Standard Operating Procedures Manual for State Drug Stores

March-2008

Central TB Division, Directorate General of Health Services
Ministry of Health and Family Welfare, Nirman Bhavan,
New Delhi 110001
FOREWORD

It gives me immense pleasure to present the Standard Operating Procedures Manual for District & State Drug Stores. The DOTS programme was started in the country in the year 1997 & has since then become the second largest Programme in the world. The Government of India has fully committed itself to provide DOTS to the entire population of the country & today the entire country is covered under DOTS.

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

The mammoth task of ensuring the uninterrupted supply of drugs to the whole country is currently being managed by Central TB Division but with a view to decentralize activities, CTD requested States to establish State Drug Stores to facilitate management of logistics. The advantage of decentralizing the complex drug logistics management to the State will result in improved micro-management of drug inventory within the State & access to more current information on drug availability & requirements etc. As on date, 27 States have already established 35 State Drug Stores, which are now fully operational. The SDS Manual will help the States in effective & accurate monitoring & reporting of drug logistics which in turn would help in ensuring the uninterrupted supply of drugs.

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

Dr. L.S. Chauhan
DDG (TB)
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ABBREVIATIONS

ACI Advanced Consignment Intimation
ADR Additional Drug Request
ADS Adequacy of Drug Stocks
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
DOE Date Of Expiry
DOTS Directly Observed Treatment, Short course
DTA Drugs Transfer Advise
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
IP Intensive Phase
MC Microscopy Centre
MO Medical Officer
MSS Monthly Stock Statement
PHI Peripheral Health Institute
POD Proof of Delivery
<table>
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<tr>
<th>Acronym</th>
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<td>TU</td>
<td>Tuberculosis Unit</td>
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<tr>
<td>UOM</td>
<td>Unit of measurement</td>
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<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
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<td>WRDR</td>
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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 has been implemented in a phased manner with assistance from World Bank, DANIDA, DFID, USAID, GDF and GFATM.

Ensuring continuous availability of good quality anti-TB drugs, is an essential feature of RNTCP. Under the programme, drugs are administered to patients under direct observation, through an extensive network of about 400,000 DOTS centres, in 35 states 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.

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

**PROCUREMENT**

Drugs are procured through an International Competitive Bidding (ICB) process, by an independent agency, based on requirement calculations and technical specifications formulated by CTD, pursuant to their approval by a Technical Committee.

**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 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.

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) at implementing states.

SDSs 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.

Advantages of establishing SDSs 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 SDSs.

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 drugs 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

This manual documents standard operating procedures recommended for SDSs, 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. **Physical Verification & Reconciliation of Drug Stocks**
   Procedures to be followed for the periodic physical verification and reconciliation of drug stocks at the SDS

5. **Communication & Information Technology Infrastructure (CIT)**
   Communication and Information Technology infrastructure required by the SDS

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

7. **Location, Space & Storage Arrangements**
   Location, space and storage arrangements to be created at the time of establishing the SDS

8. **Secure Custody of Drugs**
   Measures to be taken to ensure the secure custody of drugs at the SDS

9. **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

10. **Reconstitution**
    Recommended procedures to be employed when reconstitution of drugs is necessitated.

11. **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, lifted on a random basis from District Tuberculosis Centres (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

CTD
  Consignee List

Procurement Agency
  Supply Order

Manufacturer

GMSDs

Districts

Exceptional cases

SDS

Districts

R.O as per QPMR/ADR
RECEIPTS 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

SDSs may receive drugs from multiple sources including:

1. Government Medical Store Depots (GMSDs)
2. SDSs of other states
3. DTCs/SDSs of the same state

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

1. Ensure that an approved copy of the CTD-R.O: (Form Reference 1-B), prepared 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 Invoice and Challan of the GMSD. The Storekeeper will not ordinarily open sealed cartons unless:

   a. The seal and/or exterior suggests 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

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 shall be brought to the attention of the transporter. Details of the shortage/damage should be noted on the GMSD Issue Voucher / Delivery Challan 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

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 shall simultaneously report details of damaged stocks received, if any, to the GMSD and CTD. Based on the SDS report, CTD would liaise with the GMSD, for necessary action. SDS storekeeper shall segregate and preserve damaged stocks till the time of their replacement)

5. After visual inspection, acknowledge drugs received in GMSD’s Issue Voucher/Challan 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 shall forward a photocopy of the transporter attested GMSD’s Issue Voucher/Challan to the STO, for onward transmission to the GMSD 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 GMSD Issue Voucher. The Storekeeper shall forward one copy each of Issue Voucher to the GMSD, STO and CTD, within 15 days of receipt, retaining a copy of the same in the stores receipts file.

(Note:

GMSD Issue Voucher is raised by the GMSD and sent directly to the SDS or as part of the complete set of documents forwarded through the transporter, accompanying the consignment of drugs. The Storekeeper must thoroughly check the contents of consignments received prior to acknowledging the same in the Issue Voucher)

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

(Note:

i. 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).

Transfer of Drugs from State Drug Stores

Pursuant to the quarterly review, CTD may periodically authorize transfer of drugs to the SDS from other SDSs, to adjust stock imbalances and/or ensure the timely utilization of close to expiry drugs. A formal Drugs Transfer Advice (DTA: Form Reference I–C), should be emailed/faxed to both the transferor/sending unit and the transferee/recipient unit, progressed by a hard copy of the same. Following this, the Storekeeper of the transferor/sending unit shall generate a State Issue Voucher (SIV: Form Reference I–D).

On receipt of the transferred drugs the Storekeeper of the recipient unit shall repeat steps (1) to (5) and (7) detailed at above paras on the receipt of drugs transferred from other SDSs, with the exception that the authorization document in this case shall be the SIV and acknowledgement of the drugs received shall be made by signing the same. Acknowledged copies of the SIV shall be sent to the STO, as well as the transferring SDS.
**Intra-State Return/ Transfer of Drugs**

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 emailed/ faxed to both the transferor/ sending unit and the transferee/ recipient unit, progressed by a hard copy of the same. 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 Storekeeper of the recipient unit shall repeat steps (1) to (5) & (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 SIV or District Issue Voucher (DIV) respectively. Acknowledgement of drugs received shall be made by signing the SIV or DIV, as the case may be. Acknowledged copies of the SIV/ DIV shall 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. 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 by more than a fortnight vis-à-vis the timelines indicated, s/he must bring the delay to the attention of the GMSD by fax/ email, marking a copy of the same to STO/ Dy. STO/ Second Medical 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 GMSD’s name, 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).

CUSTODY/ STACKING OF INCOMING MATERIAL

The Storekeeper shall perform the following functions in this regard:

1. Ensure that different drug items are clearly segregated and stacked on separate racks within the store

2. Within each drug item, ensure that separate 'lots' of drugs with separate dates of manufacture and expiry are clearly segregated and stored together

3. Separate 'lots' of drugs with different dates of manufacture and expiry are stored so as to facilitate First Expiry First Out (FEFO) issue viz. drug 'lots' with the most recent expiry are issued first

4. Mark ‘Expiry Dates’ in Bold Letters 3" to 4" in size, on the drug cartons with a Marker Pen, for the easy identification and control of drugs, immediately on their arrival.

Forms referred to in this section of the manual

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<td>CTD Release Order (CTD-RO)</td>
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<td>State Issue Voucher (SIV)</td>
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ISSUES/DISPATCHES BY STATE DRUG STORES

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

OVERVIEW

SDSs shall issue and dispatch drugs under the following circumstances:

1. Routine quarterly supplies to District Tuberculosis Centres (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/ Dy. STO / Second MO/ Other Responsible Officer (authorized by the STO for the purpose), on the basis of analysis of 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.

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, utilization and anticipated requirement.

Information provided in the QRPML, (deriving in turn from detailed TU-wise drug stock statements), shall be incorporated in the Worksheet for Reporting Drug Requirement (WRDR: 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 STO and followed by the release of quarterly supplies to DTCs by the Storekeeper, as per the workings therein and/or the generation of Drugs Transfer Advices (DTA: Form Reference I–C) 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 ensure the timely utilization of close to expiry drugs shall be effected on the basis of DTAs).

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: Form Reference I–D) 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. Obtain acknowledgement from transporter on third copy of SIV, retaining and filing the same for store records
6. Update the Stock Register (SR: Form Reference 1–A) for issues made
7. Receive back and file the second copy of SIV (consignee copy), duly acknowledged by the concerned DTC.

**SUPPLY OF ADDITIONAL DRUG REQUESTS (ADRS) TO DTCS**

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–F) to the STO, providing details in support of the supplementary requirement.

The ADR shall be carefully reviewed and validated by the STO/ Dy. STO/ Second MO/Other Authorized Officer, 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).

**TRANSFERS 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 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 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 (7) 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 affected at the SDS and not the district level. This limitation should be recognized by CTD at the time of recommending inter-state transfer of drug stocks).*

**Monthly Stock Statement**

The SDS Storekeeper shall prepare a Monthly Stock Statement (MSS: Form Reference I–G) providing details of receipts, issues, and opening/closing balance of drug items, as at the last day of each calendar month. MSS shall be sent to the STO by the 7th 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 15th of every month. In the case of more than one/multiple SDSs within the state, the MSSs shall additionally be consolidated, prior to their being forwarded to CTD.
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INVENTORY MANAGEMENT

This section of the manual suggests procedures for on-going tracking and replenishment of the inventory of anti-TB drugs 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 gamut of activities to be carried out by the senior officer in-charge of the logistics function 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–H) is to be filled and submitted by all drug-stocking points and comprises the most important report for the purposes of IM.

The QRPML incorporates drug stocks and utilization reported by all subordinate units. Additionally, detailed information on stock transferred in/ out and reconstitution of category boxes (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 officer in charge of drugs logistics at the STO’s Office (usually the Deputy STO or Second Medical Officer), 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 | 7th of the subsequent month at the end of the qtr
DTC to SDS | 10th of the subsequent month at the end of the qtr
SDS to CTD | 24th 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 storekeepers/pharmacists across the state.

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

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

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

**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 utilization, shall be maintained with implementing states. This will include one quarter utilization for the next three months.

SDS(s) and DTCs, comprising the principal stock points of the state, shall each maintain buffer stocks equivalent to three months utilization. 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 equivalent to two months utilization shall be maintained as a buffer with each TU, at the commencement of the quarter, and one month’s buffer with each PHI. Stocks at PHIs and TUs shall be closely monitored, to ensure drug adequacy. Stocking norms 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-wide basis.

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 DTC’s QRPML, with the stocking norm suggested by CTD, for the same.

Based on the above, the designated logistics officer should flag all DTCs that are significantly under/ over stocked.

DTCs with severe drug shortages, who 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: Form Reference I–F) or Drug Transfer Advice (DTA: Form Reference I–C) 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 designated logistics officer, 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 QRPML’s 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: Form Reference I–E). 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 STO and subsequent to his/ her sign-off, progressed with the preparation of the State Issue Voucher (SIV: Form Reference I–G) 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 (CTD-RO: Form Reference I–B) for the replenishment of SDS(s) stocks for the next quarter.

**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 viewpoint of IM, the key aspect comprises the Reconstitution Register (RR: Form Reference I–I), 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**

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
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<tbody>
<tr>
<td>Quarterly Report on Programme Management &amp; Logistics (QRPML)</td>
<td>I–H</td>
</tr>
<tr>
<td>Adequacy of Drug Stocks (ADS)</td>
<td>II–A</td>
</tr>
<tr>
<td>Additional Drug Request (ADR)</td>
<td>I–F</td>
</tr>
<tr>
<td>Drug Transfer Advice (DTA)</td>
<td>I–C</td>
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<tr>
<td>State Issue Voucher (SIV)</td>
<td>I–G</td>
</tr>
<tr>
<td>Worksheet for Reporting Drug Requirement (WRDR)</td>
<td>I–E</td>
</tr>
<tr>
<td>Reconstitution Register (RR)</td>
<td>I–I</td>
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</table>
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 State TB Officer (STO)/Deputy STO/Other Authorized Officer 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 Second MO (or other officer nominated by the STO) 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–J)
2. Also record the number of Cartons/ Boxes/ Strips that should be available at the SDS per the Stock Register (SR: Form Reference 1–A), 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 shall 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.

ii. Ensure that all of the above have been posted to the SR

*(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. SO, RO, GRAN, 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.)*

iii. Where it is found that transaction documents have not been posted to the SR, it suggests that either there has been an omission, or alternately, stocks are still in transit and have yet to be received

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

d. Correlate issues with the number of patients put on treatment during the period

e. Check that all reconstituted boxes have been properly accounted for as receipts in the SR and considered as part of physical inventory

5. The STO/ Deputy State TB Officer/ Second Medical Officer/ Nominated Officer shall review and sign-off the PVS after thorough verification, comprising the following steps:

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

b. Validate that all issues have been recorded in the SR, based on first and last and/or discrete numbers of related issue documents

c. 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.

d. Verify that details of Batch of Manufacture and Date of Expiry of anti-TB 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

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

f. Compliance with key best practices such as First Expiry First Out (FEFO), proper stacking and housekeeping, etc

6. Un-reconciled discrepancies determined through the above process should be reported to the STO, Health Secretary for the State and CTD.

(Note: In the case of shortage, 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 STO in the first week (i.e. by the 7th day) of the next month.

SURPRISE CHECKS DURING THE YEAR

The State TB Officer (STO)/ Deputy State TB Officer shall conduct surprise verification of anti-TB drug stocks at each of the State Drug Stores in the state.

Procedures to be followed for surprise verification shall be on the same 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.

(Notes: 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

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
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<tbody>
<tr>
<td>Physical Verification Sheet (PVS)</td>
<td>I–J</td>
</tr>
<tr>
<td>Stock Register (SR)</td>
<td>I–A</td>
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COMMUNICATION AND INFORMATION TECHNOLOGY INFRASTRUCTURE

This section of the manual deals with Communication and Information Technology (CIT) infrastructure needs, that are required to be established at the State Drug Store (SDS) and District TB Centres (DTCs).

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 follow.

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 (not shared) 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.
Depending on local needs, the SDS Storekeeper may be expected to spend several hours daily at the STO’s Office, during which period the telephone at the SDS shall remain unattended. To deal with such situations, the telephone number of the Deputy STO should be circulated to DTCs and subordinate units, so that important messages can be taken and relayed to the SDS Storekeeper through the Deputy STO’s Office.

**Computer**

Each SDS should preferably have an independent computer*. The computer shall be required to enable the functions of Inventory Tacking, 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 email, 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, it shall share the computer 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 email communication with various entities. The SDS computer would have to be email enabled for the purpose (viz. fitted with an internal/external modem and wired accordingly). Additionally, the SDS and/or the Storekeeper would require an email 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 however, still be required.

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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. 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:

<table>
<thead>
<tr>
<th>Staff/ Reporting</th>
<th>SDS</th>
<th>DTC</th>
<th>TU</th>
<th>PHI</th>
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<tbody>
<tr>
<td>1. Staffing Requirement:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Pharmacist</td>
<td>Required</td>
<td>Required</td>
<td>Required*</td>
<td>Not Required</td>
</tr>
<tr>
<td>b) Watchman/ Helper(s)</td>
<td>Required</td>
<td>Not Required</td>
<td>Not Required</td>
<td>Not Required</td>
</tr>
<tr>
<td>2. Reporting by above Drug Stores Staff:</td>
<td>Deputy STO/ Second Medical Officer</td>
<td>DTO/ MO In-charge</td>
<td>MO In-charge</td>
<td>MO In-charge of PHI</td>
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</table>

* 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.

Pharmacist

The Pharmacist shall be responsible for all operations at the store including the upkeep of stores records. The educational qualification of the Pharmacist shall comprise a degree or diploma in pharmacy. In addition, the Pharmacist should also possess excellent computer skills, as s/he shall be required to prepare and analyze inventory reports.
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

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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 instituted at the time of establishing 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, Fax, 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**

1. For every 10 lakh population, provision should be made for the storage of about 35 cartons (of 20 boxes each), of Cat I, II and III patient-wise boxes taken together. This is approximately equivalent to six months requirement of drugs

**Stocking Norms**

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

**Storage in Cupboards/ Almirahs**

3. For loose drugs under NON-DOTS regimen, space provision would be 10% of space allocated to Cat I, II and III, PWB cartons. These should also be stored in cupboards/almirahs under lock and key.

**Other Specifications for the Drug Store**

Other specifications for the SDS include the following:

1. The store should preferably comprise one large room. Where multiple rooms already exist, these should be contiguous or proximate to each other

2. The ceiling must have a height of at least 3 metres

3. A lockable door

4. At least one window with grill

5. Brightly 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

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.
SHELVES, RACKS & STORAGE ARRANGEMENTS

Storage shelves should be fabricated ensuring sufficient ‘gap’ between cartons from the ceiling, floor and walls, facilitating ventilation and the 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. Expiry dates indicated on stickers on the face of cartons/ drug boxes by the supplier, should be written again by hand, in large, easily visible characters, using a coloured, permanent marker pen
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 Cat I 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. 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.

6. 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**

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SECURE CUSTODY OF DRUGS

This section of the manual discusses arrangements to be instituted at the State Drug Store (SDS) for assuring secure custody of drugs to safeguard against the 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 workplace 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.

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 EXTINGUISHERS

In addition to the above preventive steps, fire-fighting equipment should in any case be installed to deal with the outbreak of fire.
Multiple fire extinguishers should be installed commensurate with the area of the store and materials at risk.

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.

**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.

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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, with provision for onward distribution therefrom to TUs and possibly PHIs.

(Note: The above shall be applicable only in case the state does not have arrangements 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 Deputy STO/ Second Medical Officer/ Other Authorized Officer, 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 programme 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 SDS in the state, SDSs along with their routine feeding districts shall 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
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.

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</table>
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–E)

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**

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequacy of Drug Stocks (ADS)</td>
<td>I–A</td>
</tr>
<tr>
<td>Expiry Age Analysis of Drug Stocks (EAADS)</td>
<td>II–B</td>
</tr>
<tr>
<td>Inconsistency in Drug Stock Reporting (IDSR)</td>
<td>II–C</td>
</tr>
<tr>
<td>Timely Execution of Critical Indents (TECI)</td>
<td>II–D</td>
</tr>
<tr>
<td>Delay in Distribution of Drugs by Transporter (DDDT)</td>
<td>II–E</td>
</tr>
<tr>
<td>Delay in Drug Stock Reporting (DDSR)</td>
<td>II–F</td>
</tr>
</tbody>
</table>
## APPENDIX I

(List of Operational Formats Available in this Appendix)

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stock Register (SR)</td>
<td>1–A</td>
</tr>
<tr>
<td>CTD Release Order (CTD-RO)</td>
<td>1–B</td>
</tr>
<tr>
<td>Drugs Transfer Advice (DTA)</td>
<td>1–C</td>
</tr>
<tr>
<td>Stores Issue Voucher (SIV)</td>
<td>1–D</td>
</tr>
<tr>
<td>Worksheet for Reporting Drug Requirement (WRDR)</td>
<td>1–E</td>
</tr>
<tr>
<td>Additional Drug Request (ADR)</td>
<td>1–F</td>
</tr>
<tr>
<td>Monthly Stock Statement (MSS)</td>
<td>1–G</td>
</tr>
<tr>
<td>Quarterly Report on Programme Management &amp; Logistics (QRPML)</td>
<td>1–H</td>
</tr>
<tr>
<td>Reconstitution Register (RR)</td>
<td>1–I</td>
</tr>
<tr>
<td>Physical Verification Sheet (PVS)</td>
<td>1–J</td>
</tr>
</tbody>
</table>
# Appendix I–A

## STOCK REGISTER (SR)

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Particulars of Receipts &amp; Issues</th>
<th>Receipt (Qty.)</th>
<th>Issue (Qty.)</th>
<th>Balance (Qty.)</th>
<th>Date-wise expiry details of balance (Qty.)</th>
<th>Signature of Store-Keeper</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Date (Dd/ mm/ yy) of Transaction (Receipt/ Issue)</td>
<td>Name of Party (Supplier/ GMSD/ SDS/ DTC)</td>
<td>Invoice No./ Receipt Voucher No. (For Issues only)</td>
<td>Date of Invoice/ Issue Voucher</td>
<td>Batch No.</td>
<td>Date of Expiry</td>
<td>Expiry Date (….)</td>
</tr>
<tr>
<td>a</td>
<td>b</td>
<td>c</td>
<td>d</td>
<td>e</td>
<td>f</td>
<td>g</td>
<td>h</td>
</tr>
<tr>
<td></td>
<td>Opening Balance</td>
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<td></td>
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</tr>
</tbody>
</table>

**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.
Appendix I–B

CTD RELEASE ORDER

No. T-18019/………….-TB
Directorate General of Health Services
(Central TB Division)

Nirman Bhavan, New Delhi - 11
Dated: ……………..

OFFICE MEMORANDUM

Sub: Supply of Anti-TB Drugs to State/ Union Territory Drug Stores/ TB Clinics/ Centres from Central Government Stock for RNTCP.

Please supply the following anti TB drugs to State TB Officer/ District TB Control Officer of ……………………………… :

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>State (SDS) District (DTC)</th>
<th>CAT-I (PWB)</th>
<th>CAT-II (PWB)</th>
<th>CAT-III (PWB)</th>
<th>Prolongation Pouches (Pouches)</th>
<th>INJ SM-0.75G (Vials)</th>
</tr>
</thead>
</table>

Either copies of I.V. issued or a statement indicating quantities of different drugs issued should be submitted to this Directorate.

The cost of anti-TB drugs will be adjusted against the total Central subsidy available to the State/Union Territory under the National TB Control Programme during the current financial year. The 4% incidental charges may be recovered from the Budget grant under the National Tuberculosis Control Programme instead of from the consignees and will be similarly adjusted against the total Central subsidy to the State/UT.

The stores may be dispatched immediately by courier or Road Transport on freight paid basis/ Authorised representative of the State Drug Store/ TB Centre, under intimation to this Directorate and suitable advice to the State Drug Store/TB Centre.

(………………………)
Chief Medical Officer (TB)

To
ADG (Stores)
Govt. Medical Stores Depot

.....................
.....................
RNTCP drugs are usually supplied for seven months requirement to all districts, initially based on population, and subsequently on the basis of actual consumption of drugs in the previous quarter.

1. The stock of drugs supplied is after consideration of the shelf life. Therefore, it is the responsibility of the DTO that the drugs in his/her district do not expire and that they are properly utilized.

2. STO is expected to monitor the drug stock of the RNTCP districts and he must ensure that if drugs are in excess in one RNTCP districts the same are diverted to the other RNTCP districts well in time. Drugs should not be diverted to non-RNTCP districts without prior approval of Central TB Division.

3. If the STO inspite of his best efforts is not able to ensure proper utilization of drugs within their shelf life, then Central TB Division must be informed. This request for diversion of drugs should reach the Central TB Division at least 10 months before the date of expiry. Information on the quantity of drugs to be diverted along with the date of expiry should invariably be sent with the request.

4. First Expiry First Out (FEFO) principles should be strictly followed at the time of issue/utilization, to avoid expiry of drugs.

5. It is emphasized that if the drugs expire in the district then the responsibility is with the DTO and he is answerable in this regard. Thus it is imperative to monitor monthly utilization of various categories of drugs and drug-stock especially the stock that is in the periphery.

6. The programme management report must be filled accurately and must give the correct position of drugs taking into account the stock present at the periphery.

7. Request for more drugs should be made when there is at least 2 months stock at the district. It takes about a month for the necessary orders to be issued and for the supply to reach the district.

8. Request for additional medicines must be strictly as per the proforma circulated.

9. The loose tablets must be reported in terms of number of tablets and the inj. in terms of vials, Cat I, II and III drugs in terms of patient-wise boxes and prolongation pouch in terms of pouches (5 pouches per box, 1 pouch per patient).

10. Please ensure that a parallel stock of Inj Streptomycin is maintained such that there are 24 vials for every one Cat II box.

Copy to:

State TB Officer
District TB Officer
WHO Medical Consultants
# Appendix I–C

## DRUGS TRANSFER ADVICE (DTA)

### 0000

**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 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.

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Drug</th>
<th>UOM</th>
<th>Quantity</th>
<th>Transfer Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>(b)</td>
<td>(c)</td>
<td>(d)</td>
<td>(e)</td>
</tr>
</tbody>
</table>

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. If CTD generates DTA then DDG (TB)/CMO (TB)/Authorized WHO Consultant, 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.
STATE ISSUE VOUCHER (SIV)

Issue Particulars:  
Issued To (Name of SDS/DTC)……… 1. Dispatched By (Name of SDS/DTC)……………………
SIV No. ………………… 2. Name of Transporter: …………………
SIV Date ………….. 3. LR/ RR/ ST No.: ………………

Issue Authorization Document:  
RO/ADR/DTA/
with Date of Approval………………………

<table>
<thead>
<tr>
<th>S. No</th>
<th>Drug</th>
<th>UOM</th>
<th>Quantity Issued</th>
<th>Batch No.</th>
<th>Date of Expiry</th>
<th>Stores Register Folio No. of Issuer</th>
<th>Stores Register Folio No. of Recipient</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>(b)</td>
<td>(c)</td>
<td>(d)</td>
<td>(e)</td>
<td>(f)</td>
<td>(g)</td>
<td>(h)</td>
<td>(i)</td>
</tr>
<tr>
<td>1</td>
<td>Cat I</td>
<td>PWB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Cat II</td>
<td>PWB</td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td>Cat III</td>
<td>PWB</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>4</td>
<td>PP</td>
<td>Pouch</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>5</td>
<td>Inj SM 0.75 g</td>
<td>Vials</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Rif 150 mg</td>
<td>Capsule</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Pza 500 mg</td>
<td>Tablet</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>8</td>
<td>INH 100 mg</td>
<td>Tablet</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Etha. 800 mg</td>
<td>Tablet</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>10</td>
<td>INH 300 mg</td>
<td>Tablet</td>
<td></td>
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</tbody>
</table>

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 SIV.
## WORKSHEET FOR REPORTING DRUG REQUIREMENT (WRDR)

State TB Office: For the Quarter Ending:

Drug: Category I/ II/ III/ Loose Drugs

<table>
<thead>
<tr>
<th>Stocking Unit</th>
<th>Stock on first day of quarter</th>
<th>Stock received during the quarter</th>
<th>Stock Transferred in</th>
<th>Reconstitution of boxes during quarter</th>
<th>Total availability of drugs during the quarter</th>
<th>Stock transferred out</th>
<th>Patients started on treatment/consumption during quarter</th>
<th>Issues to DTC</th>
<th>Stock on the last day of quarter</th>
<th>Quantity requested</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(a)</td>
<td>(b)</td>
<td>(c)</td>
<td>(d)</td>
<td>(e)</td>
<td>(g)</td>
<td>(h)</td>
<td>(i)</td>
<td>(j)</td>
<td>(f)</td>
</tr>
<tr>
<td>DTC 1</td>
<td>XXXXX</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTC 2</td>
<td>XXXXX</td>
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<tr>
<td>DTC 4</td>
<td>XXXXX</td>
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<td>TOTAL DTCs</td>
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<tr>
<td>SDS Own</td>
<td>XXXXX</td>
<td>XXXXX</td>
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<tr>
<td>TOTAL – State</td>
<td>XXXXX</td>
<td>XXXXX</td>
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</table>

**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 SDS shall match with the total of stocks received by all DTCs, serviced by the SDS
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 Category I and Category III patient-wise box, then complete one sheet each for Category I and for Category III.

Item Requested (tick one):  □ Category I  □ Category II  □ Category III
Prolongation  □ Isoniazid  □ Rifampicin  □ PZA  □ SM
Pouches  100 mg  150 mg  500 mg  750 mg
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:

<table>
<thead>
<tr>
<th>Date Received</th>
<th>Total Number Received</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
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<td></td>
</tr>
</tbody>
</table>

Stock Position on Last Day of Previous Month

<table>
<thead>
<tr>
<th>Total Balance of the Unused Item on-hand at DTC Drugstores (a)</th>
<th>Total Balance of the Unused Item on-hand at TU Drugstores (b)</th>
<th>Total Balance of the Unused Item on-hand in PHIs (c)</th>
<th>Total Balance of the Unused Item on-hand in the Entire District (d=a+b+c)</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

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: _____________________
### MONTHLY STOCK STATEMENT (MSS)
(Report Showing Receipts & Issues of Anti-TB Drugs as at

State: State Drug Store:

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Drug</th>
<th>UOM</th>
<th>Opening Balance</th>
<th>Receipts During the Month</th>
<th>Total Drugs Trfd. In</th>
<th>Total Stores</th>
<th>ISSUES Store Supplied</th>
<th>ISSUES Drugs Trfd. Out</th>
<th>Balance Stores with DOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>(b)</td>
<td>(c)</td>
<td>(d)</td>
<td>(e)</td>
<td>(f)</td>
<td>(g = d+e+f)</td>
<td>(h)</td>
<td>(i)</td>
<td>(j = g-(h+i))</td>
</tr>
<tr>
<td>1</td>
<td>Cat-I</td>
<td>PWB</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Cat-II</td>
<td>PWB</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Cat-III</td>
<td>PWB</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Prolongation</td>
<td>Pouches</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Rifampicin-</td>
<td>Caps</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>INH-100 mg</td>
<td>Tabs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Pza-500 mg</td>
<td>Tabs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Inj-SM 0.75 g</td>
<td>Vials</td>
<td></td>
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<td></td>
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<td></td>
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<tr>
<td>9</td>
<td>INH-300 mg</td>
<td>Tabs</td>
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<tr>
<td>10</td>
<td>Ethambutol-800</td>
<td>Tabs</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>PWB (6-10 kg)</td>
<td>PWB</td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>12</td>
<td>PWB (11-17 kg)</td>
<td>PWB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>PP (6-10 kg)</td>
<td>Pouches</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>PP (11-17 kg)</td>
<td>Pouches</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**KEY:** UOM: Unit of Measurement

**Note:** In the case of Inj. SM, please maintain stock at the rate of 24 injections for each Cat-II box in stock
Appendix I–H

QUARTERLY REPORT ON PROGRAMME MANAGEMENT AND LOGISTICS

State Level (including all SDSs)

State: Quarter:
Email Address of STO: Year:
Total Population under SDS (in nos.): Population under SDS covered by RNTCP (in nos.)

Monthly drug-stock report attached? Yes No

Medications

<table>
<thead>
<tr>
<th>Item</th>
<th>UOM</th>
<th>Stock on first day of Quarter</th>
<th>Stock received during Quarter</th>
<th>Stock transferred in</th>
<th>Reconstitution of boxes during Quarter</th>
<th>Stock Transferred Out</th>
<th>Patients started on treatment</th>
<th>Stock on last day of quarter ( (c+d+e+f) - (g+h) )</th>
<th>Quantity Requested ( (h/3 \times 10) - i )</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>(b)</td>
<td>(c)</td>
<td>(d)</td>
<td>(e)</td>
<td>(f)</td>
<td>(g)</td>
<td>(h)</td>
<td>(i)</td>
<td>(j)</td>
</tr>
<tr>
<td>Category I Boxes</td>
<td>Boxes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category II Boxes</td>
<td>Boxes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category III Boxes</td>
<td>Boxes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item</th>
<th>UOM</th>
<th>Stock on first day of Qtr.</th>
<th>Stock received during Qtr.</th>
<th>Stock transferred in</th>
<th>Reconstitution of boxes during Quarter</th>
<th>Stock Transferred Out</th>
<th>Consumption incl. reconstitution</th>
<th>Stock on last day of quarter ( (c+d+e+f) - (g+h) )</th>
<th>Quantity Requested ( (h/3 \times 10) - i )</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>(b)</td>
<td>(c)</td>
<td>(d)</td>
<td>(e)</td>
<td>(f)</td>
<td>(g)</td>
<td>(h)</td>
<td>(i)</td>
<td>(j)</td>
</tr>
<tr>
<td>Pouches of blister strips for IP prolongation</td>
<td>Pouches each with 12 blister strips</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INH 300 mg Tablets</td>
<td>Tablets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>INH 100 mg Tablets</td>
<td>Tablets</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SM 0.75g Capsules</td>
<td>Vials</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rifampicin 150 mg</td>
<td>Capsules</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PZA 500 mg Tablets</td>
<td>Tablets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Ethambutol 800 mg</td>
<td>Tablets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PWB (6-10 kg) PWB</td>
<td>PWB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
(KEY: UOM: Unit of Measurement; SN: Stocking Norm)

% (and names) of districts having drug stocks for less than one month at the end of quarter (from “Medications” portion of District PM Report):

Name of State Tuberculosis Officer Reporting (in Capital Letters):

Signature: Date:

Notes:

This report is to furnish details of Category Boxes and Loose drugs available at SDS(s) and all downline stocking points within the state viz. DTCs, TUs, PHIs, etc., as at the quarter end

Boxes reported in this form shall comprise full/ unopened boxes only [e.g. only fully reconstituted boxes shall be reported in column (f) in the top half of the form, etc.]

Stock received during the quarter reported in column (d) shall comprise stock received by the SDS from higher levels viz. GMSD, etc. Stock received from subordinate stocking point shall be reported in column (e)

Stocking Norm (SN) refers to the desirable level of inventory, to be maintained by the programme at the state-level. This currently comprises 10 months, as a consequence of which SN shall be column (h/3*10)

<table>
<thead>
<tr>
<th>Stock Type</th>
<th>Quantity</th>
<th>Stock Type</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>PWB (11-17 kg)</td>
<td></td>
<td>PWB</td>
<td></td>
</tr>
<tr>
<td>PP (6-10 kg)</td>
<td>Pouches</td>
<td>PP (11-17 kg)</td>
<td>Pouches</td>
</tr>
</tbody>
</table>
# RECONSTITUTION REGISTER (RR)

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Date</th>
<th>DOT/PHI (From which drugs have been transferred)</th>
<th>TB Register No.</th>
<th>Category</th>
<th>Input (No. of Blisters)</th>
<th>Output (No. of Boxes)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(a)</td>
<td>(b)</td>
<td>(c)</td>
<td>(d)</td>
<td>(e)</td>
<td>(f)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(g)</td>
<td>(h)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(i)</td>
<td>(j)</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>(k)</td>
<td>(l)</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>(m)</td>
<td>(n)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(o)</td>
<td></td>
</tr>
</tbody>
</table>

**KEY:** CAT: Category; IP: Intensive Phase; CP: Continuation Phase

**Notes:**
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 Category 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.
Appendices

Appendix I–J

PHYSICAL VERIFICATION SHEET (PVS)
Reporting Unit: SDS/ DTC/ TU

Date of Physical Verification:

<table>
<thead>
<tr>
<th>S. NO.</th>
<th>Drug</th>
<th>UOM</th>
<th>Qty as per stock register</th>
<th>Qty. as per physical count</th>
<th>Discrepancy between stock register and physical count</th>
<th>Nature of discrepancy</th>
<th>How discrepancy was dealt with</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>(b)</td>
<td>(c)</td>
<td>(d)</td>
<td>(e)</td>
<td>(f=d-e)</td>
<td>(g)</td>
<td>(h)</td>
<td>(i)</td>
</tr>
</tbody>
</table>

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

PREPARED BY: ______________  REVIEWED BY: __________  APPROVED BY: _______
# APPENDIX II

## List of MIS Formats Available in this Appendix

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequacy of Drug Stocks (ADS)</td>
<td>II–A</td>
</tr>
<tr>
<td>Expiry Age Analysis of Drug Stocks (EAADS)</td>
<td>II–B</td>
</tr>
<tr>
<td>Inconsistency In Drug Stock Reporting (IDSR)</td>
<td>II–C</td>
</tr>
<tr>
<td>Timely Execution of Critical Indents (TECI)</td>
<td>II–D</td>
</tr>
<tr>
<td>Delay in Distribution of Drugs by Transporter (DDDT)</td>
<td>II–E</td>
</tr>
<tr>
<td>Delay In Drug Stock Reporting (DDSR)</td>
<td>II–E</td>
</tr>
</tbody>
</table>
## ADEQUACY OF DRUG STOCKS (ADS)

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

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

**PREPARED BY:** _________________  **APPROVED BY:** _________________
### Expiry Age Analysis of Drug Stocks (EAADS)

**Month/ Quarter Ending: _______________**

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Drug/ Remaining Shelf Life</th>
<th>Principal Stocking Unit (SDS/ DTC/ TU)</th>
<th>Subsidiary Stocking Units (DTC/ TU/ MC/ PHI)</th>
<th>Total Stocks</th>
<th>Recommended Action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>SSU 1</td>
<td>SSU 2</td>
<td>SSU 3</td>
<td>SSU 4</td>
</tr>
<tr>
<td>(a)</td>
<td></td>
<td>(c)</td>
<td>(d)</td>
<td>(e)</td>
<td>(f)</td>
</tr>
<tr>
<td>CAT - I (PWBs)</td>
<td>10 to 12 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>13 to 15 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>16 to 18 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>19 to 21 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; 22 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAT - II (PWBs)</td>
<td>10 to 12 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>13 to 15 Months</td>
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<td>16 to 18 Months</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>19 to 21 Months</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; 22 Months</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>TOTAL</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>CAT - III (PWBs)</td>
<td>10 to 12 Months</td>
<td></td>
<td></td>
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<td>13 to 15 Months</td>
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</tr>
<tr>
<td></td>
<td>19 to 21 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; 22 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

**Prepared By:** __________________________  
**Approved By:** __________________________
INCONSISTENCY IN DRUG STOCK REPORTING (IDSR)

Month Ending: ____________________

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Name of Stocking Unit</th>
<th>DTC/TU/MC/PHI</th>
<th>Deficiency in Drug Stock Reporting</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>(b)</td>
<td>(c)</td>
<td>(d)</td>
<td>(e)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Opening Stock Not Correct</td>
<td>Stock Requirement Estimation Incorrect</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Utilization ≠ Pts. Put on Treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Estimation Incorrect</td>
<td></td>
</tr>
</tbody>
</table>

PREPARED BY: ____________________ APPROVED BY: ____________________
TIMELY EXECUTION OF CRITICAL INDENTS (TECI)

Month Ending: __________________

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Stocking Unit</th>
<th>Critical RO/DTA Document</th>
<th>Date</th>
<th>No.</th>
<th>Consignee Unit</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Dispatched by Stocking Unit</td>
<td>Received by Consignee Unit</td>
</tr>
<tr>
<td>(a)</td>
<td>(b)</td>
<td>(c)</td>
<td>(d)</td>
<td>(e)</td>
<td>(f)</td>
<td>(g)</td>
</tr>
</tbody>
</table>

PREPARED BY: ___________________  APPROVED BY: ___________________
## DELAY IN DISTRIBUTION OF DRUGS BY TRANSPORTER (DDDT)

Supplying Unit: ___________________  Month Ending: ________________

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Dispatch Transaction Reference</th>
<th>Transporter</th>
<th>Consignee Unit</th>
<th>Delay Date Received</th>
<th>Turn-around Time (g-c)</th>
<th>Delay</th>
<th>Explanation</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>(b)</td>
<td>(c)</td>
<td>(d)</td>
<td>(e)</td>
<td>(f)</td>
<td>(g)</td>
<td>(h)</td>
<td>(i)</td>
</tr>
</tbody>
</table>

PREPARED BY: ___________________  APPROVED BY: ________________
# Appendix II–F

## DELAY IN DRUG STOCK REPORTING (DDSR)

Month Ending: _______________

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Name of Stocking Unit</th>
<th>DTC/ TU/ PHI</th>
<th>Reporting Efficiency</th>
<th>Explanation/Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>(b)</td>
<td>(c)</td>
<td>(d)</td>
<td>(e)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PREPARED BY: ________________

APPROVED BY: ________________
APPENDIX III

QUALITY ASSURANCE SCHEME

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.

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 shall be drawn from the following:

1. One GMSD, selected randomly
2. One SDS, selected randomly
3. Four District TB Centres (DTC), selected randomly.
4. The following persons shall be responsible for collecting samples:
   5. From GMSD: STO/ Officer or Consultant of CTD
   6. From SDS: Officer or Consultant of CTD/ STO
   7. 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:

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Samples to be Collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td>2 boxes of Product Code-1 containing Treatment box for Cat-I patient from each batch</td>
</tr>
<tr>
<td>(2)</td>
<td>2 boxes of Product Code-2 containing Treatment box for Cat-II patient from each batch</td>
</tr>
<tr>
<td>(3)</td>
<td>2 boxes of Product Code-3 containing Treatment box for Cat-III patient from each batch</td>
</tr>
<tr>
<td>(4)</td>
<td>2 boxes of Product Code-4 containing Treatment box for prolongation of Intensive Phase of Cat-I &amp; Cat. II from each batch</td>
</tr>
<tr>
<td>(5)</td>
<td>80 vials of Product Code-5 [Injection Streptomycin] from each batch</td>
</tr>
<tr>
<td>(6)</td>
<td>8 strips of Product Code-6 [Rifampicin 150mg] from each batch</td>
</tr>
<tr>
<td>(7)</td>
<td>10 strips of Product Code-7 [INH 100mg] from each batch</td>
</tr>
<tr>
<td>(8)</td>
<td>10 strips of Product Code-8 [PZE 500mg] from each batch</td>
</tr>
<tr>
<td>(9)</td>
<td>10 strips of Tab. Pyridoxine from each batch</td>
</tr>
</tbody>
</table>

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, Kolkata.

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 IV

GUIDELINES FOR RECONSTITUTION OF CATEGORY BOXES

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/ new category boxes/ 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 Category Box, Prolongation Pouches may be used to complete the PWB

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 Category I Boxes**

A single CAT-I box contains the following drugs:

<table>
<thead>
<tr>
<th>Intensive Phase (IP)</th>
<th>Continuation Phase (CP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Months (24 Doses)</td>
<td>4 Months (54 Doses)</td>
</tr>
<tr>
<td>24 Blister Combi-packs</td>
<td>18 Multi Blister calendar combi-packs</td>
</tr>
<tr>
<td>Containing</td>
<td>Containing</td>
</tr>
<tr>
<td>2 Tabs Isoniazid 300 mg</td>
<td>6 Tabs Isoniazid 300 mg</td>
</tr>
<tr>
<td>1 Cap Rifampcin 450 mg</td>
<td>3 Caps Rifampcin 450 mg</td>
</tr>
<tr>
<td>2 Tabs Pyrazinamide 750 mg</td>
<td>4 Tabs Pyridoxine 5 mg</td>
</tr>
<tr>
<td>2 Tabs Ethambutol 600 mg</td>
<td></td>
</tr>
</tbody>
</table>

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

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 CAT-I Boxes
2. Prolongation Pouches
3. IP Pouch of other defaulted CAT-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 CAT-I” and record the shortest expiry date of blister Combi-packs on the label.

Label the CAT-I box as “Reconstituted CAT-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 CAT-I Boxes
2. Prolongation Pouches
3. IP Pouch of other defaulted CAT-II Boxes.

Thereafter label the polythene bag as “Reconstituted IP of CAT-I” and record the expiry date on the label. Also label the box as “Reconstituted CAT-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 CAT-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 CAT-I Boxes
   
   b. Prolongation Pouches
   
   c. IP Pouch of other defaulted CAT-II Boxes
2. Thereafter label the polythene bag as “Reconstituted IP of CAT-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 any of the following sources:
   a. CP Pouch of other defaulted CAT-I Boxes
   b. CP Pouch of other defaulted CAT-III Boxes

2. Thereafter label the polythene bag as “Reconstituted CP of CAT-I” and record the expiry date and Label the Box as “Reconstituted CAT-I box” and record the expiry date.

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

**Reconstitution of Category II Boxes**

A single CAT-II box contains the following drugs:

<table>
<thead>
<tr>
<th>Intensive Phase (IP)</th>
<th>Continuation Phase (CP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Months (36 Doses)</td>
<td>5 Months (66 Doses)</td>
</tr>
<tr>
<td>36 Blister Combi-packs</td>
<td>22 Multi Blister calendar combi-pack</td>
</tr>
<tr>
<td>Containing</td>
<td>Containing</td>
</tr>
<tr>
<td>2 Tabs Isoniazid 300 mg</td>
<td>6 Tabs Isoniazid 300 mg</td>
</tr>
<tr>
<td>1 Cap Rifampcin 450 mg</td>
<td>3 Caps Rifampcin 450 mg</td>
</tr>
<tr>
<td>2 Tabs Pyrazinamide 750 mg</td>
<td>6 Tabs Ethambutol 600 mg</td>
</tr>
<tr>
<td>2 Tabs Ethambutol 600 mg</td>
<td>4 Tabs Pyridoxine 5 mg</td>
</tr>
</tbody>
</table>

In case of defaulting, dead and transferred-out patients, the following situations may arise with respect to balance drugs available in the CAT-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 CAT-II Boxes.
2. Prolongation Pouches
3. IP Pouch of other defaulted CAT-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 CAT-II” and record the expiry date.

Label the patient wise box as “Reconstituted CAT-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 CAT-II Boxes
2. Prolongation Pouches
3. IP Pouch of other defaulted CAT-I Boxes

Thereafter label the polythene bag as “Reconstituted IP of CAT-II” and record the expiry date thereon. Also label the box as “Reconstituted CAT-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 CAT-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 CAT-II Boxes
   b. Prolongation Pouches
   c. IP Pouch of other defaulted CAT-I Boxes

2. Thereafter label the polythene bag as Reconstituted IP of CAT-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 CAT-II Boxes

2. Thereafter label the polythene bag as “Reconstituted CP of CAT-II” and record the expiry date and Label the Box as “Reconstituted CAT-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).

Reconstitution of Category III Boxes
One box of Category III contains the following drugs:

<table>
<thead>
<tr>
<th>Intensive Phase (IP)</th>
<th>Continuation Phase (CP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Months (24 Doses)</td>
<td>4 Months (54 Doses)</td>
</tr>
<tr>
<td>24 Blister Combi-packs</td>
<td>18 Multi Blister calendar combi-pack</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Containing</th>
<th>Containing</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Tabs Isoniazid 300 mg</td>
<td>6 Tabs Isoniazid 300 mg</td>
</tr>
<tr>
<td>1 Caps Rifampcin 450 mg</td>
<td>3 Caps Rifampcin 450 mg</td>
</tr>
<tr>
<td>2 Tabs Pyrazinamide 750 mg</td>
<td>4 Tabs Pyridoxine 5 mg</td>
</tr>
</tbody>
</table>

In case of defaulting, dead and transferred-out patients, the following situations may arise with respect to balance drugs available in the Category III 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-packs of IP Pouch Missing (Situation I)
If the box has a number of blister strips missing from IP, the same can be added to the IP Pouch of the box from any of the following sources:

1. IP Pouch of other defaulted CAT-III Boxes

2. Prolongation Pouches (after removing tablets of Ethambutol 600 mg from each Blister Strip).

3. IP Pouch of other defaulted CAT-I Boxes (after removing tablets of Ethambutol 600 mg from each Blister Strip)

4. IP Pouch of other defaulted CAT-II Boxes (after removing tablets of Ethambutol 600 mg from each Blister Strip)
After adding the missing Blister Combi-packs to the Intensive Phase Pouch, place it in polythene bag and label it as “Reconstituted IP of CAT-III” and record the expiry date.

Label the patient wise box as “Reconstituted CAT-III box” and record the expiry date.

If it is reconstituted with the use of CAT-I, CAT-II or PP, put all the removed Ethambutol Tablets in a polythene bag and label it “Tab. Ethambutol 600 mg, for use of Non-DOTS patients, pediatric patients or otherwise”, 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, full Pouch of blister strips of Intensive Phase is missing, put 24 blister strips in one polythene bag from any of the following sources:

1. IP Pouch of other defaulted CAT-III Boxes
2. Prolongation Pouches (after removing tablets of Ethambutol 600 mg from each blister strip).
3. IP Pouch of other defaulted CAT-I Boxes (after removing tablets of Ethambutol 600 mg from each blister strip)
4. IP Pouch of other defaulted CAT-II Boxes (after removing tablets of Ethambutol 600 mg from each blister strip)

Thereafter label the polythene bag as “Reconstituted IP of CAT-III” and record the expiry date.

Label the Box as “Reconstituted CAT-III box” and record the expiry date.

If it is reconstituted with the use of CAT-I, CAT-II or PP, put all the removed Ethambutol tablets in a polythene bag and label it “Tab. Ethambutol 600 mg, for use of non-DOTS patients, pediatric patients or otherwise.” 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).

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

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

Step I
1. Put 24 blister strips in one polythene bag from any of the following sources:
   a. IP Pouch of other defaulted CAT-III Boxes
b. Prolongation Pouches (After Removing Tablets of Ethambutol 600 mg from each Blister Strip)

c. IP Pouch of other defaulted CAT-I Boxes (After Removing Tablets of Ethambutol 600 mg from each Blister Strip)

d. IP Pouch of other defaulted CAT-II Boxes (After Removing Tablets of Ethambutol 600 mg from each Blister Strip)

2. Thereafter label the polythene bag as Reconstituted IP of CAT-III

3. If it is reconstituted with the use of CAT-I, CAT-II or PP, put all the removed Ethambutol Tablets in a polythene bag and label it “Tab. Ethambutol 600 mg, for use of Non-DOTS patients, pediatric patients or otherwise.” 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 Pack of this box from any of the following sources:

   a. CP Pouch of other defaulted CAT-III Boxes

   b. Prolongation Pouches (after removing tablets of Ethambutol 600 mg and Pyrazinamide Tablets from each Blister Strip- lowest for expiry option out of the three)

   c. CP Pouch of other defaulted CAT-I Boxes

2. Thereafter label the polythene bag as “Reconstituted CP of CAT-III” and Label the Box as “Reconstituted CAT-III 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).

3. In case Prolongation Pouch has been used, put all the removed Ethambutol Tablets in a polythene bag and label it “Tab. Ethambutol 600 mg, for use of Non-DOTS patients, pediatric patients or otherwise.” Pyrazinamide Tablets should be put in a separate polythene bag and label it “Tab Pyrazinamide 750 mg “ to be used as loose drugs.

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 Category I Boxes

If the Category 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 CAT-I and CAT-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 CAT- I or CAT-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 Category II Boxes

If the Category 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 CAT-I and CAT –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 CAT- I or CAT-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).

Conversion of Category III Boxes

If the CAT-III Box is near expiry or has expired then following procedure may be adopted for the conversion of CAT-III Box.

Intensive Phase Pouch

1. Put 12 blisters strips from IP pouch in a polythene bag. Take a separate polythene bag with 18 tablets of Ethambutol 800 mg and label it as polythene bag containing Ethambutol

2. Put both the polythene bag 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. Label this larger polythene bag as “Reconstituted Prolongation Pouch for prolongation of intensive Phase of Cat I and Cat II patients” and record the expiry date

4. Two 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, which has 18 Multiblister Calendar Combipacks. Take out 4 Multiblister Calendar Combipacks & put in separate Polythene bag (make 4 such packs). Into each bag add a separate polythene bag with twenty-four (24) tablets of Pyrazinamide 750 mg and eighteen (18) tablets of Ethambutol 800mg. Label each polythene
pouch containing “Pyrazinamide 1500 mg (2 tablets) and Ethambutol 1200mg (one and a half tablet) to be taken along with Isoniazid and Rifampicin.” Place all four blister strip polythene bags, each of which should now include a smaller polythene bag containing Pyrazinamide and Ethambutol, into a larger polythene bag marked “Reconstituted prolongation pouch for prolongation of intensive phase of Category I or Category II patient.” and record the expiry date. Prepare four such prolongation pouches in this manner.

2. Remaining two blister packs will be cut and the tablets labeled separately 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).

Apart from reconstitution and conversion as above, there could be other possible combinations. Subject to availability of drugs for reconstitution/conversion and impending requirements, the DTO shall judiciously decide for making best use of available resources.

Maintenance of Records for Reconstitution of Drugs

All DTCs shall maintain Reconstitution Registers (RR: Form Reference I–I) 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