge of PHI

* If Pharmacist is not available, the STS shall take care of the work.

Qualifications/ skills required to be possessed by staff at the SDS and other stocking units are discussed in the paragraphs that follow.

Post – Pharmacist
Essential Qualification – Degree / Diploma in Pharmacy
Preferential Qualification –

1. 1 year experience in managing drug store in a reputed hospital / health center recognized by Govt.
2. Conversant with various computer programming including MS Word, Excel and simple statistical packages

Job Specification / responsibilities –

1. Handling of drug stores in the State Drug Stores including Receipts & Issues
2. Recording & reporting of drug stocks at the stores
3. Reconstitution / Repacking of 1st & 2nd Line drugs
4. Repacking of 2nd Line loose drugs into 1 monthly boxes
5. Assistance to State in consolidation of district quarter reports & analysis of stock reports.
6. Preparation of State level quarter reports
7. Data entry in web based software for Drug Logistics
8. Communication with State/District & Central TB division officials
9. Assistance in imparting drug logistics trainings to district level pharmacists
10. Possible visits to districts on issues relating to drug management
11. Any other job assigned as per programme need.

Post –Store Assistant (State Drug Store)
Essential Qualification – 10 + 2
Preferential Qualification –

1. Diploma in Pharmacy
2. Conversant with various computer programming including MS Word, Excel and simple statistical packages

Job Specification / responsibilities –

Assist Pharmacist in

1. Handling of drug stores in the State Drug Stores including Receipts & Issues
2. Recording & reporting of drug stocks at the stores
3. Reconstitution / Repacking of 1st & 2nd Line drugs
4. Repacking of 2nd Line loose drugs into 1 monthly boxes
5. Data entry in web based software for Drug Logistics
6. Imparting drug logistics trainings to district level pharmacists
7. Any other job assigned as per programme need.

Helper

In addition to the above regular positions, the stocking unit shall hire the services of a watchman/ helpers, on a need basis, for the purpose of loading/ unloading / stacking drugs from or to the store.

Forms referred to in this section of the manual

Title	Reference
-	NA

LOCATION, SPACE AND STORAGE ARRANGEMENTS

This section of the manual deals with matters relating to location, space and storage arrangements that are required to be in place at the time of establishment/upgradation of State Drug Stores (SDS).

LOCATION

The SDS should be properly located. Key criteria for selecting the site for the SDS are enumerated below:

Access: The SDS should be located on a wide road, providing easy access to transportation vehicles throughout the year. Proper selection of the location of the SDS shall facilitate free movement of drugs to and from the store.

Drainage: The location selected should have a good drainage system and not be prone to flooding.

Communication: The site/ location selected should have telephone and internet connectivity.

STORAGE SPACE

SDS shall require space for the following:

1. Accommodation of staff and equipments
2. Storage of Records
3. Storage of Drugs

Provision for the same has been discussed in subsequent paragraphs.

Space Provision for Staff and Records

There should be adequate space for accommodating staff, office equipments (such as the Computer, Printer, etc.) and store records and registers. An area of about 100 square feet should be sufficient for this purpose.

Space for Drugs

The space required for storing drugs shall depend on the maximum quantity of drugs to be maintained at each Drug Store. This shall depend on the population to which the store caters, as well as the number of months for which stocks are to be stored (viz. the stocking norm for the location).

Estimation of Space Requirement for Drugs

The following approach could be used for working out the total space requirement for storing drugs:

Cartons Required Based on Population

For every 10 lakh population, provision should be made for the storage of about 45 cartons (of 20 boxes each), of PWBs for new cases (PC-1) and PWBs for retreatment cases (PC-2) taken together. This is approximately equivalent to six months requirement of drugs. For this volume of drugs, minimum space requirement may be approximated 50 cubic feet, when 4 boxes are stacked on over the other, considering the current dimensions of cartons.

Stocking Norms

SDS should ideally be able to stock a maximum of six months consumption/ utilization of drugs.

Storage in Cupboards/ Almirah

For loose drugs under Non-DOTS regimen, space provision would be 10% of space allocated to PC-1 and PC-2 PWB cartons. These could alternatively be stored in cupboards/ almirahs where volumes are low & should be kept under lock and key.

Other Specifications for Drug Store

Other specifications for SDS include the following:

1. The store should preferably comprise one large room. Where multiple rooms exist, these should be contiguous or proximate to each other.
2. The ceiling must have a height of at least 5 meters
3. A lockable door
4. At least one window with grill and wire meshing
5. Properly lit with extra light points for plugging in required office equipments
6. An even-level, ‘pukka’ floor
7. Overhead exhaust fan
8. Plastered walls and ceiling with whitewash without any kind of seepage in the room. The store should be clean, dry & well-ventilated

9. Ceiling and side walls should preferably be insulated, ensuring that the ambient temperature during peak summer does not result in damage to anti-TB drugs. The ambient temperature may be taken as 15-25^{o}c or depending on climatic condition, upto 30 ^{o}c

10. Stores should not have any odour, indications of contamination &

11. Sanitize periodically.

SHELVES, RACKS & STORAGE ARRANGEMENTS

Storage shelves should be fabricated ensuring sufficient 'gap' between cartons from the ceiling, floor and walls, facilitating ventilation and free movement of air.

Shelves should be positioned so that there is no possibility of seepage into cartons.

Typically, five rows of shelves are fabricated, one on top of the other into racks. A single rack is usually long enough to accommodate three cartons on each shelf. Accordingly, a rack would typically accommodate fifteen cartons.

Current dimensions for the largest PWB comprise 66.04 centimeters (length) X 55.88 centimeters (depth – front to back) X 36.83 centimeters (high). These dimensions define the dimensions of shelves and racks.

In case of a long and narrow room, racks should be positioned against the wall. In the case of a broad room, there shall be multiple rows of racks, all parallel to one another. There should be sufficient space between parallel blocks of racks, to facilitate free movement of men and trolleys for the smooth stacking and removal of cartons.

Cartons should rest on shelves and not on each other, to prevent the eventual sagging of the cartons in the bottom row.

Material for Construction

Storage shelves shall be made using 40 millimeter bore medium quality (external diameter - 48.3 millimeter) mild steel pipes. These pipes shall be embedded at least 10 centimeters into the existing walls and grouted in concrete to create horizontal shelves. Base plates measuring 7.5x 7.5 centimeter x 2 millimeters thickness shall be provided under all the vertical pipes at the floor levels. All the pipes shall be welded properly and secured to create a stable shelving system.

Cupboards/ Almirahs

Steel cupboards/ almirahs of quality brands may be used for storage of loose drugs.

STACKING ARRANGEMENTS

Stacking arrangements are discussed below:

1. Ensure that different drug items are clearly segregated and stacked on separate racks within the store.
2. Insofar as possible, the same drug should be stored at a single location within the store.
3. Additionally, drugs of the same expiry should be stored together, at the same location.
4. Recognizing the above rules, drugs expiring earliest, should be so stored that they are issued first. For example, in case PC-1 boxes are placed on multiple shelves in a single part of the store, cartons expiring earlier should be stored at ground level and fresher cartons (which shall expire later) on elevated shelves. This method of stacking shall ensure that drugs that shall expire first shall automatically be issued first.
5. Mark expiry dates in bold letters 3” to 4” in size on the face of cartons/ drug boxes, in large, easily visible characters, using a black colored, permanent marker pen for easy identification and control of drugs, immediately on their arrival.
6. Expiry dates of short expiry batches of drugs (viz. expiring within the next 12 to 18 months in case of PWBs and six to eight months in the case of loose drugs) should be emphasized using a **yellow highlighter.** This would help flag the attention of the storekeeper and/or senior programme officers that these drugs face the risk of expiry and need to be utilized soon.
7. Expired drugs should be segregated and stored in a separate part of the store eliminating the possibility of their issue to patients. Expiry dates should be emphasized using an **orange highlighter** in these cases.

Forms referred to in this section of the manual

Title	Reference
-	NA

SECURE CUSTODY OF DRUGS

This section of the manual discusses arrangements to be made at the State Drug Store (SDS) for assuring secure custody of drugs to safeguard against occurrence of theft, fire, seepage, ingress of pests, etc.

Key practices that may be instituted in this context are discussed below.

Storage under Lock and Key

A simple precaution to safeguard drugs is to restrict access to authorized persons and ensure that the store is locked when unattended or after office hours.

The work place of the storekeeper may be at a separate location and s/he would visit the store only for the purposes of receipt/ issue of drugs or similar transaction. In all such cases, the drug store should always be locked whenever the storekeeper is not on site.

There should be only a single duplicate key to the store and this should be in the custody of the concerned, superior officer or any other arrangement as decided by the STO. Under no circumstances, should a situation arise that the store cannot be operated in absence of the pharmacist or officer-in-charge.

Prevention of Fire

Outbreak of fire can be minimized, by preventing the following activities in stores:

1. Smoking
2. Storage of flammable materials
3. Lighting of stoves, burners, heaters, etc.

Fires are frequently caused by electrical faults. Possibility of occurrence can be minimized through periodic inspection of the condition of electrical wiring, preferably by an electrical engineer.

During inspections, evaluation should also be made of the capacity of the electrical meter and wiring to withstand the maximum load of installed equipments. Corrective steps should be initiated in case of imbalance.

Fire Alarms & Extinguishers

In addition to the above preventive steps, fire alarms & fire-fighting equipment should in any case be installed to deal with the outbreak of fire. Shelving equipment & cartons must not be placed where they will obstruct the fire extinguisher.

Multiple fire extinguishers should be installed commensurate with the area of the store and materials at risk. The fire extinguishers installed should be appropriate for a drug store & should be readily available.

Storekeeper and security guards (if any), should be trained to operate the fire extinguishers.

Fire extinguishers should be frequently inspected to ensure that they are always in working condition.

Timely change/ refill of chemicals inside the fire extinguishers should be ensured through an AMC with a reliable contractor.

Pest Control

Measures to ensure no damage to drugs due to Termites, Rodents, Pests, etc. should be ensured by engaging Pest control measures.

Pest control measures employed should conform to the prescribed Health & Safety Standards.

Periodic Inspection

Periodic inspection should be carried out (at least once in a quarter), in respect of the following:

1. Electrical wiring
2. Fire extinguishers
3. Any seepage / dampness in the roof / walls
4. Termites, pests, rodents etc.

Timely corrective steps should be initiated in case of any negative observation.

Forms referred to in this section of the manual

Title	Reference
-	NA

ARRANGEMENTS FOR TRANSPORTATION OF DRUGS

This section of the manual discusses arrangements for the transportation of drugs from the State Drug Store (SDS) to various stocking units constituted within the state under the programme.

The STO shall enter into an agreement with one or more transporters for the distribution of drugs from the State Drug Store(s) to DTCs.

*(**Note:** The above shall be applicable only in case the state does not have arrangement for transporting drugs and the SDS is used exclusively for storing anti-TB drugs).*

The agreement with the transporter shall define rates to be charged on a per carton/ per km or alternate basis for transportation from the SDS(s) to each of the DTCs and/or other locations, within the State.

The following preparatory activities performed by the concerned officer-in-charge, shall typically precede the execution of the transporter agreement:

1. In consultation with the STO, compile a list of all locations that are covered/ likely to be covered by the RNTCP during the year, such as, all SDSs and DTCs within the state, SDSs in neighboring states, GMSDs in the region, etc. In case there is more than one SDS in the state, SDSs along with their routine feeding districts should be enlisted.
2. Identify leading transporters operating at the state-level and national level with the fleet-size and reach-to-service destinations as above.
3. Request priced quotations/ bids from the above, indicating per carton/ per km freight rate and guaranteed pick-up and delivery times valid through the year for shipments from SDS to various district destinations.
4. Review bids received from transport companies and shortlist on the basis of economy, demonstrable experience, coverage of destinations and turnaround time efficiency.
5. Discuss short listed options with STO and make final selection.

*(**Note:** It may also be a good idea to share details of rates negotiated with STOs in neighboring states, as similar rates are likely to prevail in the region)*

The agreement executed with the selected transporter should incorporate the following clauses:

1. Guaranteed pick-up within 24 hours of request.

2. Guaranteed delivery within 24-72 hours (may be increased in case of remote or difficult to reach locations) of pick-up to all district destinations & ensuring deliveries within office hours with on-door delivery clause included.

3. Provision for freight payment, both on, ‘Paid Basis’ or ‘To Pay Basis’.

4. Submission of Proof of Delivery (PoD) along with bills for freight charges.

5. Compliance with all documentation needs of the project.

6. No escalation of freight rates during the contract period.

7. Liability for in-transit shortage/ breakage/ damage.

8. Recourse to alternate transportation arrangements in case of failure by transporter to lift goods within the agreed turnaround time. The transporter shall be liable to pay additional costs incurred over the contracted rate in all such cases.

9. Recourse to pre-defined penal adjustments to freight rates in the case of delay in lifting and/or receipt of drugs at districts vis-à-vis agreed turnaround times.

These guidelines contemplate use of the transporter for dispatches from the SDS to DTCs only. Onward dispatches from DTCs to TUs and from TUs to MCs/ PHIs are currently expected to be effected through the existing system.

Forms referred to in this section of the manual

Title	**Reference**
-	NA

MIS FOR DRUG LOGISTICS

This section of the manual describes a tentative Management Information System (MIS) serving the managerial control needs of the officer designated to oversee drug logistics at the STO's Office.

Traditionally two parameters are considered to be critical with respect to drug logistics:

1) Ensuring uninterrupted supply of anti-TB drugs to patients
2) Safeguarding against the expiry of drugs.

Reporting protocols for GMSDs and DTCs instituted under the programme have attempted to address the above.

The additional reports proposed in this section of the manual endeavor to provide enhanced managerial control over drug stock adequacy and expiry, as well as several other parameters considered to be potentially important and worth tracking at this stage of evolution of the drugs management function of the programme.

1) Adequacy of Drug Stocks (ADS: Appendix II–A)
2) Expiry Age Analysis of Drug Stocks (EAADS: Appendix II–B)
3) Inconsistency In Drug Stock Reporting (IDSR: Appendix II–C)
4) Timely Execution of Critical Indents (TECI: Appendix II–D)
5) Delay in Distribution of Drugs by Transporter (DDDT: Appendix II–E)
6) Delay In Drug Stock Reporting (DDSR: Appendix II–F)

The above reports are discussed in the paragraphs that follow:

Adequacy of Drug Stocks (ADS)

The ADS Report shall enable the following:

1) Monthly review of the adequacy of drug balances with stocking units vis-à-vis recommended stocking norms.
2) Provide information for the purposes of stock transfers and/or early replenishment action.

Expiry Age Analysis of Drug Stocks (EAADS)

The EAADS Report enables the following:

1) Identification of 'close to expiry' drugs stocks and conversely stocks with close to 'full term' life.

2) Determination of balances at risk requiring early corrective action.
3) Preparation of a tentative plan to address the problem of short shelf life drugs, requiring approval by the STO.

Inconsistency in Drug Stock Reporting (IDSR)

The IDSR Report enables the following:

1) Identification of all units that are not complying with reporting requirements in terms of provision of detailed and consistent information .
2) Follow-up action by management against non-compliant units.

Timely Execution of Critical Indents (TECI)

The TECI Report enables the following:

1) Identification of all units that are severely under-stocked and face potential risk of interruption in treatment of patients.
2) Flagging of Release/ Transfer Orders relating to all such cases, enabling close follow-up to ensure timely replenishment.

Delay in Distribution of Drugs by Transporter (DDDT)

The DDDT Report enables the following:

1) Routine tracking of turnaround time taken by transporters for the supply of materials across the state.
2) Determination of compliance with agreed turnaround times.
3) Identification of cases of significant delay, enabling initiation of corrective action including making of alternate dispatch arrangements, recovery of punitive damages, black-listing of transporter, etc.

Delay in Drug Stock Reporting (DDSR)

The DDSR Report enables the following:

1) Identification of delays in the submission of quarterly/ monthly stock reports.
2) Determination of delinquent units, enabling follow-up and corrective action.

Formats and detailed descriptions in respect of each of the above reports have been provided in Appendix II to this manual.

Forms referred to in this section of the manual

Title	Reference
Adequacy of Drug Stocks (ADS)	II–A
Expiry Age Analysis of Drug Stocks (EAADS)	II–B
Inconsistency in Drug Stock Reporting (IDSR)	II–C
Timely Execution of Critical Indents (TECI)	II–D
Delay in Distribution of Drugs by Transporter (DDDT)	II–E
Delay in Drug Stock Reporting (DDSR)	II–F

GUIDELINES FOR MANAGEMENT OF PEDIATRIC DRUGS

This section of the manual deals with detailed guidelines & procedures for the management of Pediatric Patient Wise Boxes (PWB) recovered from defaulting, reportedly dead and transferred-out patients.

Overview

The Revised National Tuberculosis Control Programme (RNTCP) in consultation with Indian Association of Pediatricians (IAP), has made pediatric drugs available in patient-wise boxes (PWBs) similar to those supplied for adult patients under RNTCP. With the availability of pediatric PWBs, all new pediatric patients diagnosed and registered for treatment under RNTCP, would be initiated on pediatric patient wise boxes. This will enable optimum dosage for the patients, without resorting to further breaking of the tablets, as per the respective weight bands. Further, Rifampicin would be available in tablet form, which will enable easier swallowing of the drug by the pediatric patients.

Formulations & Weight Bands

The new formulations used in pediatric patient wise boxes are:

Drug	Strength of drug used
Rifampicin	75 / 150 mg
Isoniazid	75 / 150 mg
Ethambutol	200 / 400 mg
Pyrazinamide	250 / 500 mg

For the purpose of treatment, the pediatric population is divided into four weight bands. The anti–TB drugs for pediatric patients will be available in the form of 2 generic patient wise boxes i.e. Product Code 13 and Product Code 14 which shall be used across all these 4 weight bands. Product Code 15 and 16 would be available for prolongation of the intensive phase, if required and also to facilitate conversion of the boxes into Re-treatment cases and for reconstitution, if required.

Body Weight of pediatric patient
6 – 10 kg
11 - 17 kg
18 - 25 kgs
26 – 30 kgs

The composition of Product Codes 13 to 16 is given below:

Product Code Number	Product Description	Strength	
Product Code 13	Treatment box for pediatric category (6-10 Kg). Each treatment box containing 24 combi-packs of Schedule-5 in one pouch and 18 multi-blister calendar combi-pack of Schedule-6 in another pouch	Each combi-pack of	Each multi-blister calender
		Schedule-5 containing	**of Schedule-6 containing**
		1 R Tab .of 75mg	3 R Tabs.of 75 mg each
		1 H Tab. of 75mg	3 H Tabs. of 75mg each
		1 E Tab of 200mg	4 Pyridoxine Tabs of 5mg
		1 Z Tab. of 250mg	
Product Code-14	Treatment box for pediatric category (11-17 Kg). Each treatment box containing 24 combi-packs of Schedule-7 in one pouch and 18 multi-blister calendar combi-pack of Schedule-8 in another pouch	Each combi-pack of	Each multi-blister calender
		Schedule 7 Containing	**of Schedule-8 containing**
		1 R Tab.of 150mg	3 R Tabs.of 150 mg each
		1 H Tab. of 150mg	3 H Tabs. of 150mg each
		1 E Tab of 400mg	4 Pyridoxine Tabs of 5mg
		1 Z Tab. of 500mg	
Product Code-15	Treatment box for prolongation of intensive phase of pediatric cases (18-25 kg). Each box containing 5 pouches and each pouch containing 12 blister combipack of Schedule-5	Each combi-pack of	
		Schedule - 5 Containig	
		1 R Tab.of 75mg	
		1 H Tab. of 75mg	
		1 E Tab of 200mg	
		1 Z Tab. of 250mg	
Product Code-16	Treatment box for prolongation of intensive phase of pediatric cases (18-25 kg and 26-30 kg). Each box containing 5 pouches and each pouch containing 12 blister combipack of Schedule-7	Each combi-pack of	
		Schedule 7 Containing	
		1 R Tab.of 150mg	
		1 H Tab. of 150mg	
		1 E Tab of 400mg	
		1 Z Tab. of 500mg	

The generic patient wise boxes, i.e. PC 13 and PC 14, according to weight band would be used for the pediatric patients in the following manner:

2 Types of generic boxes		
Weight Bands	**Product Codes**	
	PC-13	**PC-14**
6 - 10 kg	1	
11 - 17 kg		1
18 - 25 kg	1	1
26 - 30 kg		2

For prolongation of Intensive phase, PC 15 & PC 16 according to weight band would be used for the pediatric patients in the following manner:

For prolongation of Intensive phase		
Weight Bands	**Product Codes**	
	PC-15	**PC-16**
6 - 10 kg	1	
11 - 17 kg		1
18 - 25 kg	1	1
26 - 30 kg		2

The boxes have been designed to suit the requirements of New TB Cases which are expected to dominate the pediatric patients. However, for treatment of a Re-treatment pediatric patient, following steps will have to be taken to convert the generic boxes:

Re-treatment Cases

For children to be placed on Re-treatment cases, PPs would be added for prolongation of IP. For the extra 1 month of CP, a PP would be added after removing the Pyrazinamide tablets from the PP. For the other 4 months of CP blisters, Ethambutol tablets will need to be added which can be used from the supplies of loose drugs under the Programme.

SM Inj (750 mg) supplied under the programme shall be used for such patients and the dosage would be as per body weight.

Categorization and duration of therapy

Categorization of pediatric cases will be as per RNTCP policy. The treatment regimens recommended under RNTCP shall be the same for adult and pediatric cases. The duration of therapy will also be as per the treatment regimen. If required, the duration of therapy may be extended within the current RNTCP guidelines.

Use of Prolongation Pouches

Sputum positivity in the pediatric patients of lower weight categories is usually not found and it is also difficult to get a sputum sample in such children. However, for the older patients, sputum samples can be obtained and prolongation of intensive phase may be required. For such patients, prolongation pouches will be required. In addition, PP would also be required for the purpose of reconstitution of the PWBs of patients who have died, defaulted, transferred out and indoor patients who also would be treated under RNTCP using PPs.

The use of pediatric drugs & prolongation pouches for all pediatric patients categorized as New cases or Re-treatment cases can hence be summarized as follows:

Desktop Reference Chart for the preparation and use of Pediatric PWBs

Weight Bands	Cat - I	Prolongation of Cat - I	Cat - II	Prolongation of Cat - II	Cat - III
6-10 Kg	One PC 13	One PC 15	• Add one PC 15 to IP. • Add 24 vials of Inj SM to IP (to be administered @ 15mg / kg) • Add one PC 15 to CP after removing Tab Pyrazinamide (250 mg). • Add 54 Tab Ethambutol (800 mg) to the existing 4 months of CP (200 mg to be administered and the rest discarded)	One PC 15	One PC 13 (minus Ethambutol tablets from IP)
11-17 Kg	One PC 14	One PC 16	• Add one PC 16 to IP. • Add 24 vials of Inj SM to IP (to be administered @ 15mg / kg) • Add one PC 16 to CP after removing Tab Pyrazinamide (500 mg). • Add 54 Tab Ethambutol (800 mg) to the existing 4 months of CP (400 mg to be administered and the rest discarded)	One PC 16	One PC 14 (minus Ethambutol tablets from IP)
18-25 Kg	One PC 13 + One PC 14	One PC 15 + One PC 16	• Add one PC 15 and one PC16 to IP. • Add 24 vials of Inj SM to IP (to be administered @ 15mg / kg) • Add one PC 15 and one PC16 to CP after removing Tab Pyrazinamide • Add 54 Tab Ethambutol (800 mg) to the existing 4 months of CP (600 mg to be administered and the rest discarded)	One PC 15 + One PC 16	One PC 13 + One PC 14 (minus Ethambutol tablets from IP)
26-30 Kg	Two PC 14	Two PC 16	• Add two PC16 to IP. • Add 24 vials of Inj SM to IP (to be administered @ 15mg / kg) • Add two PC16 to CP after removing Tab Pyrazinamide (500 mg) from • Add 54 Tab Ethambutol (800 mg) to the existing 4 months of CP	Two PC 16	Two PC 14 (minus Ethambutol tablets from IP)

Chemoprophylaxis

Asymptomatic children under 6 years of age, exposed to an adult with infectious (smear-positive) tuberculosis from within the same household, are to be given 6 months of Isoniazid (5 mg per kg daily) as chemoprophylaxis. Loose tablets of INH 100 mg would continue to be supplied for this purpose as was previously done.

Use of Pediatric Patient Wise Boxes for underweight adult patients (<30 Kgs)

One adult patient <30 kg would require two generic boxes of the PC 14. These boxes would be used according to the category of the patient, if required, after making alterations in the boxes as given above.

GUIDELINES ON MANAGEMENT OF DRUG LOGISTICS FOR PMDT

A comprehensive Drug Logistics Management System has been developed and implemented at various levels for RNTCP 2nd Line drug supplies. This section serves to outline the DLS framework and key procedures contemplated under the system.

Overview

The basic idea underlying DLS for 2nd Line drugs is to ensure the continuous availability of good quality drugs at all stocking/ service delivery points under the programme. Programmatic Management of Drug Resistant TB (PMDT) refers to DOTS programme that adds components for MDR-TB diagnosis, management and treatment. These guidelines promote full integration of DOTS and PMDT activities under the RNTCP, so that patients with MDR-TB are both correctly identified and properly managed under the recommendations set out in this document. The MDR guidelines have introduced new standards for registering, monitoring and reporting outcomes of multidrug-resistant TB cases. This uniform information management system will allow systematic, consistent data collection and analysis that will play an important role in shaping future policies and recommendations.

Receipt of loose PMDT drugs

SDS' may receive drugs from multiple sources including:

1) Suppliers
2) SDSs of other states
3) DTCs/ SDSs of the same state.

Drug requirements for 2nd line drugs under PMDT is determined annually by CTD and communicated to the Procurement Agent. Requirements as above are conveyed by the Procurement Agent to the Manufacturer(s) in the form of supply schedules. Supplies made to State Drug Stores under this mechanism, have typically had no relationship with stocks already available and/or immediately required by them, but are instead based on the fixed number of MDR patients to be put on treatment in the State, as per a pre-determined PMDT Plan.

Receipts from SDSs of other states are coordinated by CTD and may not necessarily be based on the response to quarterly reports/ additional stock requests made by State TB Officers (STO).

Returns/ transfers from districts/ other SDSs (in the same state) are usually a direct consequence of instructions issued by the STO to correct stock imbalances observed within the state.

Receipt of Drugs From Supplier(s)

Some of the PMDT drugs received in the programme may be imported. For such drugs the suppliers shall require some documents to be submitted prior to their dispatch. These documents are required to be filled in by the STO & dispatched within a week to the

Suppliers/Procurement Agents. On receipt of drugs the following procedures are recommended:

1) Ensure that an approved copy of the Advance Consignment Intimation (ACI–I), prepared by the Procurement Agency, is received either before or along with the consignment. The ACI serves as an authorization document, enabling the SDS to receive the consignment of drugs.

*(**Note:** Receipt of drugs at SDS culminates in the creation of a liability to be discharged by the programme with respect to the cost of drugs and transportation expenses incurred. Accordingly drugs shall be received only against an approved/ authorized order e.g. approved ACI or equivalent document.)*

2) Additionally ensure that a complete set of transmission documents (including the Supplier's Invoice, Delivery Challan, Packing List, Copy of Inspection Certificate / Dispatch Clearance, Copy of Insurance Cover Note, Goods Receipts and Acceptance Note, Consignee Copy of Lorry/ Courier Receipt, etc.) describing the contents of the shipment, is handed over by the transporter, along with the incoming shipment of drugs.

*(**Note**: While acknowledging receipt of drugs, the Storekeeper should ensure whether sufficient shelf life is available such that it could be administered to patient before the date of expiry of drugs. At least 5/6th of shelf life is required to be available at the time of drugs reaching the SDS from the supplier. If the total shelf life is 3 years or more, it becomes the responsibility of the storekeeper to confirm that drugs received from the supplier have at least 5/6th of balance shelf life.)*

3) Check the contents of the incoming consignment to ensure conformity with ACI and specifications as per the supplier's transmission documents, as above.

(***Notes:***

a. *The check shall be limited to visual inspection and count of the number of cartons received and matching the same with the Invoice and Challan of the supplier. The Storekeeper will not ordinarily open sealed cartons unless:*
    i. *The seal and/or exterior suggest damage or shortage*
    ii. *Shortages have been frequently observed in the recent past, suggesting that it would be prudent to verify contents. In such cases, verification may be carried out for a period of time or in respect of a specific Supplier.*
b. *There could also be instances where the supplier has opted to make part shipments. In such cases, the Storekeeper shall flag the ACIs in question and record details of drugs received and the balance quantity pending supply. The Storekeeper shall follow-up closely with the supplier in respect of all flagged ACIs, ensuring that balance supply is made at the earliest.*

4) In case of shortages and/ or transit damages determined through visual inspection, the same should be brought to the attention of the transporter. Details of the shortage/ damage should be noted on the Supplier's Delivery Challan / Invoice and the transporter's attestation thereof obtained by means of signature.

*(**Notes:***

a. *In the case of shortage/ damage determined by the Storekeeper through visual inspection s/he shall take the precaution of opening the seals of all cartons received and carefully checking their contents.*
b. *Ideally, SDS should take custody only of undamaged stock from the perspective of the drugs in question being in a good enough condition to be administered to patients. SDS shall simultaneously report details of damaged stocks received, if any, to the Supplier, Procurement Agency and CTD. Based on the SDS report, CTD would liaise with the Procurement Agency, for the early replacement of damaged stocks through the Supplier. SDS shall segregate and preserve damaged stocks till the time of their replacement.)*

5) After visual inspection, acknowledge drugs received in Supplier's Challan / Invoice and return it to the transporter. The Storekeeper shall retain a copy of the above document in the stores receipts file. In the exceptional cases, where shortages/ transit damages are noticed, the Storekeeper should forward a photocopy of the transporter's/ Supplier's Challan/ Invoice to the STO/CTD, for onward transmission to the Supplier/ Procurement Agent/ GDF, to highlight shortage/ transit damage.

6) Thoroughly check the contents of consignments received down to the lowest packaging unit, prior to acknowledging the same in the Goods Receipt and Acceptance Note (GRAN). The Storekeeper should forward one copy each of GRAN to the Supplier, Procurement Agency and CTD, within 15 days of receipt also retain a copy of the same in the Stores Receipts File.
*(**Note:** GRAN is raised by the Supplier and sent directly to the SDS or as part of the complete set of documents forwarded through the transporter, accompanying the consignment of drugs.)*

7) Record complete details of the drug consignment actually received (viz. Supplier, Invoice Particulars, Batch Reference, Date of Expiry, etc.) in the Bin Card & in the relevant folio of the Stock Register.

*(**Note:** In the case of shortage/ damage/ discrepancy in the quantity of drugs actually received vis-à-vis indicated as per the transmission/ authorization document, record complete details of the same in the 'Remarks' column of the SR and highlight the same.)*

Receipt of Drugs from State Drug Stores of other states

Pursuant to the quarterly review, CTD may periodically authorize transfer of drugs from one state to another state, to adjust stock imbalances and/or ensure the timely utilization of close to expiry drugs. A formal Drug Transfer Advice shall be prepared by CTD & should be e-mailed/ faxed to the transferor/ sending unit and the transferee/ recipient unit. Following this, the Storekeeper of the transferor/ sending unit shall generate a State Issue Voucher (SIV).

On receipt of the transferred drugs, the Pharmacist of the recipient unit shall repeat steps (1) to (5) and (7) detailed at paras above on the receipt of drugs transferred from other SDSs, with the exception that the authorization document in this case shall be the DTA and acknowledgement of the drugs received shall be made by signing the SIV. Acknowledged copies of the SIV shall be sent to the STO, the transferring SDS & to CTD.

Intra-State Return/ Returns of Drugs Districts

In the normal course, the SDS shall receive drugs either from Supplier(s) or SDS of another state. However, pursuant to the quarterly review, the STO may authorize transfers from multiple SDSs within the state, to adjust stock imbalances and/or to ensure the timely utilization of close to expiry drugs. Once again, a formal DTA should be generated by the STO for the purpose and emailed/ faxed to the transferor/ sending unit and the transferee/ recipient unit. In the same manner as stated above, the Storekeeper of the transferor/ sending unit shall generate a SIV and arrange for the dispatch of drugs as requested.
The Pharmacist of the recipient unit shall repeat steps (1) to (5) & (7) detailed at previous pages on the receipt of drugs transferred from other SDSs within the state or DTCs within the state, with the exception that the authorization document in this case shall be the SIV or DIV. Acknowledgement of drugs received should be made by signing the SIV/DIV & shall be sent to the STO, as well as the transferring SDS/DTC.

Packaging of Loose drugs into 1-monthly Type A , B and C Boxes:

RNTCP Category IV is a standardized regimen for treatment of M/XDR–TB patients.

RNTCP CATEGORY IV REGIMEN: 6 (9) Km Lfx_{HD} Eto Cs Z E / 18 Lfx_{HD} Eto Cs E

The SDS will need to re-pack the loose drugs into 1 monthly boxes of Type A (Core oral drugs) and Type B (IP Plus) boxes. Na PAS is also procured and supplied to States to deal with patients who need individual drug substitution due to adverse drug reactions and need to be supplied as Type C box. The three types of monthly boxes shall thus contain following drugs:

For Regimen of MDR TB:

Type A (Core oral drug box)	**Type B (IP Plus box))**	**Type C (Common box containing Na PAS)**
Levofloxacin-250/500 mg (Lfx)	Kanamycin-500mg /1G(Km)	Box containing 1 month of Na PAS and will be common for all patients
Ethionamide-125/250 mg (Eto)	Pyrazinamide-500 / 750 mg (Z)	
Cycloserine-250mg (Cs)		
Ethambutol-200/800 mg (E)		
Pyridoxine-50/100mg		
Substitute / Reserve Drugs		
Moxifloxacin- 400 mg (Mfx)	Capreomycin-750mg/1G (Cm)	

For Regimen of XDR TB:

Type A (Core oral drug box)	Type B (IP Plus box)	Type C (Common box containing Na PAS)
Moxifloxacin-400 mg (Mfx)	Capreomycin-750mg /1G(Cm)	Box containing 1 month of Na PAS and will be common for all patients
Isoniazid-300 mg (INH)		
Clofazimine-200mg (Cfz)		
Linezolid-600 mg (Lzd)		
Amoxyclav-875/125mg (Amx/Clv)		
Pyridoxine-50/100mg		
Substitute / Reserve Drugs		
Clarithromycin-500mg (Clr)		
Thiacetazone- 150 mg (Thz)**		

**** Depending on availability, not to be given to HIV +ve patients**

Technical specification of patient wise box

The technical specifications of the 1 monthly patient wise box for M/XDR TB cases is detailed in Annexure XVI. The patient on Intensive Phase (IP) shall be put on Type A and Type B boxes in each month. During the Continuation Phase (CP), the patient will be put on only Type A box for the entire duration and Type C box will be issued in case of intolerance to any of the drug in the M/XDR TB Regimen, i.e.

For IP= Type A box + Type B box of same weight band
For CP= Type A box of same weight band.
For both IP and CP= Type C box containing Na PAS only

The SDS will supply drugs to the DTC in the form of 1 monthly Type A and Type B drug boxes (excluding PAS which will be supplied separately as Type C box) during the Intensive and Continuous Phases. However, in case of drug boxes for < 16 kgs and > 70kgs, drugs to be added or removed from the existing boxes following the recommended dosage and label the boxes accordingly. These are included in the Type of boxes category for the accountability and reporting of the drugs. These drug boxes will be prepared at the SDS and will be of eleven different types:

For Regimen of MDR TB:

Type of Boxes	Type A	Type B	Type C
Weight Bands	< 16kgs	< 16kgs	Containing NaPAS only (common for all wt. Bands)
	16 - 25 Kgs	16 - 25 Kgs	
	26 - 45 Kgs	26 - 45 Kgs	
	46-70kg kgs	46-70kg kgs	
	>70kgs	>70kgs	

For Regimen of XDR TB:

Type of box	Weight Bands
Type A	< 45kgs
Type-B	>45 kgs
Type C	Containing NaPAS only (common for both wt. Bands)

The Type A box containing oral drugs shall be common in both the Intensive & the Continuation Phase for each weight band. Type B box containing Inj Km & Pza (in case of MDR) and Inj.Cm. (in case of XDR) shall be required additionally in the Intensive Phase and Type C to be given on requirement basis.

For Regimen of MDR TB:

Weight Bands	**Intensive Phase (IP) Box**	**Continuation Phase (CP) Box**	**Common Box**
<16kgs	Type A + Type B	Type A	Additional box Type C containing only NaPAS
16 - 25 Kgs	Type A + Type B	Type A	
26 - 45 Kgs	Type A + Type B	Type A	
46-70kg kgs	Type A + Type B	Type A	
>70kgs	Type A + Type B	Type A	

For Regimen of XDR TB:

Weight Bands	**Intensive Phase (IP) Box**	**Continuation Phase (CP) Box**	**Common Box**
< 45kgs	Type A + Type B	Type A	Additional box Type C containing only NaPAS
> 45kgs	Type A + Type B	Type A	

The quantity of drugs required for preparation of different categories of monthly PWBs for M/XDR are as below:

For Regimen of MDR TB:

Sr.No	**Drugs**	**16-25 Kg**	**26-45 Kg**	**46-70 Kg**	**>70kg**
1	Kanamycin (500&1G) (IP)	500 mg	500 mg	750 mg	1G
2	Levofloxacin(250&500mg) (IP/CP)	250 mg	750 mg	1000 mg	1000mg
3	Ethionamide (250mg) (IP/CP)	375 mg	500 mg	750 mg	1000mg
4	Ethambutol (200&800mg) (IP/CP)	400 mg	800 mg	1200mg	1600mg
5	Pyrazinamide (500 & 750mg) (IP)	500 mg	1250 mg	1500 mg	2000mg
6	Cycloserine (250mg) (IP/CP)	250 mg	500 mg	750 mg	1000mg
7	PAS (80% Bioavailability)	5 gm	10 gm	12 gm	12gm
8	Pyridoxine (100mg) (IP/CP)	50 mg	100mg	100mg	100mg

For Regimen of XDR TB:

Sr.No	Drugs	< 45kg	>45kg
1	Capreomycin (750&1G) (IP)	750 mg	1G
2	Moxifloxacin (400mg) (IP/CP)	200 mg	400mg
3	Isoniazid (300mg) (IP/CP)	600mg	900mg
4	Clofazimine (200 mg) (IP/CP)	200 mg	200mg
5	Linezolid (600mg) (IP/CP)	600 mg	600mg
6	Amoxyclav(875/125mg) (IP/CP)	875/125 mg (BD)	875/125 mg (BD)
7	PAS (80% Bioavailability)	10 gm	12gm
8	Pyridoxine (100mg) (IP/CP)	100 mg	100mg
Reserve/Substitute Drug			
1	Clarithromycin (500mg)	500mg (BD)	500mg (BD)
2	Thiacetazone (150mg)	150mg	150mg

- The dosages of 2nd line drugs **for cases < 16 kg** based on the Guidelines for Programmatic Management of Drug Resistant TB, Emergency Update-2008 will be used for treatment of MDR TB cases in pediatric age group weighing < 16 kg as per the table below:

Drug	Daily Dose – mg/kg body weight
Kanamycin / Capreomycin	15-20 mg/kg
Levofloxacin / Moxifloxacin	7.5-10 mg/kg
Ethionamide	15-20 mg/kg
Cycloserine	15-20 mg/kg
Ethambutol	25 mg/kg
Pyrazinamide	30-40 mg/kg
(Na-PAS)	150 mg/kg

For cases > 70 kg, use additional drug dosages of some 2nd line drugs to treat the MDR TB cases, taking the dosage to Kanamycin (1 gm), Ethionamide (1 gm), Cycloserin (1 gm), Ethambutol (1.6 gm) and Pyrazinamide (2 gm) based on the WHO Guidelines for Programmatic Management of Drug Resistant TB, Emergency Update-2008. These are well within the maximum permissible dosage for each drug as per the WHO guidelines.

Packaging Instructions:

i. Packaging of loose drugs into Type A, B & C boxes should be done under guidance of the STO/Medical Officer/Drug logistics In-charge at the State level.
ii. One monthly pouch of Cap. Cycloserine & Tab. Ethambutol to be made from plastic bag with zip lock facility in which 1 gm. pouch of silica gel desiccant should be kept. In each Type A box, one pouch of silica gel desiccant of 4 gm. weight should also be kept.
iii. Durable cardboard boxes with defined thickness and size should be used for the Type A, B & C boxes. These boxes should be made from weather resistant, triple

walled, insulated, corrugated, RSC (Universal) type 4-ply Shippers, each ply having strength of minimum 150gsm. These should be fabricated from virgin quality 'A' grade Kraft paper.

iv. Each Type A, B & C box should be numbered consecutively at the SDS. The record of the serial no. of the box should be maintained at the State, District & Sub-district (TU) Drug Stores and it will be of help while tracking a particular box.

v. Instructions should be issued to the DOT provider that the drug boxes should be closed properly every time after withdrawal of drugs from them.

vi. Label on the boxes to clearly mention the following:-

a. Item-wise name of drugs with quantity of each drug in the box.
b. Batch No. & DOE of individual drugs.
c. DOE of the boxes – should be the expiry date of the drug having shortest expiry.
d. Date of Issue of the box from SDS.
e. Serial number of the box.
f. Storage instructions on the box in English/ Hindi/ local regional language for ensuring adequate precautions in storage of the drugs, especially at the DOT provider level. Some suggested messages are:-
   - Store in a cool and dark place preferably in a clean cup board.
   - Do not expose to direct sunlight.
   - Keep away from children/unauthorized persons.
   - Box to be closed properly every time after withdrawal of drugs.

Issue of Loose drugs/ Patient Wise Boxes

This section deals with procedures to be followed for the issue and dispatch of drugs by State Drugs Stores (SDS).

SDSs shall issue and dispatch drugs under the following circumstances:

1. Routine monthly supplies of loose drugs to PMDT Sites (DOTS Plus Sites)
2. Routine quarterly supplies of 1-monthly Type A, B and C Boxes to PMDT implementing District Tuberculosis Centre's (DTCs)
3. Supplies to DTCs against Additional Drug Requests (ADR)
4. Transfers to other SDS(s) in the same state
5. Transfers to SDS(s) in other states.

Issues for the purpose of routine monthly/ quarterly and additional/ supplementary supplies to DTCs or transfers to other SDSs in the same state, shall be determined by the STO/ Dy. STO / Second MO/ Other Responsible Officer (authorized by the STO for the purpose), on the basis of analysis of Monthly Stock statements (MSS)/ Quarterly Reports on Programme Management & Logistics (QRPML) and/ or ADRs. Transfers to SDSs in other states, if any, shall be made on the basis of instructions from CTD.

Implementing DTCs shall be linked to the most convenient SDS (in terms of proximity and transportation arrangements) in the case of states having more than one SDS. Ideally DTCs shall only receive supplies from the associated SDS, identified through the above process.

Procedures recommended for the above transactions, are detailed in the paragraphs that follow.

Monthly Supplies of loose drugs to PMDT Sites

As per the PMDT guidelines, only loose drugs shall be issued to the PMDT sites. Monthly replenishment of drug stocks with PMDT sites shall be based on the MSS submitted by them, providing complete details of opening and closing stocks, receipts, utilization and anticipated requirement. The format to be used at PMDT site for reporting stock statements at end of the month is provided at Appendix III-B.

Information provided in the MSS shall help to determine the drug requirement of the PMDT Site for the next month, considering drug stocks availability, utilization/ consumption of drugs during the month, stocking norms, etc.

The SDS Store Assistant shall perform the following activities on receipt of the MSS:

1. Prepare three copies of the State Issue Voucher for the purposes of recording issue of drugs from stores
2. Identify and segregate drugs to be issued as per the MSS, ensuring strict application of FEFO principles
3. Hand-over drugs to transporter for onward dispatch, along with first and second copies of SIV
4. Obtain acknowledgement from transporter on third copy of SIV, retaining and filing the same for store records
5. Update the Bin Card & the Stock Register for issues made
6. Receive back and file the second copy of SIV (consignee copy), duly acknowledged by the concerned DTC.

Quarterly Supplies to DTCs

As per the PMDT guidelines, only 1-monthly Type A, B and C boxes are to be issued to the implementing DTCs. Hence, the SDS needs to repack the loose drugs into the 1 monthly boxes for all categories of patients as described in the above paras. Once the SDS is ready with the boxes, they need to be suitably recorded as such in the Bin Card & the Stock Register. The first time, the SDS shall send some Type A, B and C boxes to the implementing DTC, after checking with the possible number of patients at the PMDT Sites. Subsequently, the flow of boxes shall be monitored through the District QRPML. The DTC shall then forward the boxes to its implementing TU in a similar manner & then monitor through the TU QRPML. The format for QRPML is provided at Appendix III-C.
The flow of boxes shall continue to be issued from the SDS to the DTC at the end of the treatment of first three months of IP (1st Quarter), information of which shall be received through the QRPML. These boxes will then be issued to the TU by the DTC accordingly.
Quarterly replenishment of drug stocks with districts shall be based on the QRPMLs submitted by them, providing complete details of opening and closing stocks, receipts, utilization and anticipated requirement. Only Type A, B and C boxes shall be issued to the DTC & no loose drugs shall be issued. These shall be recorded in the bin card as well as in the stock register.

Information provided in the QRPML shall help to determine the drug requirement of districts for the next quarter, considering drug stocks availability, utilization/ consumption of drugs during the quarter, stocking norms, etc.

The SDS Storekeeper shall repeat steps (1) to (6) described as above for the purposes of issuing drugs to DTCs and the authorization document for this transaction shall be the QRPML.

Transfer of Loose drugs and 1-monthly Type A, B or C boxes to State Drug Stores in the same State

The quarterly review cycle by STO/ Dy. STO/ Second MO (please refer to the above paras), may suggest benefit from the transfer of temporarily excess loose drug stocks and 1-monthly Type A, B or C boxes available at any one SDS to the other(s), within the same state. Transfer as above shall be done through the means of DTA, generated by the STO.

The Storekeeper shall repeat steps (1) to (6) detailed as above, with the exception that the authorization document for this transaction shall be the DTA.

Transfers to State Drug Stores in other States

Similarly, the quarterly review of state -level QRPMLs carried out by CTD may suggest benefit from the transfer of drugs across SDSs in different states to adjust stock imbalances and/or ensure the timely utilization of close to expiry drugs. Transfer as above shall be done through the means of DTA generated by CTD.

The Storekeeper shall repeat steps (1) to (6) detailed as above, with the exception that the authorization document for this transaction shall be the DTA.

***(Note**: Transportation arrangements for effecting transfers have been discussed in the chapter on Transportation in this manual. Frequently, direct transportation links from districts of one state to districts of another, shall not be available. Accordingly, inter-state transfers should be effected at the SDS and not the district level. This limitation is recognized by CTD at the time of recommending inter-state transfer of drug stocks).*

Monthly Stock Statement

The SDS Pharmacist shall prepare a Monthly Stock Statement providing details of receipts, issues, and opening/ closing balance of loose drugs as well as details of the monthly Type A, B & C boxes, as at the last day of each calendar month in the prescribed format. The MSS shall be prepared by pharmacist and submitted to the STO by the 5th of every month, by all the SDSs, in the state. The statement shall facilitate determination of drug stocks available with SDS(s) within the state.

MSS shall thereafter be forwarded to CTD through the STO, by the 10th of every month. In the case of more than one/ multiple SDSs within the state, all the MSSs shall be forwarded to CTD within the timelines stated above.

Inventory Management

Procedures for on-going tracking and replenishment of the inventory of 2nd line anti-TB drugs at the State Drug Store (SDS) and all subordinate stocking points ensures that these are maintained at or close to the stocking norms suggested by Central TB Division (CTD).

Drug flow – distribution and supply chain management:

- **DR-TB Centre-** The loose drugs supplied by the SDS to the indoor facility of the DR-TB Centre shall be based on the number of admitted MDR patients expected at the DR-TB Centre over a period of a month. Thereafter, issue of drugs shall be based on the Monthly Stock Statement submitted by the DR-TB Centre, to ensure maintenance of adequate stocks for a month of treatment plus a buffer of 1 month. On discharge of the patient, loose drugs for 7 days shall be issued by the DR-TB Centre to the patient to cover the transit period. During this time, it is expected that the patient shall reach home for the ambulatory treatment to commence on the 1-monthly IP box which has by then been issued to the respective DOTS provider as arranged by the DTO.

- **Implementing DTC-** The Patient will report to the respective DTO who will arrange for the supply of the 1 monthly drug boxes of Type A, B & C from the respective PHI to the DOT Centre. The DTO will also be responsible for:

  a) Identification of the DOT provider in consultation with the MO-PHI and the patient.
  b) Training or briefing of the respective MO-PHI.

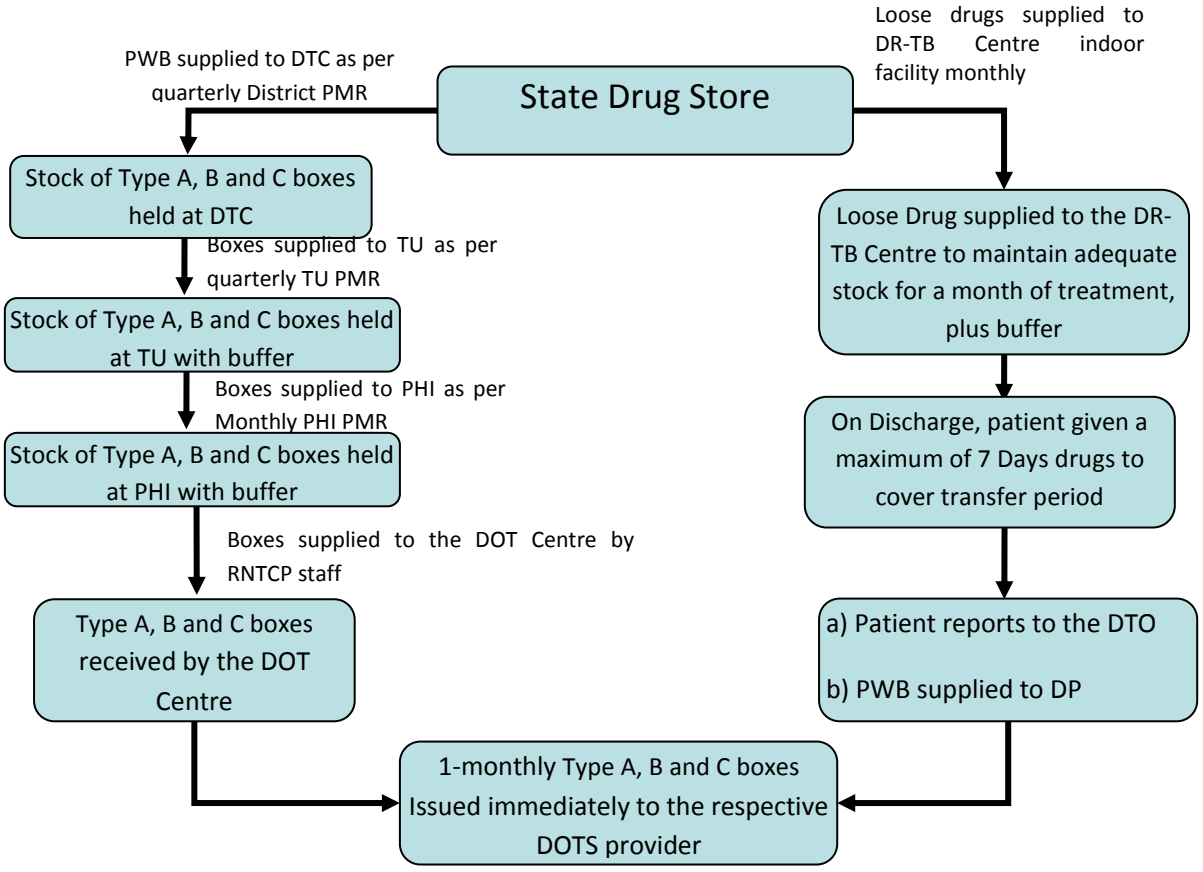
  The first time, SDS shall send some Type A, B & C boxes of the middle three weight bands (i.e 16-25kg, 26-45kg and 46-70kg) and for XDR (<45kg and > 45kg) to the implementing DTC, based on the number of admitted M/XDR patients at the DR-TB Centre for that district. Subsequently, the flow of Type A, B & C boxes shall be monitored through the District Quarterly Programme Management Report. The DTC shall send the boxes to its implementing TU in a similar manner on an quarter basis & then monitor through the TU Quarterly PMR. Buffer stocks of both Type A & B boxes of all weight bands may be held at all levels as per stocking norms as defined for the 1st Line Anti TB Drugs i.e. for 7 months at the district level. Type C boxes will be supplied on need based only as this is a substitute drug.

- **TB Unit -** Buffer stock equivalent to 4 months will be kept at the TU at the beginning of each quarter as in 1st Line Anti TB Drug management. The drug boxes will be supplied from the TU to the PHI. The drug box will be transferred from the TU to the respective PHI on instruction of the DTO for a new patient who has been discharged from the DR-TB Centre after initiation of treatment.

- **PHI** - Buffer stock equivalent to 2 months will be kept at the PHI at the beginning of each month as in 1st Line Anti TB Drug management. The drug boxes will be supplied from the PHI to the DOT Centre / DOT Provider.

If the IP of the patient is required to be extended, the respective DR-TB Centre Committee shall inform the DTO who will intimate the same to the MO-PHI and the respective TU. The PHI will release 1 Type A, Type B and Type C box (if needed) to the respective DOT Centre from where the patient is taking treatment. When the patient is switched to CP, the DTO shall intimate the same to the MO-PHI and the respective TU. On instruction of the DTO, the PHI will release 1 Type A box only to the respective DOT Centre from where the patient is taking treatment. During the period between when the DTO has been notified of the decision to change over to CP and the delivery of drug box from the PHI to the DOT centre, the patient's IP shall be continued. All patients who are given an extended IP must complete a full month of extension i.e. patient must have either 7, 8 or 9 months of IP.

The drug distribution flow may be depicted as follows:



Reconstitution at DTC in following situations :-

In a few situations where small quantities of drugs are found in the boxes returned, the DTC may reconstitute the monthly boxes from the available drugs.

Situation 1:

If complete strips of loose drugs are available in the box - then these can be used as such for reconstitution of monthly boxes at the DTC and the left over strips should be immediately sent back to SDS and from there to the DR-TB Centre.

Situation 2:
If incomplete strips of loose drugs are available in the box - then the same may be sent back to SDS and from there to the DR-TB Centre.

Definition of 'Short-expiry' for both IP & CP

It is expected that at the DTC level, any Type box having Date of Expiry less than 9 months shall be considered as a short-expiry box. The DTO shall bring the same to the attention of the STO to enable a decision on the diversion of these stocks to other DTCs where they may be able to consume them within their shelf-life. At TU level, any Type box which has a shelf-life of less than 6 months & where these boxes cannot be used within their shelf-life shall need to be transferred out. The STS/STLS shall inform the Medical Officer at the TU regarding the same & steps could be taken to divert them.

GUIDELINES FOR STORAGE OF 2nd LINE ANTI TB DRUGS FOR REVISED NATIONAL TB CONTROL PROGRAMME (RNTCP)

State Drug Store

1. **Storage Space:-**
   i. Requirements of space for various levels of drug stores should be based on the estimated number of M/XDR TB patients likely to be placed on treatment in the concerned State for whom the maximum quantity of drug stocks are to be maintained at the concerned stocking unit. As per the current guidelines of RNTCP, number of MDR TB patients who are to be placed on 2nd Line treatment are estimated as follows:-
      a. 3% of new cases of TB.
      b. 12-17% of re-treatment cases.
   ii. Based on above, storage space will need to be worked out separately for each State Drug store.

2. **Specifications for drug stores:-**
   i. The Drug Store should preferably comprise one large room. Where multiple rooms already exist, they should be contiguous or proximate to each other Preferably separate space for storage, handling and re-packing into IP/CP Boxes.
   ii. Ceiling to have a height of at least 5 meters.
   iii. A lockable door.
   iv. At least one window with grill with wire meshing.
   v. Proper lighting.
   vi. An even-level, 'pukka' floor.
   vii. Plastered walls and ceiling with whitewash without any kind of seepage in the room.
   viii. In case of a situation where separate room for storing 2nd line drugs is not possible, an attempt to demarcate and enclose a specified area for storing 2nd line drugs should be made within the larger store to ensure required temperature control for 2nd line drugs.
   ix. Architects should be consulted for suitable modifications in the existing drug store/construction of a new drug store for the same.
   x. A signage board with instructions in local language should to be put near the entrance of the store to remind the concerned officials regarding good storage practices.
   xi. Ideally, Vacuum de watered flooring (VDF) should be used for the Drug Stores. However depending on the feasibility, such flooring may be done at the State Drug Store level.
   xii. In case it is feasible at the State Drug Store level, separate areas should be demarcated for receiving and dispatching the drugs.
   xiii. Contract for Pest Control should be entered into by the State to ensure drug stores free from pests, rodents etc.

3. Shelves, Racks & Storage Arrangements:-

i. If sufficient space is available on the existing storage shelves in the State Drug Store (SDS), these shelves made of 40 mm. bore medium quality (external diameter - 48.3 mm.) mild steel pipes should continue to be used as per the existing RNTCP guidelines. New shelves, if required, are to be made from pre-fabricated slotted angles ensuring sufficient 'gap' between cartons from the ceiling, floor and walls, facilitating ventilation and the free movement of air.

ii. Shelves to be positioned so that there is no possibility of seepage into cartons.

iii. Typically, five rows of shelves to be fabricated, one on top of the other into racks. A single rack to usually be long enough to accommodate three cartons on each shelf. Accordingly, a rack would typically accommodate fifteen cartons.

iv. In the case of a broad room, there shall be multiple rows of racks, all parallel to one another. There should be sufficient space between parallel blocks of racks and the walls, to facilitate free movement of men and trolleys for the smooth stacking and removal of cartons. In case of a long and narrow room, racks to be positioned such that there is sufficient space between them and the walls.

v. Drug cartons to rest on shelves and not on each other, to prevent eventual sagging of the cartons in the bottom row.

vi. Rows & Columns, where drugs are stored should be defined and locations to be assigned a unique identification number.

In future, if the State Drug Store of a particular state has to handle large volume of drugs and occupies larger space, Isle space (between the two racks across the storeroom) can be of 3 metres. In such situation, material handling equipments shall be required.

4. Stacking Arrangements:-

i. Name of the Drugs along with their expiry dates be indicated on stickers pasted on the face of cartons/ drug boxes and should be written again by hand, in large easily visible characters using a colored, permanent marker pen.

ii. Insofar as possible, the same drug should be stored at a single location within the store.

iii. Additionally, drugs of the same expiry should be stored together at the same location.

iv. Recognizing the above rules, drugs expiring earliest should be so stored that they are issued first. For example, in case IP (< than 45 Kgs) boxes are placed on multiple shelves in a single part of the store, boxes expiring earlier should be stored at ground level and fresher boxes (which shall expire later) on elevated shelves. This method of stacking shall ensure that drugs that shall expire first shall automatically be issued first, based on the principle of FEFO (First Expiry First out).

v. Expired drugs should be segregated, sealed and stored in a separate part of the store eliminating the possibility of their issue to patients. Expiry dates should be highlighted in these cases.

vi. Bin cards at State Drug Store level be displayed which would provide details of Receipts, Issues, Closing balance (quantity) and expiry dates of drugs.

vii. Only Na-PAS is slow moving drug and should be stored at higher level shelves. Rest all other 2nd Line Drugs are fast moving, therefore, should be stored on lower level shelves.

5. Control of Humidity and Temperature:-

i. **Monitoring of Humidity & Temperature:**
Hydro thermometers are to be installed upto TU drug store levels to monitor humidity and temperature regularly. The record of both these variables should be maintained in charts properly and checked on a daily basis by the concerned Store Incharge. This should be reviewed by STO / Officer in-charge of SDS and necessary corrective measures be taken immediately.

ii. **Control of Humidity:** In order to keep humidity levels below the maximum **60%** recommended for storage of drugs, following measures may be taken:-

a. **Ventilation:** Open the windows or air vents of the store to allow air circulation. Ensure all windows have screens / wire mesh to keep out insects and birds and also should have metallic grills / iron bars. Drug Boxes/Cartons should be placed on shelves ensuring that there is sufficient space between shelves and walls of the store room.

b. **Packaging:** The cartons/drug boxes should not be opened unless necessary.

c. **Circulation:** Use fans to circulate fresh air from outside.

iii. **Protection from Sunlight:-** To protect the drugs from sunlight, following measures may be taken:-

a. Shade the windows or use curtains if they are in direct sunlight.
b. Keep products in cartons/drug boxes.
c. Do not store or pack products in sunlight.
d. Maintain trees around the premises of the drug store to help provide shade and cooling. Check their condition regularly to prevent any untoward incident.

iv. **Control of temperature:-** The 2nd Line Anti-TB Drugs should preferably be stored below **25^0 C**. In the area specified for storing 2nd Line Drugs, temperature of about **20^0 C** should be maintained with the help of Air-Conditioners (Tonnage would depend on size of the room).

v. **Power Supply:-** Regular power supply should be available for Air Conditioning in the State Drug Store. Arrangements for backup power supply should also be made through solar panels / fuel based power generators.

The purpose of information provided in the above sub-paras is to emphasise that the drugs should be stored in cool & dark place for proper efficacy. Experimental data/literature review also reveals that these drugs loose their efficacy beyond **6**

months if exposed to stressful storage conditions of **$40^0 \pm 2^0$ C** temperature and humidity of **75% ± 5** % RH.

6. Quality Assurance of Drugs:-

The quality assurance component of the RNTCP drug supply system makes certain that each drug used by a patient is safe, efficacious, and has appropriate standards of quality.

As per the protocol developed by Central TB Division (CTD), samples of 2nd Line Anti TB Drugs shall be picked up on random basis from various levels in the field and sent for testing by an independent drug testing laboratory contracted by CTD to find out any change in the quality of these drugs. This should be done based on communication sent by CTD to the concerned states and districts.

7. Waste Disposal Guidelines:-

If any drug expires due to reasons beyond control, it should be disposed off as per the procedures laid down in the Rules under Drugs & Cosmetics Act and Bio-medical Waste (Management and Handling) Rules of Govt. of India.

8. Guidelines for Recording, Reporting:-

The recording and reporting systems for drug stock management from the State Drug Store to the DR-TB Centre and to the Districts, TB Units and PHIs have been recently revised to suit the 1 monthly patient wise boxes system. Formats for Drug Logistics Management of 2nd line drugs under PMDT are described in ***Annexure XVII***.

9. Transportation of Drugs and Fire Safety:-

Measures remain the same as for 1st Line Anti TB Drugs and the guidelines of RNTCP.

GUIDELINES FOR DISTRIBUTION & SUPPLY CHAIN OF PURIFIED PROTEIN DERIVATIVE (PPD)

Introduction

Tuberculin Purified Protein Derivative (PPD) is an extract of Mycobacterium Tuberculosis, the bacteria that causes tuberculosis in humans. It is used to test if a person has been exposed to tuberculin protein, either from a previous tuberculosis vaccination, or from environmental exposure.

Tuberculin is injected under the skin to test if a person already has antibodies to the tuberculosis bacterium. The tuberculin will be injected under the skin of the forearm, where it forms a pale wheal a few millimeters in diameter. This is called the Mantoux test. The patient will be asked to return to the doctor 48 to 72 hours after having the test so that the results can be read.

Use of PPD in RNTCP

PPD is to be used for the diagnosis of tuberculosis in pediatric age group under the RNTCP.

For use of PPDs in the programme, a cold chain shall be required to be maintained for their storage purposes. As relatively larger quantities of PPDs will require to be maintained primarily at the State and district levels, the States/STOs will need to strengthen the implementation of State / District Cold Chain programme in their respective states/districts. The State Drug Stores (SDS) shall take care of the entire State's Cold Chain programme relating to PPDs in their respective regional areas.

The management function encompasses the activities of procurement, distribution, usage, monitoring and reporting.

Procurement

The procurement of PPDs has been done centrally by the Procurement Division of the MoHFW, based on requirement calculations and Technical specifications formulated by CTD and the Technical Committee. Requirement of PPD has been calculated based on the assumption of a requirement for 300 vials per million population.

Distribution

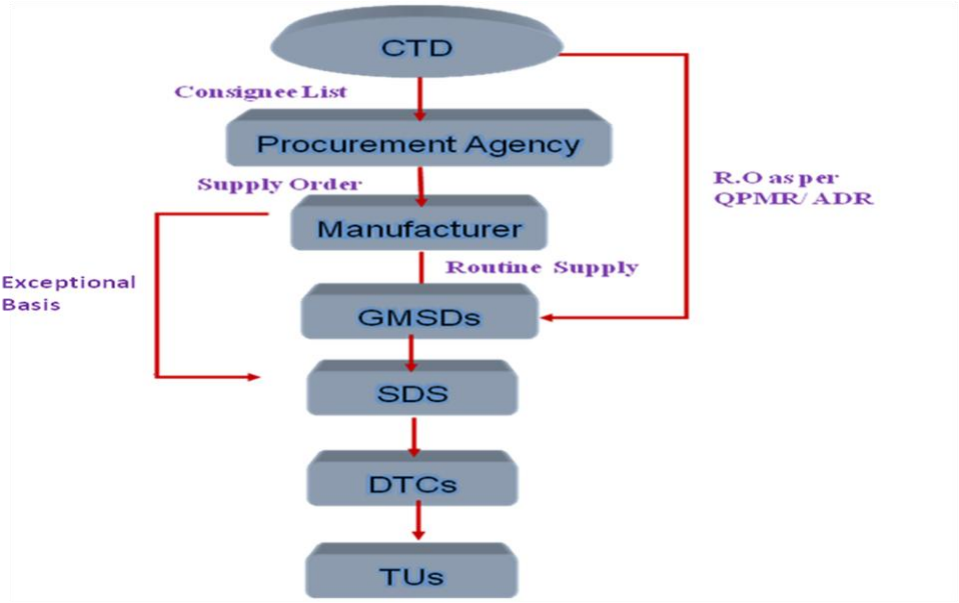
Supplies from Manufacturers shall be directed to the 4 GMSDs (Government Medical Store Depots) at Karnal, Mumbai, Kolkata and Chennai, exception just for 2 States (Andhra Pradesh & Assam). GMSDs have cold rooms where 2°-8°C temperature is maintained. These PPD vials will need to be stored in these rooms. The temperature in the cold rooms is monitored at regular periods during the day & recorded in the temperature log book for each cold room. CTD shall issue Release Orders to the GMSDs based on the requirements of the states including some buffer stocks. PPDs shall be supplied to all the SDS in

cold boxes containing ice packs. Buffer quantities of PPDs shall be stored at the SDS to meet out requirements of states from time to time.

At the State level, the PPDs shall be distributed to various Districts and TU's which includes buffer stock.

Distribution of drugs to the range of service delivery outlets under the programme will need careful monitoring, so as to ensure uninterrupted availability of quality PPD. Considering the number of pediatric TB patients diagnosed last year and expected number of suspects likely to be examined in the current year, estimated requirements at drug stocking points have been worked out. The total quantity required per district has been worked out to be about 40 vials including a 3-month buffer per district. This would translate to just about 2 vials per TU, assuming 10 TUs in a district.

Flow and Supply Chain of PPDs is depicted here below through a flow chart:-



Storage Points

Currently, as no cold chain arrangement is available at the State & district levels under RNTCP, the usual commercial refrigerator should suffice. Hence, all states & districts shall be required to procure 265 lts / 365 lts refrigerators in which the PPD vials will be kept. These refrigerators shall be kept in the drug stores. Assessment of the storage space shall be done in accordance with the quantity of stock to be stored in the refrigerator.

Care needs to be taken that PPD vials retain potency while stored at 2oC – 8oC and are not frozen. Packaging from the Manufacturer shall be in 10 Vials/Box. The boxes shall be stored in the refrigerators provided as mentioned above.

Transportation Mechanism

GMSDs to SDS - GMSDs have thermocol boxes which are lined with ice-packs.
These are used to transport vaccines from GMSDs to the SDS. The same mechanism will need to be in place for PPD vials. As per instructions from Central TB Division, GMSDs will supply the stocks of PPD to the SDS based on R.Os issued from CTD on a quarterly basis, or need-based, as the case may be.

SDS to DTC - The SDS will procure suitable sizes of thermocol boxes including ice gel packs for the transportation of PPD vials from SDS to Districts. These boxes shall be properly labeled & cold chain maintained by keeping ice bags inside the boxes. These boxes shall be transported through a courier agency, preferably the same used for sputum collection. Once these boxes reach the DTC, they shall be further used as sputum carriers only. As per past experience, these boxes can be used at least 4-5 times or till they get soggy, whichever is earlier. (eg. of thermocol boxes annexed)

DTCs to TU/PHCs - A refrigerator is generally available at all TUs. The DTOs may identify TUs which do not have a refrigerator & may accordingly arrange for one.
The following points are to be taken care of during transportation of PPD vials from GMSD to SDS and from SDS to DTC, TUs.

1. The PPD vials should be transported in thermocol boxes (big or small depending upon the requirement) along with the ice gel pack, pre-frozen to-**20° for 48 hrs.**

2. The GMSDs shall use the thermoplastic/thermocol boxes available with them to transport the PPD vials to SDS along with proper lining of the boxes with adequate ice pack gels well frozen to maintain the required temperature

3. Label the boxes providing complete information of the drug and the required temperature.

4. Mention ‘’**FRAGILE**’’ for double safety.

5. The SDS may further store these vials in the refrigerator and for further transportation to DTCs; they need to procure the thermocol boxes, ice gel packs, labels (format annexed), self adhesive tapes, markers.

6. The SDS needs to hire a courier agency who would be responsible to transport and deliver the PPD vials to the District Stores within stipulated time. These thermocol boxes may be used further to transport the vials to TUs depending on their condition.

7. Advance intimation to be given to DTC’s regarding dispatch of PPD vials.

8. PPD vials to be stored at a temperature of **2-8°C** at any point of time.

Labeling of PPD carrier boxes

The boxes shall be labeled with following information:

- Name of the item being transported
- Quantity of PPD,
- DOM & DOE of PPD vials
- Batch No of the vial,
- Temperature to be stored at **2^{o}C – 8^{o}C** and not to be frozen
- Indication for proper placing position,
- Other Instructions like - ***'Handle with care', 'Fragile'*** etc.

Usage

Injections and syringes for PPD administration to be procured by the states / districts locally. The syringes required for PPD are similar to the Insulin syringes freely available in the market.

Handling of Tuberculin Skin Testing Antigen (PPD)

1. Check expiration date on bottle before using.
2. Visually inspect product before use for particulate matter and discoloration and discard if either is seen.
3. Date and initial the bottle when the vial is opened.
4. Discard within 30 days after opening to avoid possible oxidation and degradation, which may affect potency.
5. PPD is sensitive to light; avoid exposure to strong light. Store vials in darkness except when product is being drawn up.
6. Draw up PPD just prior to injection.*

Monitoring and Reporting

Monitoring of drug supplies with regard to requirement and consumption is to be done through the existing system of Quarterly Reports, tracking the stock position at each district by providing details of the following:

a) Quantity of PPD received during the quarter

b) Quantity of PPD consumed

c) Stock of PPD received during the quarter

d) Closing stock of PPD

e) PPD required in the next quarter along with the buffer quantities

Reporting of PPD will continue to be as per the existing recording / reporting mechanism for 1st/ 2nd line Anti TB Drugs. Forms for reference of PPDs at DTC (Refer to form –III F) & TU levels (Refer to –III G) are placed in Appendix- III.

Quality Assurance

Similar to the pre & post-inspection tests undertaken in the programme, a quality check of PPD stock is to be done at the GMSDs at the time of receipt of the stock. Additionally, on a quarterly basis, as part of post-delivery QA process, samples of PPD stock shall also be regularly picked up from GMSDs, SDSs, DTCs and TU levels to ensure QA.

APPENDIX I: Operational Formats

(List of Operational Formats Available in this Appendix)

Title	Reference
Bin Card (BC)	I-A
Stock Register (SR)	I–B
State / District Issue Voucher (SIV / DIV)	I–C
Drugs Transfer Advice (DTA)	I–D
Worksheet for Reporting Drug Requirement (WRDR-DTC)	I- E
Worksheet for Reporting Drug Requirement (WRDR-TU)	I–F
Additional Drug Request (ADR)	I–G
Monthly Stock Statement (MSS)	I–H
Quarterly Report on Programme Management & Logistics (QRPML)	I–I
Reconstitution Register (RR)	I–J
Physical Verification Sheet (PVS)	I–K
District Quarter Report for PPD	I -L
TU Quarter Report for PPD	I -M

BIN CARD (BC) **1–A**

Drug Item: Unit of Measurement (UOM):

S. No.	Date of Transaction (Receipt / Issue)	Particulars of Receipts & Issues	Quantities (Nos.)		Quantity wise date of expiry of balance (Qty.)		
			Receipt (Qty.)	Issue (Qty.)	Balance (Qty.)	Expiry Date (.....)	Expiry Date (.....)
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)

Notes:

1) Please use separate Bin Cards for different drug items
2) Incase the receipt / issue transaction involves more than one batch, please use separate rows for separate batches
3) Fresh balance is to be struck on each transaction date, comprising the brought forward balance quantity plus receipt and less issues
4) Expiry date columns are for enabling tracking of expiry of drugs on hand. Expiry date shall be super scribed on the top of the column at the time of receipt of drugs and the quantity in the appropriate row. This quantity will be carried forward without change, till the time of an issue or receipt, involving the batch of drugs
5) The total of quantities reflected in columns g and h, should be equal to balance quantity reflected in column f.

I–B

STOCK REGISTER (SR)

Drug Item: _____ PC-1 Unit of Measurement (UOM): PWB Folio No.: _____

Sl. No.	Particulars of Receipts & Issues							Receipt (Qty.)	Issue (Qty.)	Balance (Qty.)	Date-wise expiry details of balance (Qty.)				Signa-ture of Store-Keeper	Remarks
	Date (Dd/ mm/ yy) of Tran-saction (Receipt/ Issue)	Name of Party (SDS/ DTC)	Invoice No./ Receipt Voucher No. (For Receipts only)	Issue Voucher No. (For Issues only)	Date of Invoice/Re ceipt Voucher/I ssue Vou-cher	Batch No.	Date of Expiry				Expiry Date (……..)	Expiry Date (……..)	Expiry Date (……...)	Expiry Date (……)		
a	b	c	d	e	f	g	h	i	j	k	l	m	n	O	p	q

Notes:

1. Please use separate Folios (viz. Stock Register Sheets) for different drug items
2. In case the receipt/ issue transaction involves more than one batch, please use separate rows for separate batches
3. Fresh balance is to be struck on each transaction date, comprising the brought forward balance quantity plus receipts and less issues
4. Expiry date columns are for enabling tracking of expiry of drugs on hand. Expiry date shall be superscribed on the top of the column at the time of receipt of drugs and the quantity in the appropriate row. This quantity will be carried forward without change, till the time of an issue or receipt, involving that batch of drugs
5. The total of quantities reflected in columns l, m, n and o, should be equal to balance quantity reflected in column k.

I–C

STATE / DISTRICT ISSUE VOUCHER (SIV / DIV)

Issue Particulars:
Issued To (Name of TU/DTC/SDS)……
DIV No & Date. ……
Issue Authorization Document: WRDR/ADR/DTA/ with Date of Approval……

Dispatch Particulars:
1. Dispatched By (Name of DTC)……
2. Name of Transporter: ……
3. LR/ RR/ ST No. and Date: ……

S. No.	Drug	UOM	Quantity Issued	Batch No.	Date of Expiry	Stores Register Folio No. of Issuer	Stores Register Folio No. of Recipient	Remarks
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)
1	PWBs for New Cases	PWB						
2	PWBs for Re-Treatment Cases	PWB						
3								
4								

KEY: UOM: Unit of Measurement; LR: Lorry Receipt; RR: Railway Receipt; ST: State Transport Receipt

Signature of Issuing Storekeeper:

Signature and Stamp of Transporter:

Signature of Recipient Storekeeper:

Signature of Issuing Officer:

Signature of Recipient Officer:

Notes:

1. Stores Register Folio No. is to be given both by the issuer and recipient of drug stocks and comprises the page number of the Stock Register on which the issue/ receipt is recorded

2. Signature and stamp of the storekeeper/ authorized signatory of both the issuing and the recipient unit are to be provided in the DIV.

DRUGS TRANSFER ADVICE (DTA) **I-D**

No. Dated:

Name of State (SDS)/District: _____

Full Name of STO/DTO: _____

Office Phone of STO/DTO (Pl. include STD Code): _____

Please ensure transfer of anti TB drugs to _____

(Name of State/District with complete Address and Phone No.) under the charge of

Dr._____ (Name of STO/DTO), as per the details below, under advice to us.

Sl.No.	Drug	UOM	Quantity	DOE	Transfer Date
(a)	(b)		(c)		(d)

Authorized Signatory: Date:

Notes:

1. This form shall be used for directing transfer of drugs by CTD from one SDS to other, and also by STO for transfer of drugs from one district to other district.
2. Transferor shall send copy of Issue Voucher (SIV or DIV) to the authorizer of this DTA, in confirmation of execution of transfer, along with details of transporter.
3. In case DTA is generated by SDS/STO then STO shall be the authorized signatory to DTA. In case DTA is generated by SDS/STO then STO shall be the authorized signatory.
4. Transferee district shall send the acknowledged copy of SIV or DIV, in confirmation of receipt of drugs, along with the folio of the Stores Register in which receipt of the drug item has been recorded.
5. In case of short expiry drugs, a cautionary note should be placed on SIV or DIV, urging immediate utilization.
6. Officials from both, transferor as well as transferee shall coordinate, to ensure quick execution of transfer.

I–E

WORKSHEET FOR REPORTING DRUG REQUIREMENT (WRDR-DTC)

District :

Drug: **For the Quarter Ending:**

Stocking Unit	Stock on first day of the quarter	Stock received during the quarter	Stock transferred in	Reconstitution of boxes during the quarter	Total availability of drugs during the quarter (f = b+c+d+e)	Stock transferred out	Patients started on treatment/ consumption during quarter	Issues to TUs	Stock on the last day of quarter [j = (f - g - h-i)]	Quantity requested [for TU: (h/3 x 4) –j] [for DTC: (h/3 x 7)-j]
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)
TU 1			xxxxxxx	xxxxxxx	0	xxxxxxx		xxxxxxx	0	0
TU 2			xxxxxxx	xxxxxxx	0	xxxxxxx		xxxxxxx	0	0
TU 3			xxxxxxx	xxxxxxx	0	xxxxxxx		xxxxxxx	0	0
TU 4			xxxxxxx	xxxxxxx	0	xxxxxxx		xxxxxxx	0	0
TU 5			xxxxxxx	xxxxxxx	0	xxxxxxx		xxxxxxx	0	0
TU 6			xxxxxx	xxxxxx	0	xxxxxx		xxxxxx	0	0
TOTAL stock position at TUs	0	0	0	0	0	0	0	0	0	0
DTC own stock position					0		xxxxxx	0	0	xxxxxxx
TOTAL stock position at District	0	0	0	0	0	0	0	0	0	0

KEY: SN: Stocking Norm

PREPARED BY: **CHECKED BY:** **APPROVED BY:**

Notes:

1. Use a separate sheet for each drug item
2. In the case of Loose Drugs, report ‘Consumption of Drugs During Quarter’ in column (h) instead of ‘Patients Started on Treatment During Quarter’
3. Issues from DTC shall match with the total of stocks received by all TUs.

I–F

WORKSHEET FOR REPORTING DRUG REQUIREMENT (WRDR-TU)

Tuberculosis Unit :
Drug : **For the Qtr Ending:**

Stocking Unit	Stock on first day of the quarter	Stock received during the quarter			Total Stock Received during the Qtr [f =(c + d +e)]	Patients started on treatment/ consumption during quarter			Total Patients started on treatment during the Qtr [j =(g+h+i)]	Issues to PHIs	Stock on the last day of quarter [l = (b+f - j-k)]	Quantity requested for Total TU: (j/3 x 4)-l]
		Month 1	Month 2	Month 3		Month 1	Month 2	Month 3				
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)
PHI 1					0				0	xxxxxx	0	0
PHI 2					0				0	xxxxxx	0	0
PHI 3					0				0	xxxxxx	0	0
PHI 4					0				0	xxxxxx	0	0
PHI 5					0				0	xxxxxx	0	0
PHI 6					0				0	xxxxxx	0	0
TOTAL stocks at PHIs	0	0	0	0	0	0	0	0	0	0	0	0
TU Own stock position					0	xxxxxx	xxxxxx	xxxxxx	xxxxxx	0	0	xxxxxx
TOTAL stock position at TU	0	0			0	0			0	0	0	0

KEY: SN: Stocking Norm

PREPARED BY: **CHECKED BY:** **APPROVED BY:**

Notes:

4. Use a separate sheet for each drug item
5. In the case of Loose Drugs, report 'Consumption of Drugs During Quarter' in column (h) instead of 'Patients Started on Treatment During Quarter'
6. Issues from TU shall match with the total of stocks received by all PHCs.

I–G

REQUEST FOR ADDITIONAL RNTCP DRUGS (ADR)

PLEASE USE BLOCK LETTERS:

Name of State/ District: _____
Full Name of STO/ DTO: _____
Office Phone of STO/ DTO, if any. (Pl. include STD Code): _____
Office Fax/ E-mail ID of STO/ DTO, if any: _____
Residential Phone of STO/ DTO, if any: _____
If none of above available, Phone No. at which message can be left for STO/ DTO: _____

Complete one sheet for each item for which additional medicines or reallocation of medicines is requested. For example, if you are requesting additional PWBs for New or Retreatment cases, then complete one sheet each for the same.

Item Requested (tick one):
□ PWB for New cases □ PWB for Re-treatment cases □ Prolongation Pouches □ Isoniazid 100 mg □ Rifampicin 450 mg □ Rifampicin 150 mg □ Pza 750 mg □ Inj SM 0.75 gms
□ PWB (6-10 kg) □ PWB (11-17 kg) □ PP (6-10 kg) □ PP (11-17 kg)

List Quantity of This Item Received in Previous and Current Quarter:

Date Received	**Total Number Received**

Stock Position on Last Day of Previous Month

Total Balance of the Unused Item on-hand at DTC Drugstores (a)	Total Balance of the Unused Item on-hand at TU Drugstores (b)	Total Balance of the Unused Item on-hand in PHIs I	Total Balance of the Unused Item on-hand in the Entire District (d=a+b+c)

Utilization of the Item for the Entire District in Previous Month:_____

Request for Additional Requirement of Drugs: □ I request _____units of _____ [item].
This will be sufficient for _____ months.

Signature of STO/ DTO: _____ Date: _____

I–H

MONTHLY STOCK STATEMENT (MSS)

(REPORT SHOWING RECEIPTS & ISSUES OF ANTI-TB DRUGS AS AT)

State: State Drug Store:

Sl. No.	Drug	UOM	Opening Balance	Receipts		Total Stores	Issues		Balance Stores with DOE
				Receipts During the Month	Drugs Trfd. In		Store Supplied	Drugs Trfd. Out	
(a)	(b)	I	(d)	(e)	(f)	(g = d+e+f)	(h)	(i)	[j = g-(h+i)]
1	PWBs for New Cases	PWB							
2	PWBs for Re-Treatment Cases	PWB							
3	PP	Pouch							
4	Inj SM 0.75 g	Vials							
5	Pza 750 mg	Tablet							
6	Rifa 150 mg	Caps							
7	Rifa 450 mg	Caps							
8	INH 100 mg	Tablet							
9	Eth 800 mg	Tablet							
10	INH 300 mg	Tablet							
11	PC-13	PWB							
12	PC-14	PWB							
13	PC-15	Pouch							
14	PC-16	Pouch							

KEY: UOM: Unit of Measurement

Note: In the case of Inj. SM, please maintain stock at the rate of 24 injections for each Re-treatment(PC-2) PWB in stock

I–I

QUARTERLY REPORT ON PROGRAMME MANAGEMENT AND LOGISTICS

DTC Level: Medication

Adult Patient Wise Box

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the quarter	Stock transferred in	Reconstitution of boxes during Quarter	Stock Transferred Out *	Patients started on treatment	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)= (c+d+e+f)-(g+h)	(j)= (h/3 x 7) - i
PC-1	PWBs								
PC-2	PWBs								

Prolongation Pouches and Inj SM

Item	Unit of Measure-ment	Stock on first day of Quarter	Stock received during the quarter	Stock transferred in	Reconstitution during Quarter	Stock Transferred Out *	Consumption during the Quarter	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)= (c+d+e+f)-(g+h)	(j)= (h/3 x 7) - i
Prolongation Pouches	Pouches each with 12 blister strips								
Streptomycin 0.75 g	Vials								

Paediatric Patient Wise Boxes (Including PWBs for Adult Patients <30kgs)

ITEM	Unit of Measure-ment	Stock on first day of Quarter	Stock received during the quarter	Stock transferred in	Reconstitution during Quarter	Stock Transferred Out *	Consumption during the Quarter	Stock on last day of Quarter	Quantity Requested
(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**	**(g)**	**(h)**	**(i)= (c+d+e+f)-(g+h)**	**(j)= (h/3 x 7) - i**
Paediatric PC 13	Boxes								
Paediatric PC 14	Boxes								
Paediatric PC 15	Pouches each with 12 blister strips								
Paediatric PC 16	Pouches each with 12 blister strips								

RNTCP Loose drugs

ITEM	Unit of Measure-ment	Stock on first day of Quarter	Stock received during the quarter	Stock transferred in	Stock Transferred Out *	Consumption during the Quarter	Stock on last day of Quarter	Quantity Requested
(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**	**(g)**	**(h)= (c+d+e)-(f+g)**	**(i)= (g/3 x 7) - h**
INH 300 mg	Tablets							
INH 100 mg	Tablets							
Rifampicin 150mg	Capsules							
Pyrazinamide 750 mg	Tablets							
Ethambutol 800 mg	Tablets						`	

Category IV Drugs for MDR TB

PWBs for	Unit of measurement	Stock on first day of quarter	Stock received during the quarter	Consumption during the quarter	Stock on last day of quarter	Quantity Requested
(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)= (c+d)-e**	**(g)= (e x 2) - f**
Type A (<16kg Body Weight)	PWB					
Type A (16-25kg Body Weight)	PWB					
Type A (26- 45 Kg Body Weight)	PWB					
Type A (46-70 Kg Body Weight)	PWB					
Type A (>70 Kg Body Weight)	PWB					
Type B (<16kg Body Weight)	PWB					
Type B (16-25kg Body Weight)	PWB					
Type B (26- 45 Kg Body Weight)	PWB					
Type B (46-70 Kg Body Weight)	PWB					
Type B (>70 Kg Body Weight)	PWB					
Type C (Na PAS Only)	PWB					

1. Is there any drug at the risk of expiry*? Yes / No If yes attach details

* PWB for New Cases – within 12 months; PWB for previously treated cases – within 14 months; PC 13 & PC 14 - within12 months; PWB for MDR TB Treatment Regimen – within 6 months.

2. Is there any expired drugs? Yes / No If yes attach details

I–J

Reconstitution Register (RR)

S. NO.	DATE	DOT/ PHI (From which drugs have been trans-ferred)	TB REGIS-TER NO.	Category	INPUT (No. of Blisters)					OUTPUT (No. of Boxes)		
					IP of PC-1 (24 Blister Combi-packs)	IP of PC-2 (36 Blister Combi-packs)	PP (12 Blisters in each PP)	CP of PC-1 (18 Multi-blister Combi-packs)	CP of PC-2 (22 Multi-blister Combi-packs)	Recon-stituted Drugs	Date of Expiry	Stock Register Folio No.
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)
		OPENING BALANCE										
		Total										

KEY: PC: Product Code; IP: Intensive Phase; CP: Continuation Phase

(1) Reconstituted IP & CP need to be put in poly bags with stickers on them, clearly mentioning that they comprise reconstituted IP or CP Pouches
(2) DOE of the reconstituted Patient Wise Box to be reported in Column (m) shall comprise the DOE of drugs used having the latest DOE
(3) Any loose drugs generated in the process may be used for patients put on non-DOTS treatment, or otherwise
(4) Reconstitution should be done under supervision of the DTO every quarter. DTO may instruct for reconstitution at shorter intervals, if required

I–K

PHYSICAL VERIFICATION SHEET (PVS)

Reporting Unit: SDS/ DTC/ TU Date of Physical Verification:

S. NO.	Drug	UOM	Qty & DOE as per stock register	Qty & DOE as per physical count	Discrepancy between stock register and physical count	Nature of discrepancy	How discrepancy was dealt with	Remarks
(a)	(b)	(c)	(d)	(e)	(f=d-e)	(g)	(h)	(i)

KEY: UOM: Unit of Measurement; QTY: Quantity; SR: Stock Register

PREPARED BY: _____ **EVIEWED BY:** _____ **APPROVED BY:** _____

I-L

Quarterly PMR for stocking and indenting of PPD at DTC Level

District Quarter Report for PPD						
Item	**Unit of Measurement**	**Stock on First Day of Quarter**	**Stock Received During the Quarter**	**Patients Started on Treatment/Consumption During Quarter**	**Stock on Last Day of Quarter**	**QTY. Requested**
		(a)	**(b)**	**(c)**	**d =(a+b)-c**	**e =(c/3*2)-d**
PPD	Vials					

I- M

Quarterly PMR for stocking and indenting of PPD at TU Level

TU Quarter Report for PPD						
Item	**Unit of Measurement**	**Stock on First Day of Quarter**	**Stock Received During the Quarter**	**Patients Started on Treatment/Consumption During Quarter**	**Stock on Last Day of Quarter**	**QTY. Requested**
		(a)	**(b)**	**(c)**	**d =(a+b)-c**	**e =(c/3*2)-d**
PPD	Vials					

APPENDIX II: MIS FORMATS

List of MIS Formats Available in this Appendix

Title	Reference
Adequacy of Drug Stocks (ADS)	II–A
Expiry Age Analysis of Drug Stocks (EAADS)	II–B
Inconsistency In Drug Stock Reporting (IDSR)	II–C
Timely Execution of Critical Indents (TECI)	II–D
Delay in Distribution of Drugs by Transporter (DDDT)	II–E
Delay In Drug Stock Reporting (DDSR)	II–F

II–A

ADEQUACY OF DRUG STOCKS (ADS)

Stocking Unit: _____ Quarter Ending: _____

S. No.	SSU	Drug	UOM	Closing Stock	Quarterly Utilization	Monthly Utilization	Availability in terms of monthly utilization	Requirement for next quarter (Qty)	Shortfall in availability	Transfers in / (out)	Adjusted closing stock	Remarks
(a)	(b)	(c)	(d)	(e)	(f)	(g)	[h=(e/g)]	[h=(g * SN)]	[i=(h-e)]	(j)	[k = (e±j)]	(l)

KEY: SN: Stocking Norm; SSU: Sub-Stocking Unit

PREPARED BY: _____ **APPROVED BY:** _____

II–B

EXPIRY AGE ANALYSIS OF DRUG STOCKS (EAADS)

Month/Quarter Ending: _____

S. No.	Drug/ Remaining Shelf Life	Principal Stocking Unit (SDS/ DTC/ TU)	Subsidiary Stocking Units (DTC/ TU/ MC/ PHI)					Total Stocks	Recommended Action
			SSU 1	SSU 2	SSU 3	SSU 4	SSU 5		
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(I)	(m)
	PC - I (PWBs)								
	10 to 12 Months								
	13 to 15 Months								
	16 to 18 Months								
	19 to 21 Months								
	> 22 Months								
	TOTAL								
	PC - 2 (PWBs)								
	10 to 12 Months								
	13 to 15 Months								
	16 to 18 Months								
	19 to 21 Months								
	> 22 Months								
	TOTAL								

Note: Above analysis is to be repeated for all drugs including PP

PREPARED BY: _____ **APPROVED BY:** _____

II–C

INCONSISTENCY IN DRUG STOCK REPORTING (IDSR)

Month Ending:

S. No.	Name of Stocking Unit	DTC/ TU/ MC / PHI	Deficiency in Drug Stock Reporting			Remarks
			Opening Stock Not Correct	Utilization ≠ Pts. Put on Treatment	Stock Requirement Estimation Incorrect	
(a)	(b)	(c)	(d)	(e)	(f)	(g)

PREPARED BY: _____ APPROVED BY: _____

II–D

TIMELY EXECUTION OF CRITICAL INDENTS (TECI)

Month Ending: _____

S. No.	Stocking Unit	Critical RO/ DTA			Consignee Unit	Status		Remarks
		Document	Date	No.		Dispatched by Stocking Unit	Received by Consignee Unit	
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)

PREPARED BY: _____ **APPROVED BY:** _____

II–E

DELAY IN DISTRIBUTION OF DRUGS BY TRANSPORTER (DDDT)

Supplying Unit :_____ Month Ending : _____

S. No.	Dispatch Transaction Reference			Transporter	Consignee Unit	Delay			Explanation	Remarks
	Document	Date	No.			Date Received	Turn-around Time (g-c)	Delay		
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)

PREPARED BY: _____ **APPROVED BY:** _____

II–F

DELAY IN DRUG STOCK REPORTING (DDSR)

Month Ending: _____

S. No.	Name of Stocking Unit	DTC/ TU/ PHI	Reporting Efficiency			Explanation/Remarks
			Scheduled Date for Receipt of Report	Actual Date for Receipt of Report	Delay	
(a)	(b)	(c)	(d)	(e)	(f)	(g)

PREPARED BY: _____ **APPROVED BY: _____**

APPENDIX III: FORMATS FOR PMDT

List of DOTS-PLUS Formats Available in this Appendix

Title	Reference
Monthly Stock Statement for stocks at State Drug Stores	III–A
Monthly Stock Statement for stocks & Indenting of Cat IV drugs at DOTS-PMDT Site	III–B
Quarterly Programme Management Report for stocking & Indenting of Cat IV drugs at DTC level	III–C
Quarterly Programme Management Report for stocking & Indenting of Cat IV drugs at TU level	III-D
Monthly PMR for stocking & indenting of Cat IV drugs at PHI Level	III-E

III–A

Monthly Stock Statement for stocks at SDS Level
(To be submitted to CTD each month by SDS)

				Receipts during the month		Issues during the month						
Sr. No.	**Nomenclature**	**A/U**	**Opening Balance**	**Receipt from Mfrs**	**Transfer In / Returns**	**Qty issued for boxes**	**Qty Issued to DRTB centre**	**Transfer Out**	**Balance Stock**	**DOM (One row for each drug)**	**DOE (One row for each drug)**	**Remarks**
			(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**	**(g)= (a+b+c-d-e-f)**			
	Loose Drugs											
1	KANAMYCIN (Km) - 500 mg	Vials										
2	KANAMYCIN (Km) - 1000 mg	Vials										
3	LEVOFLOXACIN (Lfx)-250mg	Tabs										
4	LEVOFLOXACIN (Lfx)-500mg	Tabs										
5	CYCLOSERINE (Cs) -250 mg	Caps										
6	ETHIONAMIDE (Eto) - 125 mg	Tabs										
7	ETHIONAMIDE (Eto) - 250 mg	Tabs										
8	PYRAZINAMIDE (Z) - 500 mg	Tabs										
9	PYRAZINAMIDE (Z) - 750 mg	Tabs										
10	ETHAMBUTOL(E) - 200 mg	Tabs										
11	ETHAMBUTOL(E) - 400 mg	Tabs										
12	ETHAMBUTOL(E) - 800 mg	Tabs										
13	PYRIDOXIN-50mg	Tabs										
14	PYRIDOXIN - 100 mg	Tabs										
15	SODIUM PARA-AMINOSALICYLATE(NA PAS) 4gm Sachets (Box of 250 sachets)	Sachets										
16	SODIUM PARA-AMINOSALICYLATE (NA PAS) 10gm Sachets (Box of 100 sachets)	Sachets										
17	SODIUM PARA-AMINOSALICYLATE (NA PAS)-100gm jars	Box (100g)										
	Substitute Drugs											
18	CAPREOMYCIN (Cm)-750 mg	Vials										
19	CAPREOMYCIN (Cm)-1000 mg	Vials										
20	MOXIFLOXACIN (Mfx)-400mg	Tabs										

No.	Nomenclature	A/U	Opening Balance	Receipt during the month	Qty issued	Closing Balance	D.O.E (One row for each box)
			(A)	(B)	(C)	(D = A+B-C)	
	Monthly Patient Wise Boxes						
1	Type-A (<16 Kg Body Weight Patient)	Drug Boxes					
2	Type-A (16-25 Kg Body Weight Patient)	Drug Boxes					
3	Type-A (26- 45 Kg Body Weight Patient)	Drug Boxes					
4	Type-A (46-70 Kg Body Weight Patient)	Drug Boxes					
5	Type-A (>70 Kg Body Weight Patient	Drug Boxes					
6	Type-B (<16 Kg Body Weight Patient)	Drug Boxes					
7	Type-B (16-25 Kg Body Weight Patient)	Drug Boxes					
8	Type-B (26- 45 Kg Body Weight Patient)	Drug Boxes					
9	Type-B (46- 70 Kg Body Weight Patient)	Drug Boxes					
10	Type-B (> 70 Kg Body Weight Patient)	Drug Boxes					
11	Type-C (Na PAS)	Drug Boxes					

Weight Band	**< 16 kg**	**16-25 kg**	**26-45 kg**	**45-70 kg**	**>70 kg**
Number of MDR TB patients initiated on treatment during the month					

III-B

Monthly Stock Report for Stocks & Indenting of Cat IV drugs at DOTS-PMDT Site
(To be submitted to SDS/STO by DOTS- PMDT Site)

Monthly Report showing the receipt & Issue of MDR Drugs as on _____Qtr ____ -(month/year) for DRTB Centre …… DTC _____

Sr.No	Nomenclature	A/U	Opening Balance	Receipt during the month	Qty issued	Balance Stock	D.O.M (One row for each drug)	D.O.E (One row for each drug)	Qty required
			(A)	(B)	(C)	(D= A+B-C)			(E=C x 2)-D
1	KANAMYCIN (Km) - 500 mg	Vials							
2	KANAMYCIN (Km) - 1000 mg	Vials							
3	LEVOFLOXACIN (Lfx)-250mg	Tabs							
4	LEVOFLOXACIN (Lfx)-500mg	Tabs							
5	CYCLOSERINE (Cs) -250 mg	Caps							
6	ETHIONAMIDE (Eto) - 125 mg	Tabs							
7	ETHIONAMIDE (Eto) - 250 mg	Tabs							
8	PYRAZINAMIDE (Z) - 500 mg	Tabs							
9	PYRAZINAMIDE (Z) - 750 mg	Tabs							
10	ETHAMBUTOL(E) - 200 mg	Tabs							
11	ETHAMBUTOL(E) - 400 mg	Tabs							
12	ETHAMBUTOL(E) - 800 mg	Tabs							
13	PYRIDOXIN-50Mg	Tabs							
14	PYRIDOXIN - 100 mg	Tabs							
15	SODIUM PARA-AMINOSALICYLATE(NA PAS) 4gm Sachets (Box of 250 sachets)	Sachets							
16	SODIUM PARA-AMINOSALICYLATE (NA PAS) 10gm Sachets (Box of 100 sachets)	Sachets							
17	SODIUM PARA-AMINOSALICYLATE (NA PAS)-100gm jars	Box (100g)							
	Substitute Drugs								
18	CAPREOMYCIN (Cm)-750 mg	Vials							
19	CAPREOMYCIN (Cm)-1000 mg	Vials							
20	MOXIFLOXACIN (Mfx)-400mg	Tabs							

III-C

Quarterly PMR for stocking & indenting of Cat IV drugs at DTC Level

(To be submitted to CTD & STO/SDS by DOTS- PMDT implementing districts)State _____ DTC _____

Cat-IV Regimen - DTC Level

Patient Wise Boxes

S. No.	Item	UOM	Stock on first day of the Qtr	Stock received during the Qtr	Consumption during the Qtr	Stock on last day of the Qtr (c+d) –e	Quantity Requested for DTC=(e/3 x 7) – f
	(a)	(b)	(c)	(d)	(e)	(f)	(g)
1	Type-A (<16 Kg Body Weight Patient)	Drug Boxes					
2	Type-A (16-25 Kg Body Weight Patient)	Drug Boxes					
3	Type-A (26- 45 Kg Body Weight Patient)	Drug Boxes					
4	Type-A (46-70 Kg Body Weight Patient)	Drug Boxes					
5	Type-A (>70 Kg Body Weight Patient	Drug Boxes					
6	Type-B (<16 Kg Body Weight Patient)	Drug Boxes					
7	Type-B (16-25 Kg Body Weight Patient)	Drug Boxes					
8	Type-B (26- 45 Kg Body Weight Patient)	Drug Boxes					
9	Type-B (46- 70 Kg Body Weight Patient)	Drug Boxes					
10	Type-B (> 70 Kg Body Weight Patient)	Drug Boxes					
11	Type-C (Na PAS)	Drug Boxes					
Weight Band		< 16 kg	16-25 kg	26-45 kg	45-70 kg	>70 kg	
Number of MDR TB patients initiated on treatment during							

III-D

Quarterly PMR for stocking & indenting of Cat IV drugs at TU Level

(To be submitted to DTC by DOTS-PMDT implementing TU) D.T.C._____TU: _____ Qtr-_____

Cat-IV Regimen - TU Level							
Monthly Patient Wise Boxes							
S.No	**Item**	**UOM**	**Stock on first day of the Qtr**	**Stock received during the Qtr**	**Consumption during the Qtr**	**Stock on last day of the Qtr (c+d) –e**	**Quantity Requested for TU (e/3 x 4) – f**
	(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**	**(g)**
1	Type-A (<16 Kg Body Weight Patient)	Drug Boxes					
2	Type-A (16-25 Kg Body Weight Patient)	Drug Boxes					
3	Type-A (26- 45 Kg Body Weight Patient)	Drug Boxes					
4	Type-A (46-70 Kg Body Weight Patient)	Drug Boxes					
5	Type-A (>70 Kg Body Weight Patient	Drug Boxes					
6	Type-B (<16 Kg Body Weight Patient)	Drug Boxes					
7	Type-B (16-25 Kg Body Weight Patient)	Drug Boxes					
8	Type-B (26- 45 Kg Body Weight Patient)	Drug Boxes					
9	Type-B (46- 70 Kg Body Weight Patient)	Drug Boxes					
10	Type-B (> 70 Kg Body Weight Patient)	Drug Boxes					
11	Type-C (Na PAS)	Drug Boxes					

III-E

Monthly PMR for stocking & indenting of Cat IV drugs at PHI Level
(To be submitted to TU by DOTS- PMDT implementing PHI)

D.T.C. TU: PHI: Month-

Cat-IV Regimen - PHI Level							
Monthly Patient Wise Boxes							
S.No	**Item**	**UOM**	**Stock on first Day of the Month**	**Stock received during the Month**	**Consumption during the month**	**Stock on Last day of the month (c + d) -e**	**Quantity requested for PHI (e x 2) -f**
	(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**	**(g)**
1	Type-A (<16 Kg Body Weight Patient)	Drug Boxes					
2	Type-A (16-25 Kg Body Weight Patient)	Drug Boxes					
3	Type-A (26- 45 Kg Body Weight Patient)	Drug Boxes					
4	Type-A (46-70 Kg Body Weight Patient)	Drug Boxes					
5	Type-A (>70 Kg Body Weight Patient	Drug Boxes					
6	Type-B (<16 Kg Body Weight Patient)	Drug Boxes					
7	Type-B (16-25 Kg Body Weight Patient)	Drug Boxes					
8	Type-B (26- 45 Kg Body Weight Patient)	Drug Boxes					
9	Type-B (46- 70 Kg Body Weight Patient)	Drug Boxes					
10	Type-B (> 70 Kg Body Weight Patient)	Drug Boxes					
11	Type-C (Na PAS)	Drug Boxes					

APPENDIX IV: QUALITY ASSURANCE OF DRUGS

Quality Assurance (QA) of Anti-TB Drugs has been accorded special importance by RNTCP and measures are taken at the time of procurement and also Post Procurement to maintain quality of Anti-TB Drugs. A comprehensive Quality Assurance Scheme (QAS) has been developed and implemented for RNTCP drug supplies at various levels. This appendix serves to outline the QAS framework and key procedures contemplated under the scheme.

Overview

The basic idea underlying QAS is to ensure the continuous availability of good quality drugs at all stocking/ service delivery points under the programme.

(a) QA measures at the time of Procurement : -

1st line Anti-TB Drugs

Since 2008-09, procurement of 1st Line Anti-TB Oral Drugs has been limited to 'WHO Pre-Qualified suppliers' and pre-dispatch inspection and testing of all batches is done. Injection Streptomycin is procured through International Competitive Bidding (ICB) from WHO-GMP suppliers only, Joint Inspection for verification of WHO-GMP Certificates by a team under DCG(I) is ensured and pre-dispatch inspection of all batches is done.

2nd line Anti-TB Drugs

Procurement for the World Bank funded States is done through ICB by Procurement Agency of Ministry of Health & Family Welfare. For this procurement, WHO-GMP Certification is required, Joint Inspection for verification of WHO-GMP Certificates by a team under DCG(I) is ensured and pre-dispatch inspection of all batches is done. For GFATM funded states, procurement is done through Green Light Committee (GLC) and Global Drug Facility (GDF) of Stop TB Partnership from the "WHO Pre-Qualified suppliers" only.

(b) QA Measures Post Procurement: -

The quality testing protocol is implemented in strict compliance with testing processes defined by the Central TB Division (CTD).

Specific instructions are issued by CTD every quarter, to concerned offices identified randomly, to lift samples as per the defined protocol and send them to the contracted testing laboratory.

Methodology

All implementing districts, State Drug Stores (SDS) and GMSDs have been arranged on a zone-wise basis i.e. North, South, East and West.

Zone-wise collection of drug samples has to be ensured during each quarter. For the zone selected for the quarter, drug samples for 1st Line drugs shall be drawn from the following:

1. One GMSD, selected randomly.
2. One SDS, selected randomly.
3. Five District TB Centers (DTC), selected randomly.

For 2nd line Drugs, samples shall be withdrawn from only.

1. Two SDS, selected randomly from DOTS Plus implementing states.

The following persons shall be responsible for collecting samples:

a) From GMSD: STO/ Officer or Consultant of CTD.

b) From SDS: Officer or Consultant of CTD/ STO.

c) From DTCs: Officer or Consultant of CTD/ STO/ DTO of respective districts.

CTD shall issue directions every quarter to the concerned offices to take drug samples as per the defined protocol and send them to the contracted laboratory. The contracted laboratory shall send the reports on the drug tests to the sender, with a copy to CTD, within 15 days of receipt of the drug samples.

Drug Sampling Schedules

Details of drugs and quantities to be drawn for testing purposes are indicated below:

Sl. No.	Samples to be Collected
(1)	2 boxes of Product Code-I containing Treatment box for PWB for New Cases from each batch.
(2)	2 boxes of Product Code-2 containing Treatment box for PWBs of Retreatment cases from each batch.
(3)	2 boxes of Product Code-4 containing Treatment box for prolongation of Intensive Phase of PC-1 & PC-2 from each batch.
(4)	80 vials of Product Code-5 [Injection Streptomycin] from each batch.
(5)	8 strips of Product Code-6 [Rifampicin 150mg] from each batch.
(6)	10 strips of Product Code-7 [INH 100mg] from each batch.
(7)	10 strips of Product Code-8 [PZE 500mg] from each batch.
(8)	10 strips of Tab. Pyridoxine from each batch.

Procedure for Collection of Drug samples

The following procedure should be followed for the collection of drug samples:

1. Insofar as possible, the officer in-charge should draw drug samples, from original, unopened containers/ packs, manufactured for sale by the company.
2. The sample drawn shall be divided into two equal parts, one half to be sent to the contracted laboratory in sealed condition and other half to be retained at the drug store, in sealed condition.
3. The sealed pack of drugs collected should indicate on its label or otherwise:
   a. Quantity contained
   b. Name of the drug
   c. Batch No.
   d. Date of manufacture
   e. Date of expiry
   f. Manufacturing License No.
   g. Name of the company
   h. Source of collection besides caution (if any) printed on the label for use/ storage of the product.
4. Information as above should be repeated in a covering letter, sealed and sent along with the sample to the laboratory.
5. A copy of the covering letter should also be sent to the CTD.
6. All batch numbers of available product codes shall be sampled for testing from state and district drug stores and only two batch numbers of all available product codes, selected randomly, shall be sampled for testing from GMSDs.
7. Sample quantities collected should be such that the samples collected can be analyzed twice (as indicated above, by dividing into two equal batches).
8. Half of the sample collected should be sent to the selected laboratory in a sealed condition and the remaining half-sample of the same batch retained in sealed condition at the concerned drug stores, till the lab report on the sample is received.
9. The sealed sample may be opened and used in case the lab report indicates acceptable quality.

Laboratory Report

The contracted laboratory shall report on the drug tests requested to the sender (with a copy to CTD), within 15 days of receipt of drug samples.

In case the Laboratory Report suggests that drugs are substandard, then the GMSD/ SDS/ DTC concerned shall immediately give instructions to stop further issue and consumption of the concerned batch (es) of drugs.

Concerned officers at CTD/ GMSD and the STO in question, shall also be immediately alerted, about the detection of substandard drugs.

Precautionary Measures

1. The following precautions are to be observed on identification of substandard drugs:
2. Stocking units down the line shall immediately be instructed to stop further consumption and issues from the batch declared substandard.
3. Specific instructions shall be given to stocking Units/ DOTS Centres, to replace, unconsumed drugs of substandard batch from PWBs/ drugs allocated to patients, with drugs of different batch.
4. Custody shall be taken of all unconsumed, substandard drugs. These shall be labelled 'substandard' and carefully segregated in stores, in such a way that there is no possibility of their being reissued to patients.
5. Detailed record shall be kept of segregated substandard drugs taken into custody and fresh drug allocations. Complete details of substandard drugs taken back and segregated in stores, should be recorded in the Stock Register.
6. CTD shall send a letter to the Procurement Agency, along with a copy of the test report indicating poor quality of drugs tested for taking necessary action.

Repeat Testing

The following procedures are to be followed to reconfirm existence of substandard drugs:

1. Laboratory Report suggesting substandard drugs, may be challenged/ disputed by the manufacturer/ supplier and they may request CTD to carry out an additional laboratory test through an independent, government-approved agency (e.g. CDL, Kolkata).
2. Instructions shall accordingly be given by CTD to the concerned GMSD/ SDS/ DTC for dispatching the sample retained in sealed condition, for another round of testing to CDL, Kolkatta.

If the repeat testing report suggests that the quality of drugs tested is good enough for general administration, then instructions shall be issued to GMSD/ SDS/ DTC and Stocking Units to resume issues/ consumption thereof.

Confirmation of Substandard Quality of DRUGS

The following procedures are to be followed in case repeat testing confirms substandard quality of drugs:

1. On receipt of report confirming substandard quality of the tested batch of drugs, an intimation to stop consumption shall be dispatched by the receiver to all concerned (Central TB Division, District TB Centre, SDSs, GMSDs and Procurement Agency).
2. GMSD/ SDS/ DTC shall make entries in the Stock Register for withdrawal of substandard drugs and keep them separately from the good stocks.

In case repeat testing confirms substandard quality of drugs, CTD shall send a copy of the report to the Procurement Agency and request them to take necessary action against the supplier.

Review of Substandard Drug Reports by Committee

All reports from the contracted laboratory/ independent government-approved agency, indicative of substandard drugs shall be reviewed by a Committee consisting of officials from the Ministry of Health & Family Welfare. The Committee shall recommend initiation of action, as necessary.

APPENDIX V: GUIDELINES FOR RECONSTITUTION OF PWBS

This appendix of the manual suggests detailed procedures for the reconstitution of drugs from patient wise boxes (PWB) recovered from defaulting, reportedly dead and transferred-out patients.

Overview

Reconstitution is the process of retrieving residual drugs from PWBs of defaulting, dead and transferred-out patients and repacking them in quantities equivalent to and as per the description given on fresh/ PWBs for new & retreatment cases / Prolongation Pouches/ loose drugs.

Each PWB comprises of Intensive Phase (IP) and Continuation Phase (CP) pouches. Category boxes are differentiated by colour, number of doses and regimen of drugs, embodied in blister packs. Reconstitution helps minimize wastage, ensuring optimal utilization of RNTCP drugs.

Suggested methodology, precautions and record keeping for reconstitution, are discussed in the paragraphs that follow.

Precautions for Reconstitution

The following precautions are to be exercised during reconstitution:

1. Reconstitution is a highly technical activity and shall be preferably centralized at the District Tuberculosis Center (DTC) and carried out under the direct supervision of the District TB Officer (DTO).
2. DTO/ STS shall ensure that complete information about default, death and transfer out cases is available at TU/ Periphery Units. PWBs recovered in all such cases shall be kept intact for purposes of reconstitution.
3. STS shall maintain appropriate records for PWBs collected from the above cases at peripheral units.
4. DTC shall maintain complete details for PWBs and drugs recovered from default cases (viz.; TB No.; Category; Quantity of blister packs/ pouches, etc.).
5. In case drugs available for reconstitution are not sufficient to make one full PWB, Prolongation Pouches may be used to complete the same.
6. Reconstitution by using new/ unused PWBs to make good a shortage, is strictly not allowed.
7. Reconstituted PWBs must be recorded in the Stock Register and reported in Quarterly Report on Programme Management and Logistics (QRPML) of the district.
8. Expiry dates must be clearly marked on all reconstituted boxes.
9. Reconstituted PWBs should preferably be used at DTC only. Priority must be accorded for their utilization at the earliest.
10. Utilization/ recovery of loose drugs through the reconstitution process should also be recorded in the Stock Register.

11. In case there are not enough strips of I.P (Intensive Phase) or C.P (Continuation Phase) for reconstitution of PWBs, then the available I.P/C.P strips should be converted as per instructions given under 'Conversion of blister packs/ Category boxes'.

Note: *The first attempt should always be made to reconstitute Category boxes from similar Category boxes to preserve the colour coding. In case this is not possible, only then Prolongation Pouches or other defaulted Category boxes may be used in that order.*

Reconstitution Methodology

Recommended procedures for reconstitution are described in the paragraphs that follow. It should be noted that the procedures outlined are merely indicative and not exhaustive.

Reconstitution of PWB for new cases (PC-I)

A single PWB of new case contains the following drugs:

Intensive Phase (IP)	**Continuation Phase (CP)**
2 Months (24 Doses)	4 Months (54 Doses)
24 Blister Combi-packs	18 Multi Blister calendar combi-packs
Containing	**Containing**
2 Tabs Isoniazid 300 mg	6 Tabs Isoniazid 300 mg
1 Cap Rifampicin 450mg	3 Caps Rifampicin 450 mg
2 Tabs Pyrazinamide 750 mg	4 Tabs Pyridoxine 5 mg
2 Tabs Ethambutol 600 mg	

In case of defaulting, dead and transferred-out patients, the following situations may arise with respect to balance drugs available in the PWB for new cases:

1. Part of Blister Combi-packs of IP pouch is missing (Situation 1).
2. Full pack of Blister Combi-packs of IP pouch is missing (Situation 2).
3. Part of Multi Blister Calendar Combi-packs of CP pouch is also missing (Situation 3).

Part of Blister Combi-packs of IP Pouch Missing (Situation I)

If the box has a certain number of Blister Combi-packs missing from the IP pouch, that same number can be added from any of the following sources:

1. IP Pouch of other defaulted PC-1Boxes
2. Prolongation Pouches
3. IP Pouch of other defaulted PC-II Boxes.

After adding the missing Blister Combi-packs to the IP pouch, place it in a polythene bag and label it as "Reconstituted IP of PC-I" and record the shortest expiry date of blister Combi-packs on the label.

Label the PWB as “Reconstituted PC-I box” and record shortest expiry date of blister Combi-packs on the box.

Full Pack Blister Combi-pack of IP Pouch Missing (Situation II)

If in the box, full pack of **Blister Combi-packs** of IP pouch is missing, add 24 blister strips in a polythene bag from any of the following sources:

1. IP Pouch of other defaulted PC-I Boxes
2. Prolongation Pouches
3. IP Pouch of other defaulted PC-II Boxes.

Thereafter label the polythene bag as “Reconstituted IP of PC-I” and record the expiry date on the label. Also label the box as “Reconstituted PC-I box” and record the expiry date. (Note: Shortest expiry date of blister Combi-packs shall be recorded as expiry date on the polythene bag and category box).

Part of Multi Blister Calendar Combi-packs of CP Pouch Also Missing (Situation III)

If the box has a certain number of Multi Blister calendar combi-packs missing from CP in addition to IP, reconstitution of PC-I Box shall entail the following two steps:

STEP I

1. Put 24 blister strips in a polythene bag sourced from any of the following:
   a. IP Pouch of other defaulted PC-I Boxes
   b. Prolongation Pouches
   c. IP Pouch of other defaulted PC-II Boxes
2. Thereafter label the polythene bag as “Reconstituted IP of PC-I” and record the expiry date.

STEP II

1. Add that much number of strips as missing to the CP Pouch of this box from the following source:
   a. CP Pouch of other defaulted PC-I Boxes
2. Thereafter label the polythene bag as “Reconstituted CP of PC-I” and record the expiry date and Label the Box as “Reconstituted PC-I box” and record the expiry date.

*(**Note:** Shortest expiry date of blister Combi-packs shall be recorded as the expiry date on both the polythene bag and category box).*

Reconstitution of PWBs for Retreatment Cases

A single PC-II box contains the following drugs:

Intensive Phase (IP)	**Continuation Phase (CP)**
3 Months (36 Doses)	5 Months (66 Doses)
36 Blister Combi-packs	22 Multi Blister calendar combi-pack
Containing	**Containing**
2 Tabs Isoniazid 300 mg	6 Tabs Isoniazid 300 mg
1 Cap Rifampicin 450 mg	3 Caps Rifampicin 450 mg
2 Tabs Pyrazinamide 750 mg	6 Tabs Ethambutol 600 mg
2 Tabs Ethambutol 600 mg	4 Tabs Pyridoxine 5 mg

In case of defaulting, dead and transferred-out patients, the following situations may arise with respect to balance drugs available in the PC-II Box:

1. *Part of Blister Combi-packs of IP Pouch is missing*

2. *Full pack of Blister Combi-packs of IP Pouch is missing*

3. *Part of Multi Blister calendar Combi-packs of CP Pouch is also missing.*

Part of Blister Combi-pack of IP Pouch Missing (Situation I)

If the box has a certain number of blister strips missing from IP, the number can be replenished from any of the following sources:

1. IP Pouch of other defaulted PC-II Boxes.

2. Prolongation Pouches

3. IP Pouch of other defaulted PC-I Boxes

After adding the missing Blister Combi-packs to the Intensive Phase Pouch, place it in a polythene bag and label it as “Reconstituted IP of PC-II” and record the expiry date.

Label the patient wise box as “Reconstituted PC-II box” and record the expiry date.

(***Note:*** *Shortest expiry date of blister Combi-packs shall be recorded as the expiry date on both the polythene bag and category box*).

Full Pack of Blister Combi-packs of IP Pouch Missing (Situation II)

If in the box, the full pouch of blister strips of IP is missing, put 36 blister strips in a polythene bag from any of the following sources:

1. IP Pouch of other defaulted PC-II Boxes

2. Prolongation Pouches

3. IP Pouch of other defaulted PC-I Boxes

Thereafter label the polythene bag as “Reconstituted IP of PC-II” and record the expiry date thereon. Also label the box as “Reconstituted PC-II box” and record details of the expiry date on the same.

(***Note:*** *Shortest expiry date of blister Combi-packs shall be recorded as the expiry date on both the polythene bag and category box*).

Part of Multi Blister Calendar Combi-packs of CP Pouch Also Missing (Situation III)

If the box has a certain number of blister strips missing from CP Pouch in addition to IP Pouch, reconstitution of PC-II Box shall entail the following two steps:

STEP I

1. Put 36 blister strips in one polythene bag from any of the following sources:
   a. IP Pouch of other defaulted PC-II Boxes
   b. Prolongation Pouches
   c. IP Pouch of other defaulted PC-I Boxes
2. Thereafter label the polythene bag as Reconstituted IP of PC-II and record the expiry date

*(**Note:** Shortest expiry date of blister Combi-packs shall be recorded as the expiry date on both the polythene bag and category box).*

STEP II

1. Add that much number of strips as missing to the CP Pouch of this box from CP Pouch of other defaulted PC-II Boxes
2. Thereafter label the polythene bag as “Reconstituted CP of PC-II” and record the expiry date and Label the Box as “Reconstituted PC-II box” and record the expiry date.

*(**Note:** Shortest expiry date of blister Combi-packs shall be recorded as the expiry date on both the polythene bag and category box).*

Conversion of Blister Packs/ Category Boxes

Drugs for reconstitution may sometimes not be sufficient for a full category box and run the risk of getting expired. In such an eventuality, there could be various combinations of conversion for the logical utilization of drugs. Loose drugs shall be utilized in combinations for conversion.

Conversion of PC- I Boxes

If the PC- I Box is near expiry or has expired, the following procedure may be adopted for conversion:

Intensive Phase Pouch

1. Put 12 Blister Strips each from IP Pouch in two polythene bags and label them as “Reconstituted Prolongation Pouch for prolongation of IP Phase of PC-I and PC-II Patients” and record the expiry date

2. Two such prolongation pouches shall be prepared from IP

Continuation Phase Pouch

1. Open the continuation phase pouch and take out 4 multiblister Calendar Comb packs, remove pyridoxine tablets & put the blisters in Polythene bag. Add a separate polythene bag with twenty four (24) tablets of Pyrazinamide 750 mg and eighteen (18) tablets of Ethambutol 800mg, and label the contents on polythene bag and record the expiry date
2. Put both the polythene in one larger polythene and Label that each Dose shall consist of “Pyrazinamide 1500mg (2 tablets), Ethambutol 1200mg (one & half tablet), Isoniazid 600mg (2 tablets) and Rifampicin 450mg (1 Capsule)”
3. This larger polythene bag shall be marked as “Reconstituted prolongation pouch for prolongation of intensive phase of PC- I or PC-II patient” and record the expiry date. Repeating the steps outline above, four such Prolongation Pouches may be made out of one complete pouch of continuation phase
4. Remaining two blister Calendar Combipacks will be cut and the tablets labeled separately as loose drugs.

*(**Note:** Shortest expiry date of blister Combi-packs shall be recorded as the expiry date on both the polythene bag and category box).*

Conversion of PC II Boxes

If the PC-II Box is near expiry or has expired, then the following procedure may be adopted for conversion.

Intensive Phase Pouch

1. Put 12 Blister Strips from IP pouch in a polythene bag. Record the expiry date and label it as Reconstituted Prolongation Pouch for prolongation of IP Phase of PC-I and PC –II Patients
2. Three such Prolongation Pouches shall be formed out of one IP pouch

*(**Note:** Shortest expiry date of blister Combipacks shall be recorded as the expiry date on both the polythene bag and category box).*

Continuation Phase Pouch

1. Open the continuation phase pouch and take out 4 Multiblister Calendar Comb packs, remove pyridoxine tablets & put the blisters in polythene bag
2. Take a separate polythene bag and place twenty-four (24) tablets of Pyrazinamide 750 mg and label the contents
3. Put both the polythene in one larger polythene and Label that each Dose shall consist of “Pyrazinamide 1500mg (2 tablets), Ethambutol 1200mg (one & half tablet), Isoniazid 600mg (2 tablets) and Rifampicin 450mg (1 Capsule)”
4. This larger polythene bag shall be marked as “Reconstituted prolongation pouch for prolongation of intensive phase of PC- I or PC-II patient” and record the expiry date. Five such Prolongation Pouches may be made out of one complete pouch of continuation phase

5. Remaining two blister packs shall be cut and the tablets labeled separately to be used as loose drugs.

(***Note:*** *Shortest expiry date of blister Combipacks shall be recorded as the expiry date on both the polythene bag and category box).*

Maintenance of Records for Reconstitution of Drugs

All DTCs shall maintain Reconstitution Registers in the format suggested, for recording details of drugs recovered from defaulted patients, utilized for reconstitution and balance quantity available. Step wise procedure for maintaining the RR is given below:

1. Pharmacist/ Store Keeper at DTC shall maintain information of default cases received from STS;
2. Cross-verify quantities with the treatment cards of patients
3. Record quantity of drugs in respective columns of RR, as specified
4. Each PWB has two pouches – IP and CP. Separate columns have been assigned across Category Boxes
5. As and when drugs are sufficient enough for reconstitution, quantities withdrawn shall be deducted from respective columns, and the PWB reconstituted shown under reconstituted drugs
6. Receipt transactions shall be recorded in the RR in blue ink, whereas withdrawals for reconstitution purposes, shall be in red ink for clear demarcation
7. Expiry of reconstituted box shall be the same as that of earliest expiry of any of the drugs contained in the box
8. Update Stock Register (SR: Form Reference 1–A) for receipts on account of reconstitution of boxes and mention folio number of the SR in the RR.