Module 6

Procurement, Supply Chain Management & Preventive Maintenance

Introduction:

Timely procurement and uninterrupted supply of medicines & other consumables is one of the important requirements for the successful implementation and sustainability of the Programme. Procurement, storage, maintenance of stock and in-time distribution of anti-TB drugs & other materials are essential for quality services under Revised National TB Control Programme. One of the most important tasks is to make sure that all health facilities have the adequate stock of drugs and consumables. Monitoring of drug supply from centre to PHI level through a web-based real time software i.e. Nikshay-Aushadhi, to avoid any shortage and expiry of medicines.

Learning objectives:

In this module participants will learn the roles and responsibilities of program manager at each level in Procurement, Supply Chain Management, Logistics and Preventive maintenance as mentioned below:

1. Procurement and Supply Chain Management of Anti TB drugs

- Selection
- Procurement
- Storage
- Distribution
- Usage
- Reporting & Monitoring
- Quality Assurance of Drugs

2. Supply Chain Management of other items

- I. **Treatment-related supplies** such as syringes, needles, water for injections, water containers, disposable tumblers etc.
- II. Diagnostics CBNAAT Machines and Cartridges, Binocular microscopes (BM) & LED-Fluorescence Microscopes, X-Ray Machines with supportive accessories, Lab consumables (sputum containers and slides)
- III. **Stationary & Printing** IEC material, Forms, registers, reports and Envelops for 99 DOTS
- 3. Preventive maintenance of vehicles & other office equipments etc.
- 4. Supervision & Monitoring of TB Medicines
- 5. Nikshay-Aushadhi (NA)

1. Procurement and Supply Chain Management system of Anti TB drugs under RNTCP

A strong procurement and supply chain management with respect to drugs is essential to strengthen every link in the drug supply chain, from manufacturer to patient for an uninterrupted supply of quality Anti TB drugs under the programme. In India RNTCP provides quality drugs to all the diagnosed TB patients without any interruption. Under RNTCP, 1st line drugs are being provided in monthly blister strips of Fixed Dosage Combination (FDC) for Drug Sensitive TB patients according to their weightbands. For drug resistant TB patients, drugs are provided in monthly boxes depending upon their weight-band and resistance pattern (Mono-resistance, poly-drug resistance, Multi Drug Resistance, Extensive Drug Resistance).

An efficient drug supply chain system should ensure:

- Continuous availability of quality anti-TB drugs
- Maintenance of adequate drug stocks at all levels
- Prevention of expiry of drugs at all levels
- · Effective timely transportation of drugs
- · Proper maintenance of drug record
- · Quality of drugs throughout its shelf life
- Safeguarding against pilferage

An effective Procurement & Supply Chain Management system encompasses the activities :



1.1 Selection:

The essential first line drugs used in the Revised National TB Control Programme are: Rifampicin, Isoniazid, Ethambutol and Pyrazinamide. In RNTCP, 2ndline drugs are used in monthly patient wise boxes (Type-A & Type-B) for the different weight bands. Loose anti TB drugs are also used

in the programme. E.g., adverse reaction, modification of boxes/ regimen etc

1.1.1. 1st Line Anti TB drugs (a) Adult & Paediatrics anti TB drugs - FDCs (DSTB-IP/CP)

S1.	Product	Draduct Description Drug & Strongth		Dosage
No.	Code	Product Description		
1	DSTB-IP	Schedule 13 is a	Each FDC	As per
	(A) 4FDC	blister pack of 28	Tab contain	weight band
		tablets, each tablet	- Isoniazid IP 75mg	
		consisting of	Pyrazinamide IP	
		Isoniazid,	400 mg	
		Rifampicin,	Ethambutol	
		Pyrazinamide and	Hydrochoride IP	
		Ethambutol in fixed	275 mg	
		dose combination	Rifampicin 150 mg	
		(HRZE-Fixed Dose		
		Combination).		
2	DSTB-CP	Schedule 14 is a	Each FDC Tab	As per
	(A) 3FDC	blister pack of 28	contain – Isoniazid	weight band
		tablets, each tablet	IP 75 mg	
		consisting of	Rifampicin IP 150	
		Isoniazid,	mg Ethambutol	
			Hydrochloride IP	
		Ethambutol in fixed	275 mg	
		dose combination		
		(HRE-Fixed Dose		
		Combination)		
3	DSTB - IP	Schedule 15 is a	-	As per weight
	(P) 3FDC	blister pack of 28		band
		dispersible tablets of	•	
		Fixed Dose	Rifampicin IP 75	
		combination of	mg	
		Isoniazid,	Pyrazinamide	
		Pyrazinamide &	150mg	
		Rifampicin		
4	DSTB-	Schedule 16 is a	Each dispersible	As per
	CP(P)	blister pack of 28	FDC Tab contain –	weight band
	2FDC	dispersible tablets of	Isoniazid IP 50 mg	
		Fixed Dose	Rifampicin IP 75	
		combination of	mg	
		Isoniazid &		
		Rifampicin		

Note: Ethambutol should be given separately for Paediatric TB Patient as per the appropriate weight band.

(b) Drug Dosage for ADULT DSTB

Weight category	Number of	Inj. Streptomycin (when used)	
	Intensive phase	ntensive phase Continuation phase	
	HRZE	HRE	
	75/150/400/275	75/150/275	gm
25-34 kg	2	2	0.5
35-49 kg	3	3	0.75
50-64 kg	4	4	1
65-75 kg	5	5 5	
>75 kg	6	6	

Note: Adult weighing less than 25kg will be given loose drugs as per body weight.

(c) Drug Dosage for PEDIATRIC DSTB

(C) Diag Dosage ioi								
	Number of Tablets (FDCs)							
W-1-1-4 O-4	Intensive P	hase	Continuation Phase					
Weight Category	HRZ	E	HR	E				
	50/75/150	100	50/75	100				
4-7 kg	1	1	1	1				
8-11 kg	2	2	2	2				
12-15 kg	3	3	3	3				
16-24 kg	4	4	4	4				
25-29 kg	3 + 1A	3	3 + 1A	3				
30-39 kg	2 + 2A	2	2 + 2A	2				

A=Adult FDC (HRZE=75/150/400/275; HRE=75/150/275)

(d) Isoniazid Preventive Therapy (IPT)

(i) Chemoprophylaxis: Children are more prone for severe disseminated form of Tuberculosis and children aged 5 years or less who are close contact with TB patient should be given Isoniazid prophylaxis after ruling-out active TB by paediatrician or medical officer. It should be given irrespective of BCG/Nutritional status. The dosage of INH preventive therapy is 10mg per kg body weight administered for 6 months. Loose tablets of Isoniazid 100 mg are supplied by CTD based on the district/state requirement submitted through Nikshay-Aushadhi.

- (ii) For PLHIV: INH Preventive therapy should be considered in following situation:
 - For all HIV infected children who either had a known exposure to an infectious TB case or are tuberculin skin test positive (>=5mm induration) but have no active TB disease.
 - All TST positive children who are receiving immunosuppressive therapy (e.g. Children with nephrotic syndrome, acute leukaemia, etc.).
 - A child born to mother who was diagnosed to have TB in pregnancy should receive prophylaxis for 6 months, provided congenital TB has been ruled out. BCG vaccination can be given at birth even if INH preventive therapy is planned.

The requirement of Tab Isoniazid and Pyridoxine for IPT is supplied by CTD based on the requirement from NACO.

(e) Requirements of loose drugs for indoor patients:

In case of loose drugs requirement for indoor patients, drugs can be obtained from the concerned DDS, based on actual consumption and requirements submitted through *Nikshay-Aushadhi*.

1.1.2 2nd Line Anti TB Drugs-

The State/ SDS supplies only loose form of second-line anti-TB drugs (SLD). The SDS/DDS repack the loose drugs into one-monthly patient-wise boxes of **Type A** (oral drugs common in IP and CP), **Type B** (IP Plus boxes) and supplies to districts/TUs/PHIs for treatment.

SDS/DDS shall be preparing 'standardized drug boxes' for standard regimen and supplies to districts/TUs/PHIs, namely for shorter MDR/RR TB regimen, conventional MDR-TB regimen and regimen for H mono/poly DR-TB. SDS shall supply additional loose quantity of SLD to districts for constituting modification in boxes.

The patient on intensive phase (IP) shall be put on Type A and Type B boxes in each month. During the continuation phase (CP), the patient will be put on only Type A box for the entire duration.

(a) Drug dosage of DR TB drugs for Adults patients:

S1.No	Drugs	16-29	30-45	46-70	>70 kg	
		kg	kg	kg	,	
1	Rifampicin(R) ¹	300mg	450mg	600mg	600mg	
2	High dose H (Hh)	300 mg	600 mg	900 mg	900 mg	
3	Ethambutol(E)	400 mg	800 mg	1200 mg	1600 mg	
4	Pyrazinamide(Z)	750 mg	1250 mg	1750 mg	2000 mg	
5	Levofloxacin(Lfx)	250 mg	750 mg	1000 mg	1000 mg	
6	Moxifloxacin (Mfx)	200 mg	400 mg	400 mg	400 mg	
7	High dose Mfx (Mfx ^h)	400mg	600mg	800mg	800mg	
8	Bedaquiline (Bdq)	We	ek 0-2: Bdo	q 400 mg d	aily	
		Week 3	8–24: Bdq 2	00 mg 3 tir	nes per	
				ek		
9	Linezolid (Lzd)	300 mg	600 mg	600 mg	600 mg	
10	Clofazimine (Cfz)	50 mg	100 mg	100 mg	200 mg	
11	Cycloserine (Cs) ⁴	250 mg	500 mg	750 mg	1000 mg	
12	Delamanid (Dlm)	50 mg twi	ce daily (10	00 mg) for 2	4 weeks	
			ears of age			
		_	vice daily (2	200 mg) for	24 weeks	
		for >11 ye				
13	Imipenem/cilastatin		mipenem/	1000 mg cil	lastatin	
	(Ipm / Cls) ⁴	twice daily	/			
14	Meropenem(Mpm) ⁴		three times		native	
			2000 mg tw			
15	Amikacin (Am) ²	500 mg	750 mg	750 mg	1000 mg	
16	Capreomycin (Am) ²					
17	Kanamycin(Km) ²	500 mg	750 mg	750 mg	1000 mg	
18	Ethionamide (Eto) ⁴	375 mg	500 mg	750 mg	1000 mg	
19	Na-PAS (60%	10 gm	14 gm	16 gm	22 gm	
	weight/vol) 3,4					
20	Amoxyclav	875/125	875/125	875/125		
	(Amx/Clv)	mg BD	mg BD	mg	(2 morning +1 evening)	
	(In child: WHO			(2 morning	· r evening)	
	80mg/Kg in 2			+1 evening)		
	divided doses)					
21	Pyridoxine(Pdx)	50 mg	100 mg	100 mg	100 mg	

¹For H mono/poly resistant TB;

 $^{^2}$ For adult more than 60 yrs of age, dose of SLI should be reduced to 10mg/kg (max up to 750 mg)

 $^{^3}$ In patient of PAS with 80% weight/volume the dose will be changed to 7.5gm (16-29Kg); 10 gm (30-45 Kg); 12 gm (46-70 Kg) and 16 gm (>70 Kg)

⁴Drugs can be given in divided doses in a day in the event of intolerance

(b) Drug dosage of DR TB drugs for Paediatric patients:

DRUGS	Daily Dose (Pediatric)	DAILY DOSE (Adult)
Isoniazid1	7–15 mg/kg; max dose 300mg daily (average 10)	4–6 mg/kg once daily High – dose: 16–20 mg/ kg once daily
Rifampicin	10–20 mg/kg; max dose 600mg daily (average 15)	8–12 mg/kg once daily
Pyrazinamide	30–40 mg/kg; max dose 2000mg daily (average 35)	20–30 mg/kg once daily
Ethambutol	15-25 mg/kg once daily ; max dose 1500 mg (average 20)	12–18 mg/kg once daily
Levofloxacin	5 years and under: 15–20 mg/kg split into two doses (morning and evening) Over 5 years: 10–15 mg/kg once daily	10-15 mg/kg once daily
Moxifloxacin	7.5–10 mg/kg	400 mg once daily
Ethionamide/ Protionamide	15–20 mg/kg	15-20 mg/kg/day in 2 divided doses
Cycloserine	10–20 mg/kg	10-15mg/kg/ day in 2 divided doses
p- aminosalicylic acid	200–300 mg/kg for patients less than 30 kg	8- 12 g/day in 2 divided doses
Linezolid	10 mg/kg given three times daily (pyridoxine should also be given)	600 mg once daily
Clofazimine	Limited data, but 1 mg/kg once daily has been given	200–300 mg daily (2 first month) then reduce to 100 mg daily (alternative dosing 100 mg daily)
Amoxicillin clavulanic acid 7/1	80 mg/kg (based on the Amoxicillin component) in two divided doses	80 mg/ kg/ day in 2 divided doses
Kanamycin	15–30 mg/kg once daily (Max 1000 mg)	15–20 mg kg once daily
Amikacin	15–30 mg/kg once daily (Max 1000 mg)	15–20 mg kg once daily
Capreomycin	15–30 mg/kg once daily (Max 1000 mg)	
Imipenem cilastatin	Meropenem is preferred in children	1000 imipenem/ 1000 mg cilastatin twice daily
Meropenem	20–40 mg/kg intravenous every eight hours	1000 mg three times daily (alternative dosing is 2000 mg twice daily)
Bedaquiline	Dose not yet determined in Children	400 mg once daily for 2 weeks then 200 mg 3 times per week for next 22 weeks
Delamanid	Dose not yet determined in children	100 mg twice daily (200 mg) for 24 weeks.

Children at risk for peripheral neuropathy (e.g. malnutrition or HIV coinfection) should also receive pyridoxine 5-10 mg/day

- **(c) Newer Anti TB Drugs:** The newer drugs i.e. Bedaquiline and Delamanid are procured centrally and supplied to GMSDs/CMSS warehouses for further distribution:
 - **Bedaquiline**: Each Bedaquiline bottle contains 188 Tabs having dosage strength of 100mg with 24 months of shelf life. This is sufficient for 6 months of duration as per RNTCP treatment guidelines. BDQ is given to Patient at DR-TB centre to hand over to treatment supporter to be included in first monthly Type B box along with other drugs. Bottle to be remained under custody of treatment supervisor up to 24 weeks, while the Type B box will be issued on a monthly basis. DDS entered the BDQ stock in Stock Register and Nikshay-Aushadhi, on information from DRTB centre. District TB centre needs to ensure the availability of automatic ECG machine reader, if patient is started on BDQ.
 - **Delamanid** Delamanid is supplied in the form of Strips of 8 Tabs having dosage strength of 50mg with 60months of shelf life. As per RNTCP guidelines, 672 Tabs of Delamanid will be issued for a patient for a period of 24 weeks @ 100mg BD daily dosage. DLM is issued to Nodal/ DRTB centre as loose drugs where patient is initiated on treatment. DLM is given on monthly basis in type B box till the end of IP along-with other drugs used in DRTB. Drugs are issued from SDS to DDS/ NDR-TB centres based on request through Nikshay-Aushadhi

1.2 Procurement of Anti TB Drugs and other consumables:

1.2.1 At Centre Level: A Procurement and Supply Chain Management (PSM) Unit has been established at Central TB Division (CTD) of the Revised National Tuberculosis Control Programme (RNTCP) for the Government of India for coordinating the Procurement and management of Supply Chain of all types of anti TB drugs, diagnostics and consumables. This unit is headed and supervised by Addl. Deputy Director General (TB). The procurement is done centrally depending on the policies and funding mechanism either through the Procurement Agency of Government of India which is Central Medical Services Society (CMSS) or through the Global Drug Facility (GDF) of the Stop TB Partnership. The procurement is done based on Technical Specifications formulated by CTD and approved by a Technical committee of MoHFW. The annual/periodic requirements of the drugs and diagnostics are finalized at Central Level based on the inputs on the stock levels and consumption pattern of the States/TUs.

Currently all procurement of First line drugs under the domestic budget (DBS), the World Bank and funded by 'The Global Fund' (TGF or GFATM) are made through CMSS. However, the Second Line Drugs which are funded by The Global Fund are procured through the Global Drug Facility (GDF).

Provision of emergency procurement of drugs is available under the programme in order to handle critical situation. These drugs and diagnostics are occasionally procured through GDF.

The First Line Drugs should be Pre-Qualified for the eligibility of procurement for any funding sources under any Procurement Agencies. However, the Second Line Drugs should be manufactured from a site which is WHO - GMP compliant when the Domestic/ World Bank funding is used. However, when the fund from The Global Fund is used, the Procurement of the Second Line Drugs are made only through GDF and the products are Pre-Qualified or from any countries under the Stringent Regulatory Authorities (SRA). The No Objection Certificate needs to be obtained by the Programme from the TGF when a product recommended by the Expert Review Panel (ERP) which may not fall under any one of the above categories.

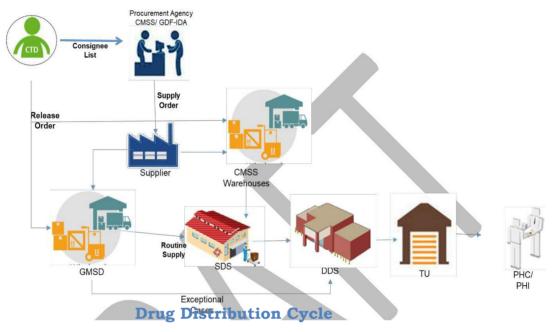
In addition to Anti TB drugs, Binocular Microscopes, LED-Florescence Microscope, CBNAAT/TruNAAT Machines, Cartridges, LPA, Solid and Liquid Culture laboratory equipment & consumables, PDA/Tablet Computers and services are also procured at Central level.

1.2.2 At State / District Level: In case of emergency only, few Anti TB drugs are procured locally at State / district level after approval from Central TB Division following RNTCP guidelines. In addition to drugs, Laboratory consumables and equipment, computers, vehicles, printing material, IEC material in different language, PPD vials, refrigerator, Air conditioner, services etc. procured at state/district level following RNTCP guidelines / General Financial Rules (GFR).

1.3 Distribution:

1.3.1 First Line Drugs distribution: Distribution of drugs is to be carefully monitored, so as to ensure uninterrupted availability of quality drugs. Requirements at drug stocking points are based on current utilization patterns and expected stocks at the time of delivery. Distribution of first line drug supplies is primarily supplied from the manufacturer to Government Medical Stores Depots (GMSDs) at Karnal, Mumbai, Kolkata, Chennai, Guwahati and Hyderabad. In addition to GMSDs, drugs are supplied through 21 Central Medical Store Society (CMSS) also which is operating across the country. Central TB Division issues drugs based upon consumption, closing stocks and stocking norms. The drugs are issued from the GMSDs/CMSS warehouses to the State Drug Stores (SDSs) for onward distribution to the districts. In case of any emergency, drugs are issued directly to the districts. GMSDs/CMSS take about 21 days to dispatch the drugs up to State Drug Store or districts. The SDS is operating in all the states in the head quarter catering to 50 million populations per SDS. In larger states/difficult terrine, more than 1 SDS has

been established as per RNTCP guidelines. The SDS/ Districts should follow up with the GMSDs/CMSS in case of delay in receipt of drugs after receipt of Release Order from Central TB Division. Drugs once received by the SDS are then transported to the districts. The districts then transfer the drugs to the TUs which in turn supply them to the PHIs. Drugs from SDS to DDS and subdistrict level transported through a well-defined transportation mechanism/ Third-party Logistics (3PL).



- **1.3.2 Second Line Drugs distribution:** Distribution system of second line drug supplies is same as first line anti TB drugs.
- **1.3.3 Flow of Drugs:** The flow of drugs is the direct reverse of the flow of reports. Drug requirements, consumption and stock positions at district and State levels are monitored at the State/Central TB Division through the Nikshay-Aushadhi software. Regular, accurate information of consumption, drug stock and supplies at PHI, TUs, Districts & State levels are essential for correct monitoring of the stock position at all levels.

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

Hence, at the beginning, the PHIs are supplied with a stock of two months (ie. stock for utilization in the first month along with a reserve stock equal to the consumption for one month). Then every month, as per the monthly PHI request/report through Nikshay-Aushadhi, they are supplied with stock from the TU which helps to maintain the reserve stock for a month utilization at the PHI. This reserve stock helps the PHI to provide drugs if more patients are

put on treatment in a particular month and to provide cover for delay in supplies from TU. Thus, no patient is sent back due to lack of drugs even on a single occasion.

For the TU level to ensure that the PHIs have a month's utilization stock plus a reserve stock of one-month consumption, it needs to have a reserve stock of two months at the beginning of the quarter. This will ensure a continuous supply of drugs.

The district drug store should have at least a reserve stock of 3 months at the beginning of the quarter. Similarly, the state drug stores should have at least a reserve stock of 3 months for utilization of the state.

The regular process of supply of fresh stock of drugs from the GMSD/CMSS to the state/SDS begins only when the states submit their requirement/report to the CTD through Nikshay-Aushadhi. Once the drug requests are received by Central TB Division, it takes around 7-10 days for CTD to process the requirement. The state should have at least a utilization stock of 10 months at the beginning of the quarter.

During the first week of each quarter, TU/district and state will have to submit their requirement through Nikshay-Aushadhi. In case of any disruption, the requirement can be submitted in the hard copy also in the prescribed RNTCP format. Later, it can be submitted/uploaded through Nikshay-Aushadhi to avoid interruption in supply of medicines.

1.3.4 Movement of Drugs:

GMŠDs/ CMSS Quarterly (Drugs are issued to SDSs on basis of Release order from Central TB division based on the states/districts request/report)

SDS

 Quarterly (Drugs are issued to the DDSs/ NDRTBC based on requirement. At the same time drugs are received from GMSDs)

DDS

 Quarterly (Drugs are issued to the TU drug store/ DDRTBC based on requirement. At the same time DDS receives drugs from SDS)

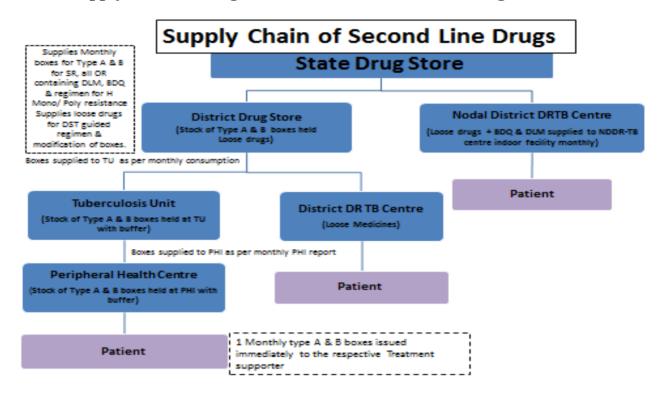
TUs

 Monthly (Drugs are issued to the PHIs based on requirement. At the same time TU receives drugs from DDS)

PHIs

 Drugs are received at PHIs from concerned TUs and issued for the treatment of TB Patients

1.3.5 Supply Chain Management of 2nd Line Anti TB Drugs



1.3.6 Stocking norms for 1st and 2nd Line Drugs

Thus, the quantity of reserve stocks and total stocks at each level at the start of the quarter (considering the receipt from one higher level) should be as follows:

Level	Utilization (in months)	Reserve stocks in store (in months)	Combined total stock of all stores in the area(in months)
PHI	1 month	1 month	2 months
TU	-	2 months	4 months
District	-	3 months	7 months
State -		3 months	10 months

It is expected that buffer stocks shall also be ensured at each level as per the above **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 drug store	0 month	2 months	(Quarterly consumption / 3) x 4 – (existing stock in TU including PHI drug stores at end of the quarter)
DTC Drug store	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 month	3 months	(Quarterly consumption / 3) x 10- (existing stock in SDS including stocks at all districts at end of the quarter)

1.4 Storage:

1.4.1 State Drug Store (SDS): Over the past few years, the responsibility of drug logistics management has been commendably taken up by the States which can be seen in the fact that more than 45 State Drug Stores (SDS') have been established in various States/UTs in the country. SDSs are essential for decentralizing drug management at State level and in sharply reducing lead-times for fulfilling drug requests (norm – 1 SDS for 50 million population). In larger states/difficult terrine, more than 1 SDS can be established as per RNTCP guidelines.

An official should be nominated as Nodal Person responsible for Procurement and Supply Chain Management activities at state level/SDS. A qualified Pharmacist cum Storekeeper and Store Assistant (additional post if >1800 monthly boxes preparation per month) is required for management of drugs and other consumables at SDS.

1.4.2 District Drug Store (DDS): District Drug Store (DDS) should be established as per RNTCP guidelines with proper infrastructure and temperature control facilities for storage of anti TB drugs and consumables. Sufficient space is required at DDS to accommodate the requirement of all concerned TUs/PHIs as per RNTCP stocking norms. A qualified Pharmacist under the supervision of District TB officer is required for management of drugs and other consumables at DDS.

The pharmacist/store assistant should be trained in RNTCP drug management and Nikshay-Aushadhi and has to undergo regular refresher training as and when the revised RNTCP drug management is conducted.

- **1.4.3 TU/PHI store** Anti TB drugs are stored at Tuberculosis Unit (TU) and PHI store also as per the RNTCP guidelines/ stocking norms.
- **1.4.4 Stacking of Anti TB Drugs:** The STO/DTO must ensure that the Storekeeper performs the following activities with respect to the storage/stacking of Anti-TB Drugs and consumables:
- Ensure that different drug/consumables items are clearly segregated and stacked on separate racks.
- Different batches of drugs with different dates of manufacture and expiry are stored separately so as to facilitate First Expiry First Out (FEFO) principles viz. drug batches with the most recent expiry are issued first.
- Mark 'Expiry Dates' in Bold Letters 3" to 4" in size, on the drug cartons with a Marker Pen, for easy identification and control of drugs immediately on their arrival.
- **1.4.5 Guidelines for proper storage of Anti TB Drugs:** Importance of good storage conditions and safe custody of drugs in addition to good supply chain management is also stressed upon the States. The STO/ DTO must ensure that the pharmacist/store-keeper adheres to the following guidelines on proper storage of drugs:
- Clean and disinfect storeroom regularly
- Store supplies in a dry, well-lit, and well-ventilated storeroom, out of direct sunlight.
- Secure the storeroom from water penetration.
- Ensure that fire safety equipment is available & accessible and personnel are trained to use it. These should also be covered under AMC.
- Drug cartons should not be stacked on the floor, away from the walls and not all one over the other.
- Store medical supplies separately, away from rodents, insecticides, chemicals, old files, office supplies, and other materials.
- The identification label, expiry date & manufacturing date of the Anti TB drugs and CBNAAT Cartridges etc. should be marked with a bold marker pen on the visible side of the carton.
- Store supplies in a manner accessible for First-Expiry-First-Out (FEFO), counting, and general management.
- Separate and dispose off damaged or expired products without delay as soon as approval of the same has been received.
- The disposal of expired drugs needs to be done as per Bio-medical waste management guidelines.
- **1.5 Usage:** The monthly blister strips/ boxes should be provided to the patients through the DOT Providers only from the PHIs. Besides timely availability of

drugs to the patients after diagnosis, thorough dispensing instructions should also be provided to the patient.

1.6 Recording, Reporting and Monitoring:

1.6.1 Recording -

Stock Register: Stock Register is maintained at the SDS, districts & TU level drug stores in the prescribed format as given overleaf. A Stock Register is maintained to record receipt, issue and balance stock of drugs. The status of stock along with their expiry details can be ascertained at any point of time through this register. All receipts should be entered neatly in RED colour including transfers from other districts. The issue of drugs should be entered in BLUE colour including all transfer outs to other districts/SDS.

Example:

There are four batches of DSTB-IP drug in the DTC with expiry dates as Jan-21, May-21, Sept-21 and Dec-21. Column '1' should contain balance quantity of drugs with expiry date as Jan-21, Column 'm' with expiry date as May-21, Column 'n' with expiry date as Sept-21 and Column 'o' with expiry date as Dec-21.

As and when, the entire quantity of the drug with a particular expiry date stands completely issued, the balance in that particular column (l to o) shall become "Nil" or "Zero" on the date on which the last issue is made. As and when, the drugs with a new Expiry Date are received; the new Expiry Date is mentioned at the top of the column.

Before making any issue of drugs, the storekeeper should always look at columns (l) to (o) and check as to which drugs are due to expire first. The drugs, which are due to expire first, are to be issued first so that all the drugs issued will follow the FEFO principles

Carry Forward of Balances: While carrying forward the balances with different expiry dates from a filled-up page on to a new page of the Stock Register, it should be ensured that the columns (l) to (o) should record the Expiry Dates in an ascending order, i.e. the balance of drugs with an earliest expiry date should be recorded in column (l), whereas balance of drugs with a later expiry date should be recorded in column (m) and so on.

As seen in the above example, the Stock Register facilitates issue of drugs as per FEFO principles. However, while the Store keeper shall strictly follow FEFO principles, it is also expected of him to ensure that all short-expiry drugs do not get issued to one district/sub-district.

Instead, distribution shall be based on the utilization pattern of each district/sub-district.

An Exercise on Stock Register along with the format is available overleaf. Solution to the Exercise is available at **Annexure-3**



Exercise on Stock Register: The following transactions occurred during the month of April 2018.

Opening Balance of DSTB-IP (A) as on 1.04.2018: 1000 strips of 28 Tabs (from the batch no XY received from SDS Agra; Date of Expiry – Aug-2020).

Receipts of Drug: DSTB-IP (A)

Bat ch No.	Date of Receipt	Date of Mfg.	Date of Expiry	Qty Received (Nos.)	Name of Party (Supplier)	Invoice No./ Receipt Voucher No.	Date of Invoice/ Voucher No.
AB	10.04.2018	Nov-17	Oct-20		GMSD Karnal	IV 35	10.04.2018
CD	15.04.2018	Dec-17	Nov-20		GMSD Mumbai	IV 14	8.04.2018
EF	25.04.2018	Jan-18	Dec-20	1000	SDS Delhi	DTA 68	12.04.2018

Issues of Drug: DSTB-IP (A)

Date of Issue	Quantity Issued (Nos.)	Sent / Issued to	Issue Voucher No.	Date of Issue Voucher
17.04.2018	3000	DTC – Agra	SIV No. 1	17.04.2018
26.04.2018	4000	DTC - Mathura	SIV No. 2	26.04.2018
29.04.2018	4000	DTC - Firozabad	SIV No. 3	29.04.2018

Please record the above transactions in the Stock Register format provided on the page overleaf.

Stock Register (SR)

	Kemarks		(Ъ)										
io No.:	Signature of store- reeper		(b)										
Folio		Expiry Date ()	0	0	0								
	(4ty.)	Expiry Date ()	a	0	0								
	Date-wise expiry details of balance	Expiry Date (Oct-20)	(E)	0	0009								
Tabs	,	Expiry Date (Aug-20)	(1)	1000	1000								
28	Balance (qty.)		(k)	1000	7000							2 5	
štrip (Issue (qty.)		9	0	0								
): §	Receipt (qty.)		(<u>i</u>)	0	0009								
nent (UC		Date of Expiry	(h)	Aug-20	Oct-20								
ıren	nes	Batch No.	(g)	XX	AB								
of Measurement (UOM): Strip of	articulars of receipts & issues	Date of Issue/ Receipt Voucher	(£)	T	1.04.2018								
Unit c	s of rec	Issue Voucher No.(For Issues only)	(e)	1									
70	Particular	Receipt Voucher No. (For Receipts only)	(q)	T	IV-35								
Drug Item: DSTB-IP(A)		Name of Party (GMSD/ SDS/ DTC/TU)	(c)	Op Balance	GMSD Karnal								
Item: D		Date (Dd/ mm/ yy) of Transaction (Receipt/ Issue)	(P)	1.04.2018	10.04.2018								
Dru	SL. NO.		(a)	1	2	က	4	2	9	7	8	6	10



1.6.2 Reporting: The regular process of supply of new stock of drugs to the districts / SDS begins only when the districts submit their requirement. For effective reporting, the programme has implemented a web-based real time Logistics Management Information System(LMIS) software i.e. Nikshay-Aushadhi. This software is used at all levels for reporting of drugs availability, consumption and future requirement. The request of the stocking units is to be submitted as per the scheduled mentioned below:

Drug Request of Stocking unit	Date for submission of Quarterly/Monthly Drug Request			
PHI to TU	1st week of each subsequent month			
TU to DTC	1st week of the month after subsequent quarter			
DTC to SDS / STO	1st week of the month after subsequent quarter			
SDS to CTD	By 10th of the month after subsequent quarter			

All PHIs submit Monthly Request for drugs and consumables through Nikshay-Aushadhi to the concerned TUs. All TUs/DTCs/SDSs also submit their quarterly requirement through Nikshay-Aushadhi as per RNTCP guidelines.

The district requests are validated by the State TB Cell based on which drugs are issued by the SDS before end of the first month after the quarter. Respective states are also expected to make arrangements for transportation of drugs from SDS to District Tuberculosis Centres (DTCs) and onwards.

The state requests are analysed by CTD based on which drugs are issued to SDSs through their respective GMSDs/ CMSS warehouses.

It is very important to make sure that every health facility in the district gets adequate supply of anti-tuberculosis drugs. Timely initiation of treatment is not possible if the supply of drugs is inadequate. The basis for stocking adequate amount of drugs at various levels is described in the stocking norms table.

- **1.6.3 Monitoring:** Monitoring supply chain of drugs & other items is important to ensure:
- Uninterrupted supply of drugs, consumables etc.
- Prevention of overstocking to avoid wastage of unusual resources leading to expiry of high value drugs.
- Prevention of stock-outs to avoid delay in treatment initiation.

Monitoring drugs and logistics is done through a two-tier monitoring system:



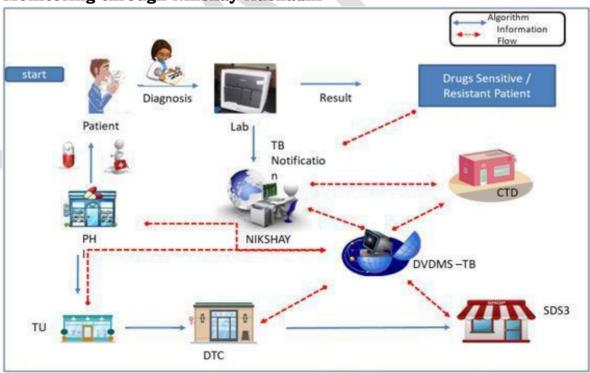
Two-tier monitoring system under RNTCP

- **Central system** at central level, Central TB Division (CTD) reviews and ensures adequacy of drugs and consumables at State level.
- **Decentralized system** by the State TB Officers (STOs) and the District TB Officers (DTOs) whereas they ensure adequacy of drugs and consumables up to the level of the DOT Centers.

Nikshay-Aushadhi ensure the real-time monitoring of drugs and consumables availability, usage, requirement along-with expiry management.

CTD ensures drug adequacy at states/districts by reviewing stock availability through Nikshay-Aushadhi which enables continuous monitoring of drug stock position at all levels.

(a) Monitoring through Nikshay-Aushadhi



(b) Physical Verification of drug stocks in the stores: - Ensure that the quantity of drugs in the Stock Register/Nikshay-Aushadhi matches with the physical stock balance in the drug store. For this purpose, physical verification should be carried out under the supervision of officer-in-charge at the State, DTC, TU & PHI drug stores regularly at the end of each month. Any shortage or



excesses should be substantiated by submission of a separate report and to be rectified in Nikshay-Aushadhi after approval from competent authority. The Physical Verification Register/Sheet should be verified by officer-in-charge and maintained at drug store.

(C) Criteria for identification of short expiry Boxes / strips: There may be instances when the stores may have some short-expiry drugs. It is important that proactive measures be taken to ensure transfer of such drugs to other districts/states to prevent expiry of such batch of drugs. The DTO shall inform the State requesting for an approval for transfer to other districts.

Note: The loose drugs can be used till the last date of expiry i.e. Drugs with DOE of Dec-2020 can be used till 31_{st} Dec-2020.

- **(d) Additional Drug Request (ADR):** The need for an Additional Drug Request arises only if the more patients put on treatment in the previous month in a quarter goes up, resulting in an insufficient stock in the store. To get the additional supply from CTD/SDS/DDS/TU, an Additional drug request for each item needs to be submitted by the SDS In-charge/DTO/MOTC. Before sending the ADR, should consider and track the drugs that have been already released and are being transported from central/state/district/TU stores.
- **(e) HIV positive TB patients who are on second line ART:** Information on the need for Cap Rifabutin (150mg) for HIV positive TB patients who are on second line ART or ART containing Protease Inhibitors should be provided by the incharge of ART Center providing second line ART (Centres of Excellence) to the DTO.

The District TB Officer needs to supply the loose drugs to the concerned ART Center on a case to case basis. The DTO would ensure that loose anti TB drugs are given to the 2nd Line ART patient along with Cap Rifabutin instead of Rifampicin. MO-PHI should sensitize the DOT provider regarding the changes made and monitor the same.

Reconstitution: Partially used boxes/strips/bottles in case of lost to follow up, failure or death of a patient are sent to district tuberculosis centre and are reconstituted. Partially used drug box/strip is at the risk of expiry if they are not reconstituted. This should be performed at the DTC/SDS and carried out under the direct supervision of the DTO/MO/office-in-charge. Complete information about LTFU, death and transfer out cases, including TB number, name of PHI and number of blisters remaining unused in the boxes/strips/bottle should be made available and entered in 'Nikshay Aushadhi'.



There may be instances where drugs for reconstitution may not be sufficient and run at the risk of expiry. In such cases they may be used as loose drugs to avoid expiry in case of Second line drugs except new drugs where specific instructions given to be followed.

Expiry Management: If any drug expires due to reasons beyond control, the write-off of expired drugs should be as per the guidelines given in RNTCP National Strategic Plan. As per NSP, the State is allowed to write off up to 2% of cost of annual supply of drugs on implementation of DST guided treatment and 2% cost of rapid molecular test cartridges. The expired stock should be disposed-off as per the Bio-medical Waste (Management and Handling) guidelines of Govt. of India.

- **1.7 Quality Assurance of drugs:** Maintaining quality of drugs remains a critical programme requirement. This is enabled through a system of pre-dispatch & post-dispatch testing of drugs and monitoring of the quality throughout their shelf-life up to consumption by the patients. The following steps have been taken by the Programme in ensuring best quality drugs:
 - At the time of Procurement: Stringent Quality Assurance requirements (WHO-GMP certification) have been laid down under RNTCP. First line Drugs are procured from WHO Pre-qualified source & second line drugs from WHO-GMP compliant suppliers under DBS/WB procurement. However, in case of The Global Fund funding, 2nd line drugs are procured form WHO-PQ source only. A Pre-dispatch inspection of all batches is undertaken prior to their dispatch from the factory premises.
 - Post-Procurement: Samples are lifted from various sites as per protocol developed by the programme. These samples are picked up randomly from the GMSDs, SDS' District & TU level each quarter and tested by an Independent Quality Assurance Lab engaged by RNTCP. Additionally, quality is also monitored by State & Central Drug Inspectors independently.



2. Supply Chain Management of other items

- I.**Treatment-related supplies** such as syringes, needles, water for injections, water containers, disposable tumblers etc.
- II. **Diagnostics** CBNAAT Machines and Cartridges, Binocular microscopes (BM) & LED-Fluorescence Microscopes, X-Ray Machines with supportive accessories, Lab consumables (sputum containers and slides)
- III. **Printing & Stationary** IEC material, Forms, registers, reports and Envelops for 99 DOTS
- 2.1 **Treatment-related supplies:** Sufficient no. of water containers and disposable tumblers be made available at the DOT centres for providing DOT. It is very important for every health facility that administers treatment under RNTCP to have an adequate supply of sterile water, disposable needles and syringes for giving injections. The requirements of these items should be matched with those of Injection vials. Ensure that there is a sufficient supply of cotton and methylated spirit so that injections are always given under sterile conditions.

2.2 Diagnostics -

- 2.2.1 **CBNAAT Machines and Cartridges:** The CBNAAT machines and cartridges are procured at centrally and supplied to state/district/CBNAAT sites based on their requirement. Cartridges are supplied based on the stock availability, consumption and expected cases load. Recording, reporting and monitoring of cartridges is done through Nikshay-Aushadhi.
 - 2.2.2 Binocular Microscopes (BMs) & LED Fluorescence Microscopes (FM): Sputum Microscopy is an essential part of RNTCP. It plays a major role in the programme and hence procurement of LED-FM and BMs is an important component in RNTCP and the procurement of both items is undertaken by CTD and are delivered to the States / Districts. All LED-FM/BMs should be covered by annual maintenance contracts by states/districts, at the end of their warranty periods.
 - (a) **Binocular Microscopes (BMs):** As per RNTCP guidelines, 1 BM is required for every designated microscopy centre (DMC). One DMC exists for every 1 lakh population (0.5 lakh population in hilly, tribal and difficult areas). In addition, RNTCP may also supply BMs to DMCs established in other sectors like ESIS, Public Sector Undertakings, Medical College etc., if required. BMs are also supplied by RNTCP to districts (depending on the number of DMCs/TUs) for implementation of EQA.



(b) **LED Fluorescence Microscopes (FM)**: LED FMs are supplied to the high case load facilities where the workload is more than 25 slides per day.

2.2.3 Laboratory consumables:

- 2.2.3.1 **Sputum containers and slides:** To keep health facility and microscopy laboratories supplied with sputum containers and slides, calculate the number of sputum containers needed for diagnosis and follow-up examinations in each quarter. Then determine the number of slides needed. Place an order for the sputum containers and slides with the appropriate source. Visit each health facility that collects sputum specimens and microscopy laboratories to make sure there is an adequate stock of sputum containers and slides.
- 2.2.3.2 **Calculation of requirement of sputum containers:** During the first week of each quarter, calculate the quantity of sputum containers your district will need for that quarter. The following steps are required for this calculation:
 - Determine the number of new smear-positive cases registered and treated during the last quarter. Use the detail of number of TB patients put on treatment both new and previously treated cases through Nikshay for this.
 - Determine the quantity of sputum containers needed for diagnosis as described below:
 - Multiply the number of new pulmonary smear-positive cases by 10. The number of smear-negative, extrapulmonary, and previously treated smear-positive cases should not be considered, because 10 symptomatic cases include all types of patients and because patients with failure and default are examined as follow-up. Ten is the average number of symptomatic required to be examined for detecting one case of New pulmonary smear-positive tuberculosis (including a smear negative X-ray positive case).
 - Multiply the number obtained in *Step 2a* by 2. (2 sputum specimens are taken for each symptomatic patient.)



• Determine the number of sputum containers needed for follow-up examinations. Follow-up specimens are taken for the majority of smear-positive patients on 2 separate occasions during their treatment (at the end of the intensive phase and at the end of treatment). One sputum container is needed for each follow-up examination because 1 sputum specimen is taken for each follow-up sputum examination.

For each pulmonary smear-negative case, follow-up sputum is taken *twice*. Hence, multiply the number of pulmonary smear-negative patients by 2 (1 sputum sample each at the end of the intensive phase and at the end of treatment)

Add the number of sputum containers needed for diagnosis to those needed for follow-up examinations. After you determine the number of sputum containers needed for diagnosis and follow-up examinations, add these numbers to obtain the approximate number of sputum containers required for the quarter.

- Allowance for reserve stock: Allow sufficient reserve stock for 3 months.
- Account for wastage: Add 10% to account for wastage of sputum containers.
- Account for the sputum containers in stock.

On the last working day of the quarter, count the number of sputum containers presently in stock. Then, during the first week of the new quarter, subtract the number of sputum containers in stock from that needed for diagnosis and follow-up examinations as calculated (*Step 4*).

2.2.3.3 **Calculation of requirement of slides:** There should be approximately the same number of slides in stock as sputum containers, because one slide is used to examine one specimen in a sputum container. Therefore, once you have determined the number of sputum containers needed for the next quarter, order the same number of slides. There may be a need for slightly more number of slides than containers because of unavoidable breakage of slides.



- 2.2.3.4 **Order for sputum containers and slides:** After you have calculated the number of sputum containers and slides needed for your district, order the supplies. Order the sputum containers during the first week of the quarter so that the health units and microscopy laboratories have enough sputum containers to collect sputum specimens and the DMCs have enough slides to conduct sputum smear examinations. In the RNTCP, these supplies will be procured by the State/District It is important that good quality slides, containers and reagents are purchased.
- 2.2.3.5 **Distribution of sputum containers and slides:** After you receive the supply of sputum containers and slides for the quarter, distribute the sputum containers to all peripheral health institutions in the district. The supply of sputum containers to those PHIs that are not functioning as sputum collection centres or DMCs would facilitate follow-up examinations because patients can be provided with the same for morning samples. Reserve stocks should be maintained at all levels.
- 2.2.3.6 Ensuring adequate supply of sputum containers and slides: When you visit the PHIs, check the supply areas for an adequate stock of sputum containers and slides. Ask the health workers or laboratory technicians if they think the stock is sufficient. Estimate if there is enough stock to last until the end of the quarter, and if there is sufficient reserve stock.
- 2.2.3.7 **50-ml polypropylene conical tubes:** Determine the quantity of Polypropylene tubes needed for diagnosis as described below:

Multiply the number of new pulmonary smear-positive cases by 10. Additional 25% of smear-negative, extra-pulmonary, previously treated smear-positive cases, UDST, follow-up cases and key population should be considered.

Multiply the number obtained in *Step above by 2*. (2 sputum specimens are taken for each symptomatic patient.)





EXERCISE

In this exercise you will calculate the number of sputum containers and slides needed by a district for the current quarter.

According to the Quarterly Report on New and Retreatment Cases, Thane District began treatment of 80 New pulmonary smear-positive cases, 20 retreatment (smear-positive) cases and 60 pulmonary smear-negative cases last quarter. There were 125 sputum containers and slides currently in stock in the beginning of the quarter.

Calculate the number of sputum containers and slides needed for the quarter.

Answer the following questions:

- 1. How many sputum containers should you order for Thane District?
- 2. How many slides should you order for the district?



2.3 Stationary & Printing:

2.3.1 IEC Material -

2.3.1 Forms, registers and reports: As you have learned throughout this course, there are several tuberculosis forms, registers and reports used in the district.

I	Forms, registers & Reports	Person responsible for maintenance
		of records/forms/reports
Form	ıs	
1.	Referral Slip	ASHA, AWW, Link Workers etc.
2.	RNTCP request form for examination of biological specimen	Medical Officer
3.	Specimen Examination	Medical Officer
4.	Tuberculosis Treatment Card	Treatment Supporter
5.	DR-TB Treatment Card	Treatment Supporter
6.	Patient's TB Identity Card	Health Care Provider
7.	DR-TB patient identity card	Health Care Provider
8.	Referral form for treatment	Medical Officer
9.	Referral form for treatment of DR-TB	Medical Officer
10.	Transfer Form	Medical Officer/ District TB Officer
11.	TB Notification Forms for	Private Practitioner
12.	Laboratories, Private Clinics/Hospitals and Chemists	Senior TB Treatment Supervisor
13.	Public Health Action form (may be converted in to register)	
Regis		
14.	register	Lab Technician, STLS
15.	Culture and DST Laboratory Register	
16.	Tuberculosis Notification Register	MOPHI / Senior Treatment Supervisor
17.	PMDT treatment register	DRTB Medical officer
18.	Stock Register	Pharmacist / Storekeeper



Rep	orts	
19.	Programme Management Report	Supervisor
20.	Supervisory checklists	Supervisor
21.	Monthly tour reports and advance tour programs	Supervisor
22.	Statement of Expenditure, audit reports, utilization certificates	STO/DTO/Accountant
23.	Physical verification report	Verifying Officer
24.	Internal Evaluation report	IE team

Determine once a year the number of all forms, registers and reports your State/district will need during the following year. Make sure there is an adequate supply of all forms, registers and reports within your State/district and sufficient funds are available for the same as per norms.

2.3.2. The number of forms, registers and reports required is calculated as below: During the first week of each year, calculate the number of forms, registers and reports your State/district will require for that year. There are three steps for this calculation:

Determination of the number of forms, registers and reports your State/district will need for the year.

The number of Tuberculosis Treatment Cards needed depends on the number of patients treated for tuberculosis in the previous year. Use the four Quarterly Reports on New and Retreatment Cases for the previous year to determine the number of patients treated for tuberculosis. Multiply by 2 to allow for a duplicate card to be kept by the Treatment Supporter.

Approximately one Tuberculosis Notification Register is needed each year for each PHI. Approximately one Tuberculosis Laboratory Register is needed for each microscopy centre in the district each year. If some pages of these registers remain blank at the end of a year, it can be used the following year. However, begin from a new page every year.

Approximately 10 copies of the Laboratory Form for Sputum Examination are needed for each pulmonary smear-positive tuberculosis case treated.

For diagnosis, approximately 10 Laboratory Forms for Sputum Examination are needed. (10 is the average number of symptomatics for each case of pulmonary smear-positive tuberculosis identified.)



For follow-up, approximately 0.2 Laboratory Forms (1 out of 10 examined will be smear positive, each need two forms for follow up. When calculated, out of 10 in will be 0.2. Hence, need not be calculated) for Sputum Examination are needed for each pulmonary tuberculosis case.

If you have access to a reference laboratory, a patient's sputum specimen can be sent for culture examination and if required, also to determine whether a patient is sensitive or resistant to an anti-tuberculosis drug. The Mycobacteriology Culture/Sensitivity Test Form contains a patient's culture and sensitivity results. Medical officers should send these through DTOs to C & S Laboratory with copy of the treatment card. Three forms should be filled up for each referral.

Four copies of the Quarterly Reports are used each quarter. Keep one copy for the district, send one copy to the STO, one copy to STDC and send one copy to the Central TB Division. Since there are 4 quarters and 4 copies are used during each quarter, 16 copies of this report are needed each year.

Preferably, all these reports should be stored in electronic format at district and state levels. These should be sent to all concerned levels through e-mail. You may avoid excess and wasteful use of paper. However, it should be noted that districts and states should have facilities for back-up of data in electronic format (CD-formats, etc) to avoid data loss due to virus attack and sabotage. The back-up materials should be kept under safe custody.

Tuberculosis Transfer Form is completed when a patient is transferred to a health facility in another district/sub-district. Once a patient reports to a new district and is registered, the bottom portion of this form is mailed back (or sent by other means) to the referring health facility. When the referring health facility receives this portion of the form, they will know that the patient's treatment is being continued.

The number of Transfer Forms needed depends on the number of patients who were transferred to another district last year. Add the total numbers in the transferred to another district column for the four Quarterly Reports on the Results of Treatment for the previous year to determine the number of patients who were transferred to another district that year.



Three copies of the Tuberculosis Transfer Form are needed for every patient who is to be transferred to another district next year. One copy each is given to:

- The patient to be transferred, to hand over to the PHI where the reports for continuation of treatment
- The TB unit to which the patient is transferred
- Office copy, to be retained at the transferring unit

Therefore, if 10 patients were transferred to another district last year, 30 Tuberculosis Transfer Forms (10 patients x 3 copies per patient) would be needed for the following year.

The Annexures I and II list the laboratory materials, tuberculosis forms and registers a district needs for one year.

Add an extra 20% of the number of forms needed to take care of the increase in tuberculosis cases or lost forms: To account for the increase in tuberculosis cases and lost forms, add an extra 20% of the number of forms needed. You do not have to make this calculation for the Tuberculosis Laboratory Register, because one register should be sufficient for one year.

The Tuberculosis Laboratory Register allows for registration of at least 2000 patients. For each lakh, 75 smear-positive patients are projected, requiring the examination of 750 patients (thrice each). Additional follow-up examinations will bring the number of registers needed to approximately one lab register / lakh.

Account for the forms, registers and reports in stock: On the last working day of the year, count the number of forms you have in stock. Then, during the first week of the new quarter, subtract the number of each form in stock from the total number of each form needed. This gives the total number of forms, registers and reports required to be indented.

Distribution of forms, registers and reports: After you receive the supply of tuberculosis forms and registers for the year, distribute the appropriate forms to the health units and the Tuberculosis Laboratory Register to the microscopy centre. Keep the excess supply which is not distributed to the facilities in the State/district to meet subsequent requirements of the health units during the year.

2.3.3. Printed materials: The districts should maintain an adequate supply of the printed materials of latest programmatic guidelines. Some of them are mentioned below, but it is not restricted to this list only:



- Technical and Operational Guidelines
- National Guidelines on Programmatic Management of Drug Resistant TB
- National Guidelines on Partnerships
- Desk Reference (Charts on Diagnostic Algorithm, Dosage of anti-TB drugs, any other)
- Laboratory Manual for Sputum Smear Microscopy and RNTCP Laboratory Network guidelines for Quality Assurance of smear microscopy for diagnosing TB
- Guidance document on Nutrition Support to TB patients
- HIV-TB Collaborative Framework
- TB Diabetes Collaborative Framework
- TB Tobacco Collaborative Framework
- Other relevant document/guidelines/Circulars as and where circulated out by CTD
- *These guidelines need not be printed. For reference, please refer to RNTCP website.
- **2.3.4 Envelops for 99-DOTS:** The RNTCP has been using 99 DOTS an IT enabled 'pill-in-hand' adherence monitoring system for all DSTB patients on daily regimen. This system requires envelops which wrap around the medicine. The envelops have printed unique phone numbers which the patient can see when taking medication and use to give free calls to report their medication. These envelops are printed at state level and distributed to districts. The cost of printing and distribution of these envelops to be budged in state PIP. Specification for printing of envelop provided by CTD to all states.

All printed materials may be printed at state-levels to ensure quality





EXERCISE 1

From the information provided about the Birbhum District, list the types and number of tuberculosis forms you need to order for this district to last throughout the next year.

Case: Birbhum District

In 2018, in Bolpur TU of Birbhum District, there were 220 tuberculosis patients, of whom 100 were diagnosed as new pulmonary smear-positive cases. There are 5 microscopy centres and 15 PHIs in the sub-district. In this year, 8 patients from the sub-district were transferred to another sub-district. Approximately 10 culture/sensitivity examinations were done in the same year. At this time, you need to order tuberculosis forms and registers for 2019. The following number of tuberculosis forms and registers are available in the reserve stock:

- 50 Tuberculosis Treatment cards
- 35 Tuberculosis Identity Cards
- 35 Tuberculosis Identity Cards
- 82 RNTCP request form for examination of biological specimen for TB
- 15 Mycobacteriology Culture / Sensitivity Test Forms
- 10 Transfer Forms
- 6 Tuberculosis Laboratory Registers
- 3 Tuberculosis notification Registers

Tuberculosis	Number	Add 20%	Subtract	Net number
Form/Register	required		Stock	





EXERCISE 2

- 1. What should be the reserve stock of drugs at the district level?
- 2. In Katurma District, 40 smear-positive cases were registered during the third quarter of year 2000. Calculate the total number of sputum containers needed for diagnosis.
- 3. What is the basis for calculation of drug stocks?
- 4. What is the purpose of maintaining reserve stock?





3. Preventive maintenance of vehicles & other office equipment etc.

- **3.1. Vehicles:** Vehicles are provided as per the financial guidelines of RNTCP. It should be ensured that the vehicles purchased by RNTCP (4 wheelers and 2 wheelers) are in working condition. This requires comprehensive annual insurance and regular & periodic maintenance preferably through authorized workshops. Funds for the same should be made available as per norms given in financial guidelines of RNTCP. Accessories like helmets, rain coats, side boxes etc. should be provided along with two wheelers for STSs/STLSs. Log books should be maintained for the vehicles.
- **3.2. Office equipments and equipments for IRLs**: All Office equipments and equipments for IRLs provided at State/District levels by RNTCP need to be maintained through Annual Maintenance Contract (AMC), utilizing funds available under the Programme. The details given in RNTCP Financial Norms which should be adhered to.
- **3.3. PDA/PC-Tablets**: PC-Tablets are procured centrally and distributed to all the states. These Tablets are used by state, district and subdistrict level officials/staff responsible for entering Nikshay and Nikshay-Aushadhi data. The arrangement of Sim Card and their tariff plans for internet facility to be done by the state through PIP. The person handling the device (PC-Tablet) is responsible for any damage /loss of same.

4. Supervision and Monitoring of TB medicines:

Role of State /District TB Officers/ MO-TCs in PSM activities under RNTCP:

The STOs / DTOs / MO-TCs have a vital role in implementing RNTCP Procurement & Supply Chain management guidelines and ensuring effective drug management systems in the state/districts.

The key responsibilities of the STO/DTO/MO-TC include the following:

- Overall supervision of State/District/TU Drug Stores operations and inventory management of drugs and consumables
- Implementation of Nikshay-Aushadhi and training of all concerned staff in
 - RNTCP drug management and Nikshay-Aushadhi upto PHI level
- Review of drug stock adequacy at all levels through Nikshay-Aushadhi, ensuring their uninterrupted supply thereby preventing stock-outs and expiry of medicines



- To ensure regular updation of inventory in Nikshay-Aushadhi and timely submission of the drug request/reports of state/district/TU/PHI through Nikshay-Aushadhi
- Timely corrective action to prevent drug expiry through necessary transfers of medicines to other needy nearby State Drug Store (SDS)/District Drug Store (DDS)
- Effective and timely distribution of drugs through a well-defined transportation mechanism
- Distribution of 2nd line drugs should be in the form of monthly boxes only from SDS/DDS to TUs/PHIs, as per RNTCP guidelines and weight bands
- Timely action to redistribute drugs to prevent local shortages

POINTS TO REMEMBER

- Uninterrupted supply of drugs and other materials is critical to the success of TB Control Programme.
- Drug requirements are based on the number of cases, existing stocks, and reserve stocks.
- Maintenance of drug stock should be as per FEFO.
- Reserve stocks are required to account for unexpected increase in TB case load, delays in procurement and distribution of drugs, improper distribution of drugs, and pilferage of drugs or lost due to improper storage.
- Ensure regular physical verification of drugs and other materials at all levels.
- Reserve drug stocks should be available at SDS, DDS, TU and PHI as per RNTCP stocking norms.
- Ensure regular use of Nikshay-Aushadhi at all levels for RNTCP drug management.
- Ensure regular training of field staff on RNTCP drug logistics management and Nikshay -Aushadhi
- AMC of LED-FM, BMs & IRL equipments and regular maintenance of vehicles should be ensured.



5. Nikshay Aushadhi:

To improve the availability of TB drugs in all the healthcare facilities across the country through an interactive software system that enables real time status of drug inventory. Programme in support with C-DAC has customized and developed a Web Based Application-Drug and Vaccine Distribution Management System (DVDMS) for the management of Anti TB Drugs and other commodities under RNTCP. The software has been formally named as "Nikshay Aushadhi".

Nikshay Aushadhi is a web-based application which deals with the management of stock of various Anti TB Drugs and items required by various State-Drug Stores, District Drug Stores, TUs and Sub stores (PHIs) of Nation. Nikshay Aushadhi helps to determine the needs of various sub-stores such that all the required drugs are continuously issued by State Drug Stores to its sub-stores without delay.

5.1 Modules Available in Nikshay Aushadhi:

- Quantification, Forecasting
- Drug Request Management-Routine request/Additional Drug Request
- Issue/Dispatch (GMSDs to SDSs DDSs TUs -PHIs)
- Receipt of drugs from Store (PHI, TU, DDS, SDS, GMSD)/Acknowledge Desk
- Return from Patient to concerned Store for reconstitution
- Stock Management (like Drug Inventory, Physical Stock Verification, Expiry Management etc)
- Packaging/Repackaging (2nd Line drugs Box Preparation)
- Quality Control Management
- Miscellaneous (Reports)

5.2 Advantage of Nikshay Aushadhi:

- Helps Programme Managers in better monitoring & control down the line through especially designed DASH BOARD
- Help in better Planning & Execution at all administrative level
- Efficient control on supply & Inventory
- Quality Control and monitoring of Drugs and consumables
- Online Drug Distribution from centre to last storage point and to Patient
- Integrated with Nikshay for patient diagnose, treatment and follow-up detail
- Accessibility on PC-Tablets and Mobile phone through 'Mobile App'
- Expiry and pilferage of drugs & consumables can be minimized.
- 24 x7 Help & Solution Desk for Users



5.3 Key Features of Nikshay Aushadhi:

- Online Indenting. (from State to CTD, DDS to SDS, TU to DDS on quarterly basis and PHI to DDS on monthly basis) beyond this through an Additional drug request (ADR) as and when an increased consumption expected.
- Online issue of Drugs based on request and availability.
- Provision to maintain expiry date / shelf life for all items.
- Quality Control for Drugs.
- Ability of online tracking of Drug Inventory in all RNTCP Institutions across the State.
- Help in better planning, execution and control on demand and supply.
- Ability to generate customized Reports.
- Various alert generation facility with different colours e.g. for expired items, near to expiry, not of standard quality etc.
- Ability to locate drugs using a Box/TB/ batch number of search criteria in all TB Institutions.
- Inter State / District Drug Transfer with proper control by CTD/State.
- Bar Code/QR code implementation for unique identification and easy, fast & accurate receipt/issue of drugs.

5.4 Drug Logistics for Private Sector / Partners:

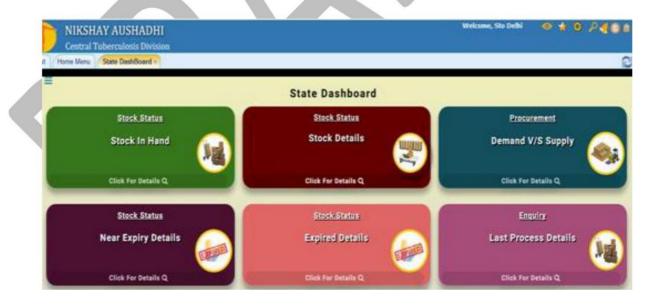
- **5.4.1. For Registered private practitioners/ medical stores/ other partners under Nikshay** If private practitioner/ medical stores/ other partners etc. are registered in Nikshay as PHI, drugs will be issued from their concerned TUs.
- **5.4.2.** For non-registered private practitioners/ medical stores/ other partners under Nikshay- drugs will be issued as 3rd party option and consumption of same should be recorded as 'Misc. consumption' in Nikshay-Aushadhi.



5.5 Output from Nikshay-Aushadhi:

5.5.1 Customised Dashboard for National, State and district level officials -







5.5.2 Stock in Hand Report (1st Line Drugs)

Report Date and Time : 01/02/2019 13:35 Username : Dds Shimla



Government of India | Central Tuberculosis Division
Directorate General of Health Services

Report Name: Stock In Hand Report, As on Date: 01-Feb-2019

S.No.	Drug Name	Item Type	Active Stock Qty.
TB Catego	ry: First Line Drug		
TB Sub Ca	ntegory : Adult_Pediatric		
1	2FDC (P) (H50 & R75) [DSTB-CP(P)]	Blister	160
2	3FDC CP (A) (H75,R150 & E275) [DSTB-CP(A)]	Blister	720
3	3FDC(P) (H50, R75, Z150) [DSTB-IP(P)]	Blister	171
4	4FDC(A) (H75, R150, Z400 & E275) [DSTB-IPA]	Blister	360
TB Sub Ca	ntegory: Loose Drugs		
5	Ethambutol 100mg [PC48]	Tablet	13900
6	Isoniazid 100 [PC7]	Tablet	9000
7	Rifampicin 150 [PC6]	Capsule	900
8	Rifampicin(450) [PC12]	Capsule	1170

5.5.3 Stock in Hand Report (2nd Line Drugs

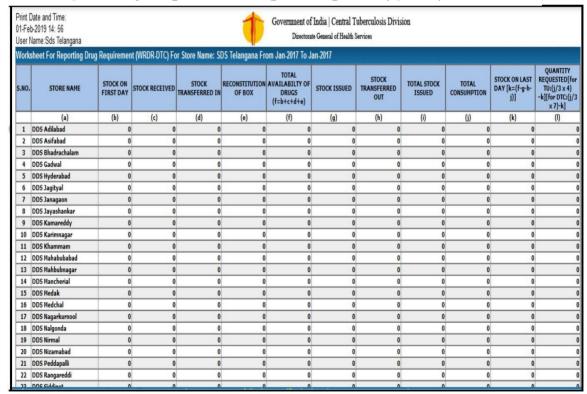
01/02/2	Date and Time : 019 13:40 me : Dds Shimla	G.		dia Central T	uberculosis Divisi Services	on
	t Name: Stock In Hand R					
S.No.	Drug Name	Item Type	Batch No.	Expiry Date	Supplier Name	Active Stock Qty.(in No.)
TB Cat	egory :	•				
TB Sub	Catgeory:					
1	Conventional MDR TB Regimen Type A (30-45 Kg) [RRA2]	Patient Wise Boxes	1860013760	Jul/2019	-	4
TB Cat	egory : Second Line Drug					
TB Sub	Catgeory : Conventional	Mdr Tb Regime	n			
2	Conventional MDR TB Regimen Type A (46 -70Kg) [CRA3]	Patient Wise Boxes	1860013761	Jul/2019	-	4
3	Conventional MDR TB Regimen Type A (46 -70Kg) [CRA3]	Patient Wise Boxes	1860017101	Jul/2019	-	14
4	Conventional MDR TB Regimen Type B (46-70Kg) [RRB3]	Patient Wise Boxes	1860014809	Jul/2019	-	6
TB Sub	Catgeory: Regimen For I	H Mono/Poly Dr	tb			•
5	INH Mono/Poly Regimen:Type A:(30-45 Kg) [2HRA2]	Patient Wise Boxes	1860013764	Jun/2019	-	2
6	INH Mono/Poly Regimen:Type A:(46-70kg) [2HRA3]	Patient Wise Boxes	1860015039	Jun/2019	-	.5
TB Sub	Catgeory: Shorter Mdr T	b Regimen				
7	Shorter MDR TB Regimen:Type A(30 -45 Kg) [2SRA2]	Patient Wise Boxes	1860010931	Jul/2019	-	2
8	Shorter MDR TB Regimen:Type A(46 -70kg) [2SRA3]	Patient Wise Boxes	1860013763	Jul/2019	-	7
9	Shorter MDR TB Regimen:Type B(30-45 Kg) [2SRB2]	Patient Wise Boxes	1860010287	Sep/2019	-	1
10	Shorter MDR TB Regimen:Type B(30-45 Kg) [2SRB2]	Patient Wise Boxes	1860014805	Jul/2019	-	2



5.5.4 Stock in Hand Report (2nd Line Loose Drugs)

Report Date and Time: Government of India | Central Tuberculosis Division 01/02/2019 13:45 Directorate General of Health Services Username : Dds Shimla Report Name: Stock In Hand Report, As on Date: 01-Feb-2019 Item Type **Expiry Date** Supplier Name Active Stock Qty.(in No.) TB Category : Second Line Drug TB Sub Catgeory : Loose_Drugs Clofazimine 100mg [PC40] Tablet CC1726 Nov/2019 | Sangrose Laboratories Ethambutol 400 mg [PC45] Tablet AS8C4311 Apr/2021 Lupin Ltd 1200 3 Ethambutol 800 mg [PC10] Tablet 17007 Aug/2020 Ms Cadila 300 Pharmaceuticals Ltd NEA742A Ethionamide 250 mg Tablet Sep/2021 Macleods Pharma Ltd [PC20] DKN743A Inj Kanamycin 500 [PC17] Vial or Kit Jul/2019 206 6 Isoniazid 300mg [PC11] Tablet VQ642 Nov/2021 2340 Linezolid 600 [PC38] Tablet BL N702A Jun/2020 Macleods Pharma Ltd 130 Sep/2020 Macleods Pharma Ltd 8 Linezolid 600 [PC38] Tablet BI N704A 300 Moxifloxacin 400 [PC39] Tablet BT1702117A Jan/2021 600 10 Pyrazinamide(500) [PC8] Tablet PRRBH0023 Jun/2021 90 Pyrazinamide 750mg [PC23] T180660 May/2021 Micron Pharmaceuticals 180 11 Tablet 12 Pyridoxine 100mg [PC26] Tablet 2BP2C008 Jul/2019 Macleods Pharma Ltd 13 Pyridoxine 100mg [PC26] Tablet 2BP2F004 Apr/2020 Macleods Pharma Ltd 2880 14 Pyridoxine 100mg [PC26] Tablet 2BP2F009 Jun/2020 Macleods Pharma Ltd 1620 15 Pyridoxine 100mg [PC26] Tablet 2BP2F016 Sep/2020 Macleods Pharma Ltd 3300 16 Pyridoxine 100mg [PC26] Tablet EPA6720A Jul/2019 600 Macleods Pharma Ltd Pyridoxine 100mg [PC26] Tablet WBA36009 Oct/2019

5.5.5 Quarterly Report on Drugs & Logistics(QRDL)





ANNEXURE I: APPROXIMATE LABORATORY REQUIREMENT FOR 3000 SLIDES FOR SPUTUM SMEAR MICROSCOPY

Reagents/ Equipment for staining	Quantity
Binocular microscope with 10x, 40x and oil immersion	Atleast 1 per
objective (100x) eyepieces (10x) and spare bulbs and	DMC
fuses	
Plastic disposable sputum containers	3,300
Slides for microscope, 25*75 mm, 1.1 mm-1.3 mm thick	3,300
Broom stick 10 cms length	3,300
Diamond marker pencil	1 number
Timer, 30 or 60 minutes	1 number
Forceps, Chitel forceps stainless steel for slides 15 cm	1 number
Scissors, 25 cm stainless steel	1 number
Slide rack, Staining slide rod of metal or plastic or glass	2 numbers
for 12 slides	
Slide boxes, For 100 slides	33 boxes + 1-2
	per DMC for
	RBRC
Tissue rolls	4 numbers
Grease marking pencil	12 numbers
Absorbent cotton, 500 gms/roll	4 numbers (2
	k.g)
Pressure cooker, For disposal by autoclaving	Optional
5% phenol	600 litres
Methylated spirit	3 liters
Aprons	2
Disposable gloves, 6 and 8 inches (box of 25 pairs)	12 boxes
Spirit lamp,	1 number
Metal wire, For swab for heating of Carbol fuchsin	1 number
Sputum specimen transport box, Insulated box, made of	2 numbers
plastic 10" x 10" x 10", thickness 1" with lid, handle and	
nylon belt 1" width 2.5 feet length, nylon strap of 1"	
width 2 feet length with Velcro to strap the lid of the box	



For preparation of reagents at DTC/TU

For preparation of reagents at DTC/TU	10 111
Reagents/ Equipment for staining	Quantity
Basic fuchsin, Pararosaniline hydrochloride, C ₁₉ H ₁₈ N ₃ Cl, molecular wt:	300 Gms
323.8, Colour: Metallic green, Dye content: Should be available on the container. Approximately 85%-88%	
Carbolic acid (Phenol), C ₆ H ₅ OH, and molecular wt: 94.11, Melting point: 40 ₀ C, Solidification point: 40.5 ₀ C, Purity: 99.5%	2 ltrs
Sulphuric acid: H ₂ SO ₄ , molecular wt: 98.08, Purity: 95-97%, Colour: Clear	10 ltrs
Methylene blue, (Methylthionine chloride), C ₁₆ H ₁₈ CIN ₃ S, molecular Wt: 319.9 Dye content: Should be available on the container. Approximately 82%	32 Gms
Alcohol (absolute)	3.2 ltrs
Funnel, 7" dia 7" height and 5" stem height	4 nos.
Funnel, 3" dia 4" height and 5" stem height	4 nos.
Drop bottles, Glass/ plastic 100 ml capacity	8 nos.
Bottles for storage of stock solutions, Brown bottles 2 litre capacity	4 nos.
Flat bottom round flask, Capacity 3 litres of pyrex of glass	5 nos.
Wash bottle, Plastic 500 ml	6 nos.
Drop plastic bottle for immersion oil, 10 ml capacity	2 nos.
Disposable bucket, Plastic foot operated 12 liters	2 nos.
Measuring cylinder, 1000 ml capacity plastic or glass	4 nos.
Measuring cylinder, 100 ml capacity plastic or glass	4 nos.
Water tanks, Plastic with tap, 100 liters where there is no running water facility.	1 no
Filter paper, Whatman no. 1 packs of 100 2" * 2"	1 box
Adhesive labels for sputum containers	6 rools
Soap, soap box towel and clean rags as needed	As requirem ent
Aluminum vessel, for the purpose of carbol fuchsin solution preparation 16" diameter 9" height	1 no.
Water bath, for the preparation of carbol fuchsin	1
Beaker, 250 ml with spout	1 no.
Display board	1 no.
Distilled water (instead of distillation apparatus)	35 liters
Stove wick type/ Bunsen burner with butane gas cylinder/ burner with gas cylinder	1



Laboratory reports and records

Laboratory form for sputum examination	2200		
Tuberculosis laboratory register	2		

ANNEXURE II: NUMBER OF TUBERCULOSIS FORMS AND REGISTERS NEEDED IN THE RNTCP

Names of tuberculosis forms and	Number needed registers						
Tuberculosis Treatment Card	2 per patient						
Tuberculosis Identity Card	1 per patient						
Tuberculosis Notification Register	1 each for a PHI per year						
Tuberculosis Laboratory Register	oratory Register 1 per year per microscopy Centre						
RNTCP request form for	15 per new pulmonary smear- positive						
examination of biological	case						
specimen for TB							
Mycobacteriology Culture /	Number determined by State						
Sensitivity Test Form	tuberculosis Officer						
Quarterly Report on Programme Management and Logistics	PHI: (3 copies x 12 months) x No. PHIs in district Sub-districts: (2 copies x 4 quarters) x No. TUs in District District: (4 copies x 4 quarters) copies						
Tuberculosis Transfer Form	Based on proportion of patients who were transferred out of the district during the preceding year. Estimate 1 for 20 patients.						
Supervisory register	As per No. of PHIs						
"Referral for treatment" forms	As per requirement						
Referral for treatment register	1 each for Medical College, big Hospital, etc						



ANNEXURE-III

SOLUTION TO STOCK REGISTER EXERCISE:

STOCK REGISTER (SR)

Drug Item: DSTB-IP(A) Unit of Measurement (UOM): Strip of 28 Tabs

Folio No.:

SL. NO.	Particulars Of Receipts & Issues							Receipt (Qty.)	Balance (Qty.)	Date-Wise Expiry Details Of Balance (Qty.)				Signature of Store- Keeper	Remarks	
	Date (Dd/ mm/ yy) of Transaction (Receipt/ Issue)	Name of Party (GMSD/ SDS/ DTC/TU)	Receipt Voucher No. (For Receipts only)	Issue Voucher No.(For Issues only)	Date of Issue Voucher	Batch No.	Date of Expiry				Expiry Date (Aug-20)	Expiry Date (Oct-20)	Expiry Date (Nov-20)	Expiry Date (Dec-20)		
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(i)	(k)	(1)	(m)	(n)	(0)	(p)	(q)
1	1.04.18	Op Balance	a a	-	-	XY	Aug-20	0	0	1000	1000	0	0	0		
2	10.04.18	GMSD Karnal	IV-35		1.04.18	AB	Oct-20	6000	0	7000	10	600	0	0		\vdash
3	15.04.18	GMSD Mumbai	IV-14		8.04.18	CD	Nov-20	5000	0	12000	10	6000	50	0		
4	17.04.18	DTC-A		SIV - 1	17.04.18	XY	Aug-20	0	1000	11000	0	6000	50	0		
	17.04.18	DTC -A		SIV - 1	17.04.18	AB	Oct-20	0	2000	9000	0	4000	50	0		
5	25.04.18	SDS – Delhi	DTA- 68		12.04.18	EF	Dec-20	1000	0	10000	0	4000	5000	1000		
6	26.04.18	DTC-B		SIV – 2	26.04.18	AB	Oct-20	0	4000	6000	0	0	5000	1000		
7	29.04.18	DTC - C		SIV - 3	29.04.18	CD	Nov-20	0	4000	2000	0	0	1000	1000		