

Procurement & supply chain management

An uninterrupted supply of good quality Anti TB Medicines is an essential component of DOTS strategy under RNTCP. Managing the supply chain in a programme requires continuous monitoring at all levels.

Procurement

At Centre level – Anti-TB drugs, Binocular microscopes, LED Fluorescence microscope, CBNAAT equipment, CBNAAT cartridges, LPA, Solid and Liquid culture lab equipment and consumables, PDA/Tablet computers, barcode printers and scanners

At State / District level – Laboratory consumables and equipment, computers, vehicles, printing materials, IEC materials, PPD vials, refrigerator, air conditioners etc.

For **1st Line treatment**, RNTCP has two regimens: treating new and retreatment cases. The medicines for patients are available as independent Patient-Wise Boxes (PWBs) containing medicines for the entire treatment of the patient.

For **2nd line treatment**, monthly Patient Wise Boxes (Type -A, Type-B & Type-C PWBs) for the different patient weight bands are made available by the programme.

Further, Cap Rifabutin-150mg is also procured centrally for co-infected TB HIV patients, put on 2nd line ART regimen. With regard to distribution, supplies of Cap Rifabutin are also delivered at GMSDs by manufacturers and are further distributed to RNTCP State Drug Stores, based on the NACO requirement. Upon receipt of Rifabutin supplies at SDS, they are further distributed to respective SACS (State AIDS Control Societies) based on their monthly stock reports.

Procurement of 1st Line Anti TB Medicines is limited to 'Prequalified Suppliers' defined as GMP compliant manufacturers as assessed by WHO Pre-qualification Programme (PQP) whereas 2nd Line Anti TB Medicines are procured from suppliers having WHO GMP certification as a requirement for the bidding process. For GFATM, procurement of 2nd line medicines is through Global Drug Facility (GDF) of Stop TB Partnership.

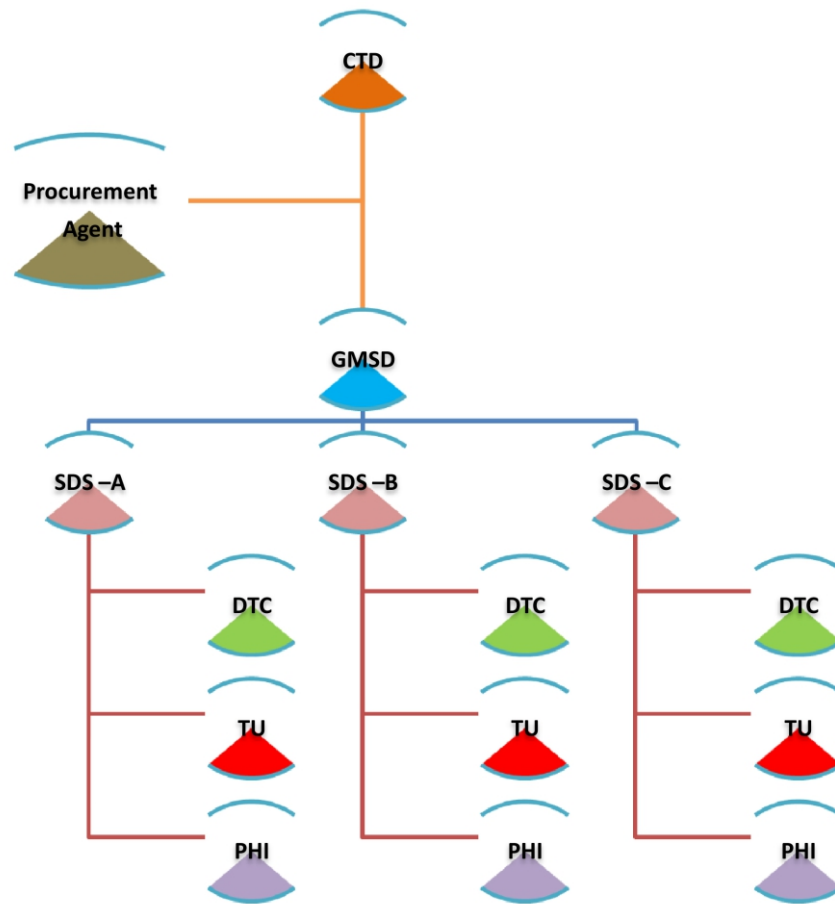
LED / Binocular Microscopes are also procured at the Central level by the Procurement Agency as per the General Finance Rules / World Bank procurement guidelines as funding for these is through Domestic Budget Support/World Bank credit.

Supply Chain Management

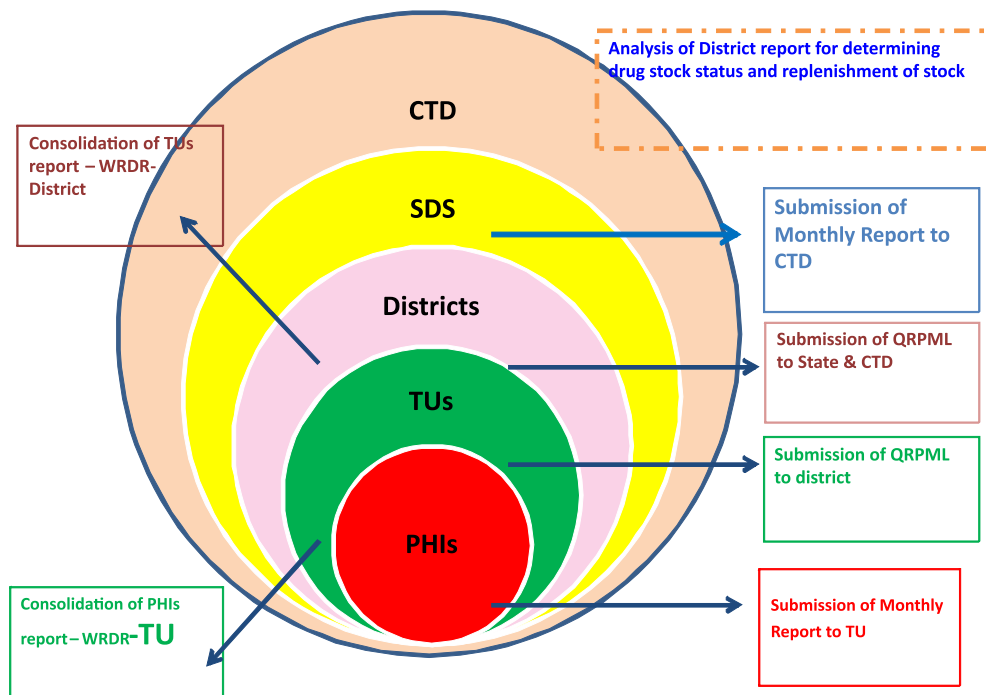
A good Supply Chain Management knows when to order or issue and how much to order or issue in order to maintain appropriate stock levels of all products to avoid stock outs and overstocking which can lead to product loss due to expiry. This is critical to the success of all health programs.

Distribution: The First Line Medicines are received at the GMSDs from the suppliers and based on the Monthly State Drug Stores and District Quarterly Programme Management and Logistics Report (QRPML), medicines are issued from the GMSDs.

For 2nd Line medicines, loose medicines are supplied at the GMSDs/SDS which have to be repacked into 1-monthly Type A, B and C Boxes for all the different weight bands. These Monthly boxes are then labelled, taken into record and distributed by the SDS as per requirement of the districts. The DTC in turn sends these boxes based on the quarter reports to its implementing TU to the PHI and finally to the DOT Centre/Provider, as the case may be.



Monitoring of Anti-TB Medicines is done based on Monthly and Quarterly Programme Management & Logistics Reports from PHIs and TU & Districts respectively. . The underlying presumption for consolidation of downline reports is that the QRPML should indicate accurate data on actual stock consumption and stock availability at all its downline medicine stores.



One of the important aspects of monitoring is Expiry Management wherein it is important that Principles of First-Expiry-First-Out (FEFO) are strictly adhered to by the drug stores at all levels to prevent expiry of medicines..

Reconstitution of medicine boxes is a process of retrieving residual medicines from PWBs of lost to follow up, dead and transferred-out patients and repacking them in quantities equivalent to and as per the description given on fresh PWBs for new & retreatment cases / Prolongation Pouches / loose medicines etc. It should be strictly centralized at the District Tuberculosis Center (DTC) or SDS for First line and Second Line medicines respectively.

Quality Assurance of Anti-TB Medicines has been accorded special importance by RNTCP and measures are taken at the time of procurement and also Post Procurement to maintain quality of Anti-TB Medicines. A comprehensive Quality Assurance (QA) Protocol is in place wherein samples from the field are regularly picked up for testing. This ensures continuous availability of good quality medicines at all stocking/ service delivery points under the programme.

Standard Operating Procedures (SOP) and Training Manuals have been developed for management of medicines. The SOP covers following aspects of supply chain management and provides detailed best practices to be followed by the State/ district/TU/PHI :-

- **Arrangement for transportation of Medicines-** States should enter into a contract with these transporters for dispatches from SDS to districts and downline destinations.
- **Physical Verification** of inventory of anti-TB medicines and reconciliation thereof with store records should be carried out under the supervision of the concerned officer-in-charge at the State, DTC, TU & PHI drug stores, regularly at the end of each month.
- **Communication Infrastructure / Staffing** at the medicine stores
- **Location, Space and Storage arrangements** should be adequately available as per Good Storage Practices (GSP).
- **MIS for Medicines stock management**

For details, refer to SOP for district drug store and State drug stores available at tbcindia.gov.in.

Capacity building and Trainings on the SOPs are regularly conducted by CTD at the central & state level, as part of decentralization of this key area.

Stocking Norms for 1st Line Anti TB Drugs :-

Level	Stock for utilization	Reserve stock	Drug requirements
PHI	1 month	1 month	(Monthly consumption x 2) – (existing stock in PHI at end of the month)
TU drugstore	0 months	2 months	(Quarterly consumption / 3) x 4 – (existing stock in TU including PHI drug stores at end of the quarter)
DTC drugstore	0 month	3 months	(Quarterly consumption / 3) x 7 – (existing stock in DTC drug store including TU & PHI drug stores at end of the quarter)
SDS	0 months	3 months	(Quarterly consumption / 3) x 10 – (existing stock in SDS including stocks at all districts at end of the quarter)

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

It is important that proactive measures be taken to ensure transfer of drugs to other districts/states to prevent expiry . The table below explains how to identify short-expiry drugs in the stores.

Item	Months				
	Duration of treatment	Extension in IP	Possible Interruption	Max transit time for shifting of box	At risk of expiry, if less than *
PC-1 PWB	6	1	2	1	10
PC-2 PWB	8	1	2	1	12

* At the district level

Stocking Norms for 2nd Line Anti TB Drugs

Flow of Drugs: At the beginning, the PHIs are supplied with a stock of two months (ie. stock for utilization in the first month along with a reserve stock of one month). Then every month, as per the monthly PHI report, they are supplied with stock from the TU which helps to maintain the reserve stock for a month at the PHI.

For the TU level to ensure that the PHIs have a month's utilization stock plus a reserve stock for one month, it needs to have a reserve stock of two months at the beginning of the quarter. District drug stores to replenish the stock at TU, upon the receipt of the drugs from their respective State Drug Stores, as per the stocking norms.

The district drug store should have at least a utilization stock of 1 month at the beginning of the quarter. Similarly the State Drug Stores should have at least a reserve stock of 3 months of consumption of the state.

It is expected that buffer stocks shall also be ensured at each level as per the stocking norms given in the table below.

Level	Stock for utilization	Reserve stock	Drug requirements
PHI	1 month	1 month*	(Monthly consumption x 2) – (existing stock in PHI at end of the month)
TU drugstore	0 months	2 months	(Quarterly consumption / 3) x 4 – (existing stock in TU including PHI drug stores at end of the quarter)
DTC drugstore	0 month	1 months	(Quarterly consumption / 3) x 5 – (existing stock in DTC drug store including TU & PHI drug stores at end of the quarter)
SDS	0 months	3 months	(Quarterly consumption / 3) x 8 – (existing stock in SDS including stocks at all districts at end of the quarter)

**All PHIs may not have a reserve stock. Only PHIs where patient/s are initiated or on treatment will have reserve stock of second line drugs.*

With regard to substitution of Tab Levofloxacin (Type-A Box) with Tab Moxifloxacin for Levofloxacin resistant MDR patients and substitution of Inj. Kanamycin (Type-B Box) with Inj Capreomycin for Kanamycin resistant MDR patients, the same needs to be addressed and done at State Drug Stores only.

Anti TB Drugs for adult patients in Daily Regimen

The daily regimen is being initiated in five states and to be scaled up in other states in a phased manner.

Medicines for daily regimen are being supplied in Patient-wise Boxes (PWBs) in following weight bands :-

Weight category	New TB Case	Previously Treated Case
25-39 kg	PC-1 DI	PC-2 DI
40-54 kg	PC-1 DII	PC-2 DII
55-69 kg	PC-1 DIII	PC-2 DIII
=70	PC-1 DIV	PC-2 DIV

Further, procurement of loose drugs for 5% of expected TB patients who may have side effects from fixed dose combinations (FDCs) and may require loose drugs instead of FDCs is also done through same mechanism and as per the procurement standards of GOI.

Dosages:-

Type of TB Case	Doses in IP	Doses in CP
New	56 doses (7 days * 8 weeks)	112 doses (7 days * 16 weeks)
Previously treated	84 doses (7 days * 12 weeks)	140 doses (7 days * 20 weeks)

Supply Chain Management

- **Distribution and monitoring:** Drugs to be distributed in the same manner as it is being distributed under Intermittent Regimen.
- **Reconstitution of medicine boxes** The reconstitution shall be done as per the existing RNTCP guidelines.
- **Treatment to Hospitalised patients** – preferably from the balance strips of PWBs from default / death patients. If same is not available, fresh boxes may be used.
- **Quality Assurance** of Anti-TB Medicines under daily regimen is same as it being done for Intermittent Regimen.
- **Storage:** Anti TB Drugs should be adequately maintained in quality condition; at room temperature, dry, pest / termite free area and secured under lock and key.
- **MIS for Medicines stock management** have been annexed at Annexures I-IV.

Stocking Norms for adult drug boxes:

For First three weight bands: 25-39 kg ,40-54 kg and 55-69 kg

Flow of Drugs: At the beginning, the PHIs are supplied with a stock of two months (ie. stock for utilization in the first month along with a reserve stock of one month). Then every month, as per the monthly PHI report, they are supplied with stock from the TU which helps to maintain the reserve stock for a month at the PHI.

For the TU level to ensure that the PHIs have a month's utilization stock plus a reserve stock for one month, it needs to have a reserve stock of two months at the beginning of the quarter.

The district drug store should have at least a utilization stock of 1 month at the beginning of the quarter. Similarly the State Drug Stores should have at least a reserve stock of 3 months of consumption of the state.

It is expected that buffer stocks shall also be ensured at each level as per the stocking norms given in the table below :

Level	Stock utilization for	Reserve stock	Drug requirements
PHI	1 month	1 month	(Monthly consumption x 2) – (existing stock in PHI at end of the month)
TU drugstore	0 months	2 months	(Quarterly consumption / 3) x 4 – (existing stock in TU including PHI drug stores at end of the quarter)
DTC drugstore	0 month	1 months	(Quarterly consumption / 3) x 5 – (existing stock in DTC drug store including TU & PHI drug stores at end of the quarter)
SDS	0 months	3 months	(Quarterly consumption / 3) x 8 – (existing stock in SDS including stocks at all districts at end of the quarter)

*The stocking norms are different under daily regimen as the shelf life may be varied from 2-3 years.

For fourth weight band: >70 Kg

Flow of Drugs: whenever a patient is diagnosed and to be put on treatment at PHI, the TU will send the drug box to the PHI immediately. At the end of each quarter, the shelf life would be reviewed and if required, inter TU or inter district transfers of the PWBs will be done to manage shelf life of drugs so that drug do not expired at any point of time. Accordingly, the stocking norms for the flow of drugs for weight band >70 are briefed in the table in next page:

Level	Stock for utilization	Reserve stock	Drug requirements
PHI	0 months *	0 months	Upon diagnosis of a patient under this category, respective TU will send the drug box to PHI immediately
TU drugstore	0 months	2 months	(Quarterly consumption / 3) x 2 – (existing stock in TU including PHI drug stores at end of the quarter)
DTC drugstore	0 month	1 months	(Quarterly consumption / 3) x 3 – (existing stock in DTC drug store including TU & PHI drug stores at end of the quarter)
SDS	0 months	3 months	(Quarterly consumption / 3) x 6 – (existing stock in SDS including stocks at all districts at end of the quarter)

Criteria for identification of short expiry Patient Wise Boxes (PWBs) . The table below explains how to identify short-expiry drugs in the stores.

Item	Months			
	Duration of treatment	Possible Interruption	Max transit time for shifting of box	At risk of expiry, if less than *
PC-1 D	6	2	1	9
PC-2 D	8	2	1	11

TB HIV: State Drug Stores will issue anti-TB drugs to the respective ART Centres as per the requirement quarterly. These ART centre shall submit the monthly report to the State Drugs Stores and the SDS to indicate the issues / dispatches to ART centres in their monthly report; submitted to the Central TB Division.