Standard Operating Procedure Manual

Procurement & Supply Chain Management

Index

Overview of Programme and Structure

The Revised National TB Control Programme (RNTCP) was launched in 1997 and expanded across the country in a phased manner with full nation-wide coverage achieved in March 2006. In terms of treatment of patients, RNTCP has been recognized as the largest and the fastest expanding TB control programme in the world. RNTCP is presently being implemented throughout the country.

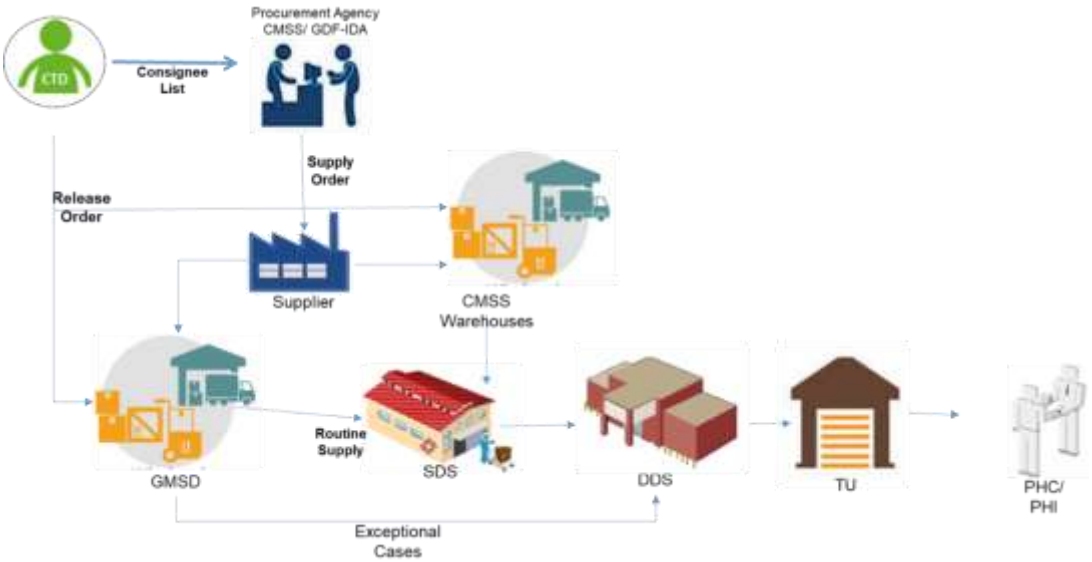
The programme, since then, has achieved various global benchmarks like successful implementation of Daily Regimen Therapy across the country for drug sensitive patients in the Year 2017 and adoption of WHO recommended guidelines for treatment of drug resistance patients.

SUPPLY CHAIN MANAGEMENT

This section of the manual suggests procedures for on-going tracking, replenishment and flow of the inventory of 1st and 2nd line anti-TB drugs including pediatric drug 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).

To improve the supply chain management 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 division in support with C-DAC has customized and developed a Web Based Application for the supply chain management of Anti TB Drugs and other commodities under RNTCP. The software has been formally named as "Nikshay Aushadhi.

Supply Chain Management under RNTCP is described in the below given chart:



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

Overview (Treatment Regimen)

Drugs for TB treatment

In India RNTCP provides quality drugs to all the diagnosed TB patients through DOTS 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 weight-bands. For drug resistant TB patients, drugs are provided in monthly boxes depending upon their weight-band and resistant pattern (Mono-resistant, poly-drug resistant, Multi Drug Resistant, Extensive Drug Resistant).

Further, Cap Rifabutin-150mg also procured centrally for co-infected TB HIV patients on 2nd line ART regimen. Tab Isoniazid/Rifampicin and Tab Pyridoxine procured by the program for Isoniazid Preventive Therapy (IPT) and for the treatment of latent TB infection.

First line Anti TB drugs

The essential first line drugs used in the Revised National TB Control Programme are: Rifampicin, Isoniazid, Ethambutol and Pyrazinamide.

Medicines for Daily Regimen are being supplied in Monthly strips of 28 Tabs, each tablet consisting of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol in fixed dose combination (HRZE–Fixed Dose Combination). The treatment in Intensive Phase (IP) will consist of 2 months of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol in daily dosage as per five weight bands and categories. There will be no extension of IP. Only pyrazinamide will be stopped in the continuation phase (CP) while the other three dugs will be continued for another 4 months as daily dosage. The CP may be extended based on clinical decision of the treating physician. Loose drugs would be added as substitutions in case of adverse drug reaction or with co-morbid conditions.

Drugs for Adult Patients –

DSTB –IP (Adult) – 4 FDC (2 Months)	DSTB –CP (Adult) – 3 FDC (4 Months)
Isoniazid IP 75mg	Isoniazid IP 75 mg
Rifampicin IP 150 mg	Rifampicin IP 150 mg
Pyrazinamide IP 400 mg	Ethambutol Hydrochloride IP 275 mg
Ethambutol Hydrochloride IP 275 mg	

Drug Dosage for Adult Patients–

Weight Category	Number of Strips (FDCs)	
	Intensive Phase (4 FDC) Strip of 28 Tabs	**Continuation Phase (3 FDC) Strip of 28 Tabs**
25-34 Kg	4	8
35-49 Kg	6	12
50-64 Kg	8	16
65-75 Kg	10	20

More than 75 Kg	12	24

Drugs for Pediatric Patients –

DSTB –IP (Pediatric) – 3 FDC (2 months)	DSTB –CP(Pediatric) – 2 FDC (4months)
Isoniazid IP 50mg	Isoniazid IP 50 mg
Rifampicin IP 75 mg	Rifampicin IP 75 mg
Pyrazinamide IP 150 mg	Ethambutol Hydrochloride IP 100 mg
Ethambutol Hydrochloride IP 100 mg	

Drug Dosage for Pediatric Patients–

Weight Category	Number of Strips (Dispersible FDCs)	
	Intensive Phase	**Continuation Phase**
	3 FDC (HRZ) + E **Strip of 28 Tabs**	2 FDC (HR) + E **Strip of 28 Tabs**
4-7 Kg	2	4
8-11 Kg	4	8
12-15 Kg	6	12
16-24 Kg	8	16
25-29 Kg	6 + 2A	12 + 4A
30-39 Kg	4 + 4A	8 + 82A

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

2nd Line Anti TB Drugs

In RNTCP, 2nd line drugs are issued in monthly patient wise boxes (Type-A , Type-B & Type C) for different weight bands. Loose anti TB drugs are also used in the programme for adverse reaction, modification of boxes etc.

The composition of Shorter Regimen, all oral longer MDR TB regimen and all oral H mono/poly DR TB regimen is given below –

Regimen class	Intensive/First phase	Continuation/Second phase
H mono/poly DR TB (R resistance not detected and H resistance)		
All oral H mono-poly DR TB regimen	(6) Lfx R E Z	

MDR / RR TB		
Shorter MDR TB regimen	(4-6) Mfxh Km* Eto Cfz Z Hh E X	(5) Mfxh Cfz Z E
All oral longer MDR TB regimen containing BDQ	(18-20) Bdq(6) Lfx Lzd# Cfz Cs X	
All oral longer MDR TB regimen containing DLM	(18-20) DLM(6) Lfx Lzd# Cfz Cs X	

**If the intensive phase is prolonged, the injectable agent is only given three times a week in the extended intensive phase.*

 # Reduce Lzd to 300 mg/day after 6 to 8 months.

In addition to the above, the conventional MDR/XDR-TB regimen already initiated, would continue to be supplied, till the State/ District fully transitions to the above regimen. All New cases after implementation of 2019 guidelines would only be placed on the regimen given in the above table.

Procurement

Procurement of Drugs and Commodities: -

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/UTs.

Currently all procurement of First line drugs under the domestic budget (DBS), the World Bank and funded by TGF (The Global Fund) 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 WHO 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.

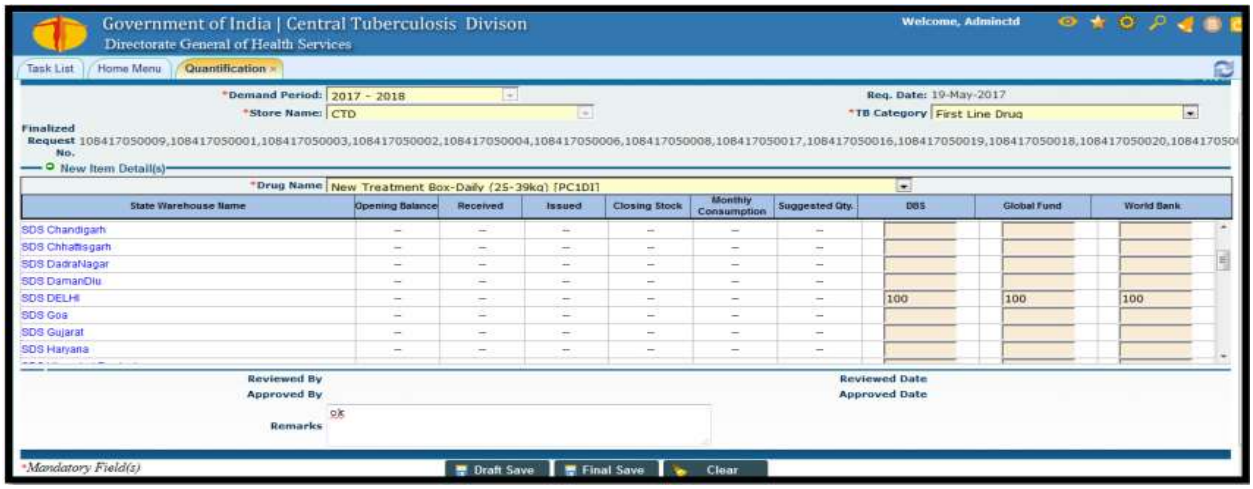
In addition to Anti TB drugs, Binocular Microscopes, LED-Florescence Microscope, CBNAAT/TruNAT Machines, Cartridges, LPA, Solid and Liquid Culture laboratory equipment's & consumables, PDA/Tablet Computers and services are also procured at Central level. In case of emergency only, few Anti TB drugs are procured locally at State / district level after approval from Central TB Division following RNTCP guidelines. In addition to drugs, Laboratory consumables and equipment's, 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).

Further, in case of any procurement delays or failures at Central level, MoHFW has advised states vide D.O. no. T-18018/04/2018-Part(2) dated 23rd May 2019 to establish rate contracts of all drugs and diagnostics items under RNTCP, except for the CBNAAT / TruNAT machines and cartridges \ chips to the extent of 25% of the annual requirements at the start of each financial year. States are also advised to monitor and regularly review stock position to avoid any shortages and hampering of patient care.

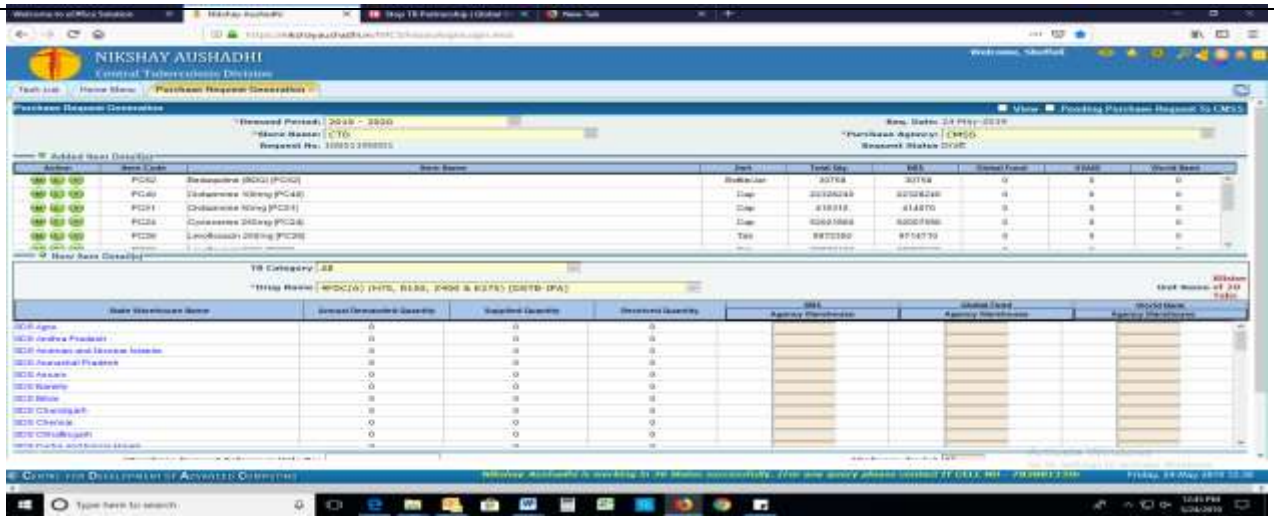
Quantification and Bidding Procedures:-

Procurement of Drugs and commodities for pan India based on their requirement, available resources is a challenging task. Quantification process is undertaken on an annual basis at central level, with consideration to numerous parameters (drug availability, requirement, patient enrolment plan, regimen & its implementation, lab scale up plans and their socio-economic factors). The estimation is further analyzed to arrive at final outcome i.e. requirement of drugs, considering stock availability at CMSS/GMSD /State level and also cater the stocks which are in pipeline or under procurement process

The quantification tool is available on Nikshay Aushadhi portal, which can only be accessed by Central TB Division. An example of the quantification tool on Nikshay Aushadhi is illustrated below:-



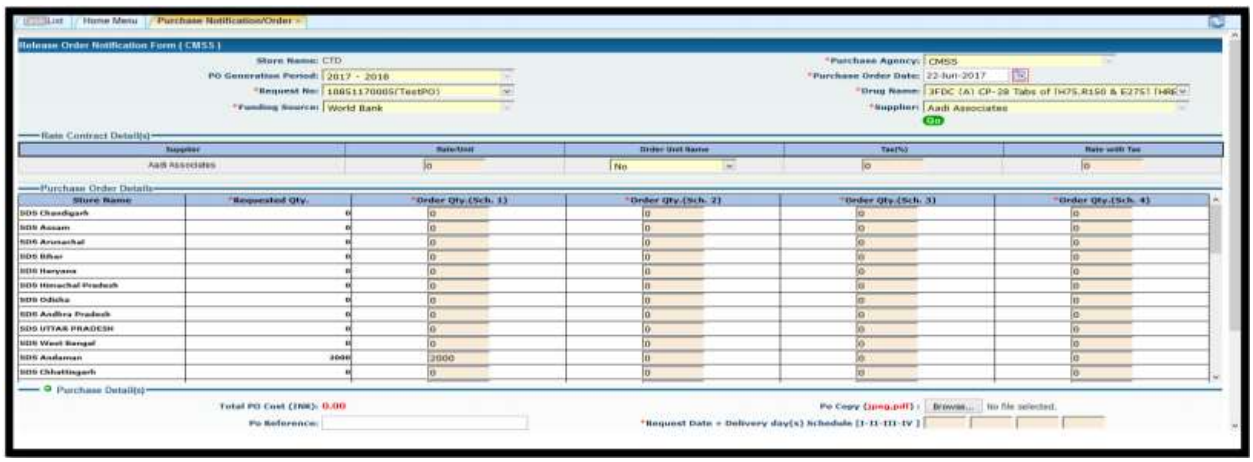
On the receipt of approval from competent Authority, Programme raises indent for the procurement of computed quantity of drugs to CMSS/GDF as the case may be. Indent Submission through Nikshay Aushadhi.



Thereafter, CMSS/GDF commences the bidding process either through National Competitive Bidding or International Competitive Bidding (ICB). CMSS undertakes procurement following General Financial Rules issued by Government of India, Ministry of Finance. GDF undertakes the procurement as per international procurement protocols

Steps to be undertaken by Procurement Agency selected by MoHFW

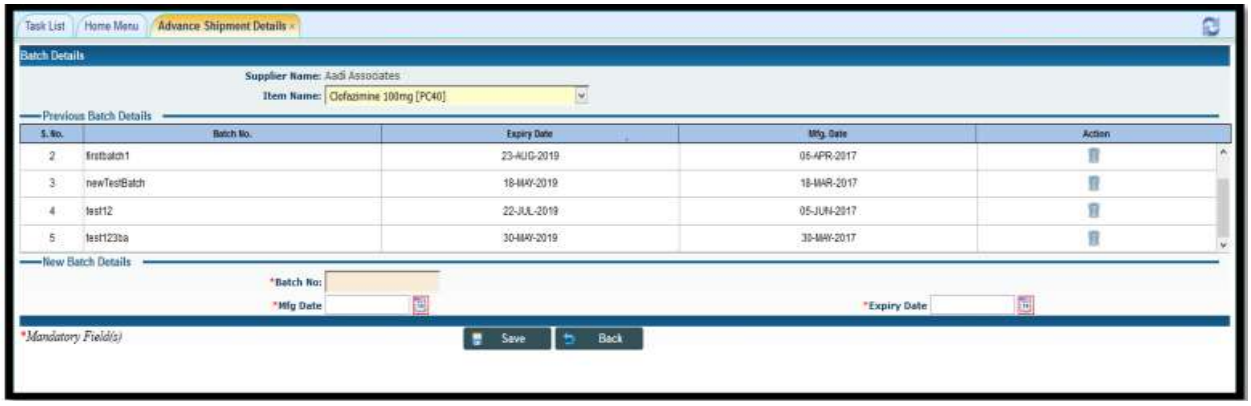
After the final approval from the competent authority, Procurement Agency issue Purchase Order to the qualified supplier and uploads the copy on Nikshay Aushadhi Portal.-



Supplier's Interface on Nikshay Aushadhi:-

Procurement Agency will issue Purchase Order to the qualified bidder for the supply of Anti TB drugs and commodities as per the schedule of requirement provided by the Central TB Division. Afterwards, bidder acknowledges the Purchase order and subsequently starts production of quoted product to meet the requirement. Supplier will upload batch wise details for drugs and

commodities in Nikshay Aushadhi as they start dispatching the consignments to designated CMSS Warehouses/GMSDs. The process is illustrated below:-



Once the consignment received with requisite documents (Invoice, Quality Reports, Packaging List, Challan etc.), the consignee will acknowledge the drugs in Nikshay Aushadhi and will be ready with to release these drugs to states.

Accordingly, after completion of procurement process, consignments are supplied at procurement agents designated warehouses or government depots.

For the procurement commenced by GDF, Consignments are supplied to GMSD Store (Government Medical Store Depot) located at 6 states to cater distribution of drugs to nearer States. Similarly, after completion of procurement process by CMSS, consignments are stored at their designated CMSS Warehouses located at 20 different states.

Local Procurement

Procurement of Anti TB Drugs is a centralized activity undertaken by the Central TB Division. Though, sometimes there are circumstances, States permitted to procure drugs locally at their level.

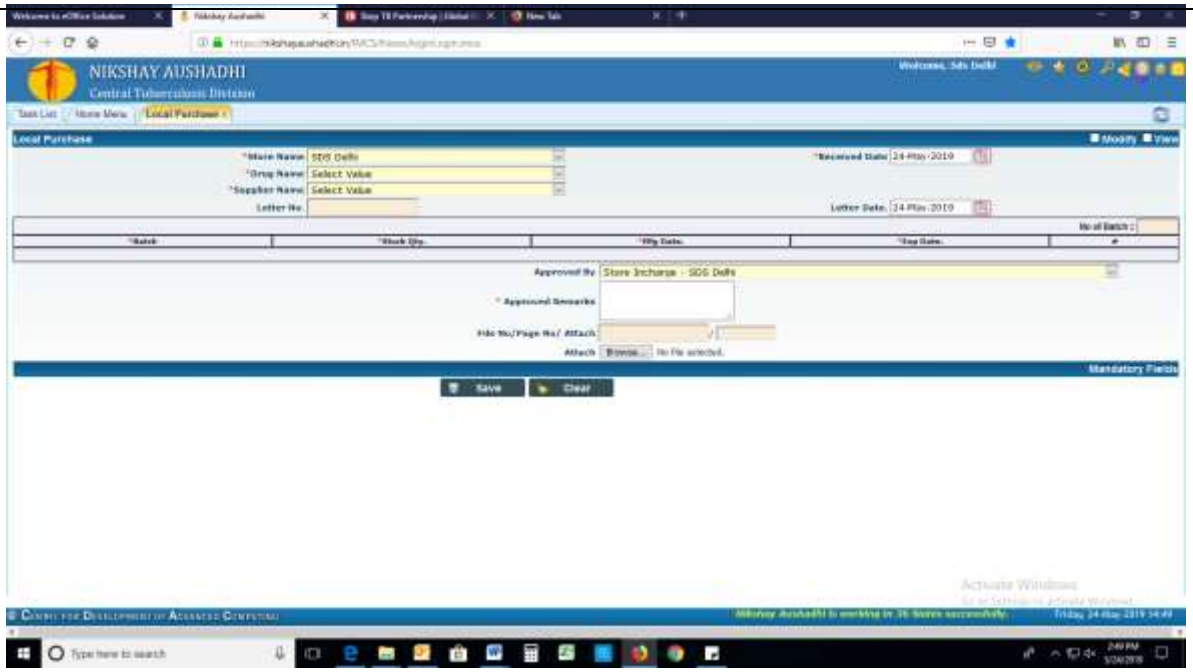
In such exceptional cases, States are allowed to procure drugs based on their requirement for the period specified by the programme division following General Financial Rule (GFR) and State Procurement Guidelines.

Drugs procured through local procurement need to be updated in the Nikshay Aushadhi using 'Local Procurement Process'. The Steps are appended below: -

PATH

Services → Stock Management → Local Purchase

Window shall be opened and requisite information to be filled; batch no. Quantity, manufacturing date and expiry date.



Local procurement order can also be uploaded for future reference

Click on save Button.

Voucher is generated

Inventory Management

Inventory management (IM) practices described in this section are developed for SDS, DDS and subordinate stocking points. The options for management of Inventory given in Nikshay-Aushadhi are also described in this section.

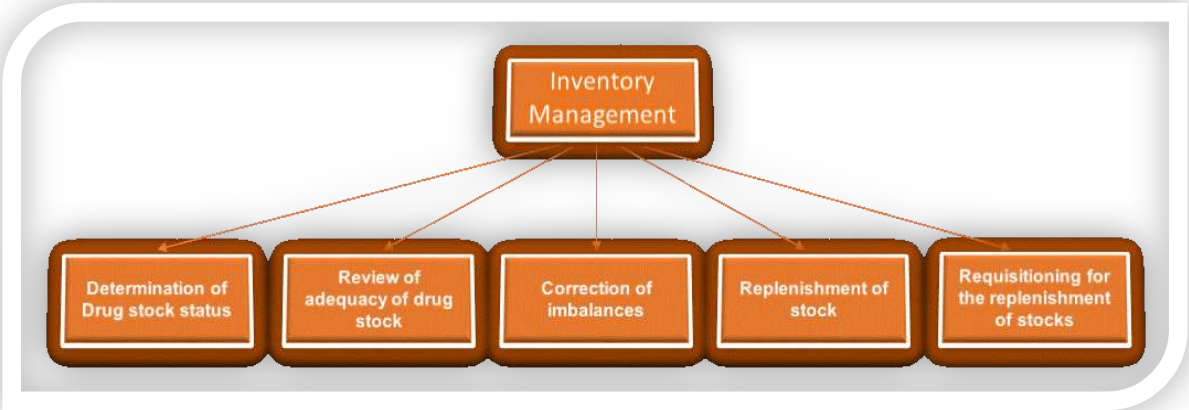
OVERVIEW

IM refers to the activities to be carried out by the officer in-charge of the logistics function at the all levels 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 sub-stores to recommended levels
5. Requisitioning for the replenishment of SDS and DTCs/ subordinate stocks.

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

Fig - Inventory Management



DETERMINATION OF DRUG STOCK STATUS

The Quarterly/ Monthly drug stock report/request on is to be submitted by all drug-stocking points and comprises the most important report for the purposes of Inventory Management.

The request of the stocking units is to be submitted as per the scheduled mentioned below:

Table No. 1

Drug Request/Report of Stocking unit	Date for submission of Quarterly/Monthly Drug Request/Report
PHI to TU	By 07th of the subsequent month
TU to DTC	By 10th of the subsequent quarter
DTC to SDS / STO	By 12th of the subsequent quarter
STO to CTD	By 15th of the subsequent quarter

The challenge shall be to ensure that the report provide correct information on drug stock status, corresponding with stocks available in the concerned store. This shall require training/re-fresher trainings of storekeepers/ pharmacists on 'Nikshay Aushadhi' across the states.

The report/requisition shall be approved by the designated officer on Nikshay Aushadhi using his/her own login ID/pwd credentials. The designated officer shall confirm the following:

1. All receipt, issues & all other entries should be entered in Nikshay Aushadhi before report is submitted.

2. The report/request should be submitted only after performing the Physical Verification activity by the concerned store keeper/Pharmacist and ensuring the correct stock balances in the report.

STOCKING NORMS

A key deliverable for RNTCP is to ensure uninterrupted supply of drugs, and to ensure the same stocking norms have been developed by CTD, with a view to meet this end-objective. It is currently planned that drug stocks equivalent to 10 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 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 receipt of quarterly/monthly requisition through Nikshay Aushadhi.

PHIs are consumption points and should maintain adequate quantities of drugs for the ongoing administration 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 buffer at each PHI. Stocks at PHIs and TUs shall be closely monitored, to ensure drug adequacy. Stocking norms may be depicted as follows:

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 month	**(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)**

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

ADEQUACY OF DRUG STOCKS

Adequacy of Drug Stocks with DTCs is to be reviewed on a quarterly/monthly basis by the officer designated for Supply chain management at the STO's Office.

This shall be done by comparing drug stocks reported in the DTC's quarterly report/requisition, with the stocking norm suggested by CTD, for the same.Based on the above, the designated logistics officer should highlight all DTCs that are significantly under/ over stocked.

DTCs with severe drug shortages, which shall not be able to continue treatment of patients, without interim replenishment before the end of the quarter, shall obviously need to be attended to right away. Needs as above are typically addressed through the Additional Drug Request or Drug Transfer Advice mechanism through Nikshay-Aushadhi. Similarly, Districts and subordinate stores need to review their stocks on monthly/quarterly basis.

The option of Additional Drug Request in Nikshay Aushadhi is given below:

Home Menu>Services>Drug Request Management>Quarterly/Monthly/ADR Request

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 /DTO. 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/TU/PHI STOCKS

Inventories of DTCs are routinely replenished on a quarterly basis, pursuant to the review and validation of the Quarterly Report/requisition 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 Quarterly report/requisition submitted for the purpose is based on the regular updation of data into Nikshay Aushadhi software.

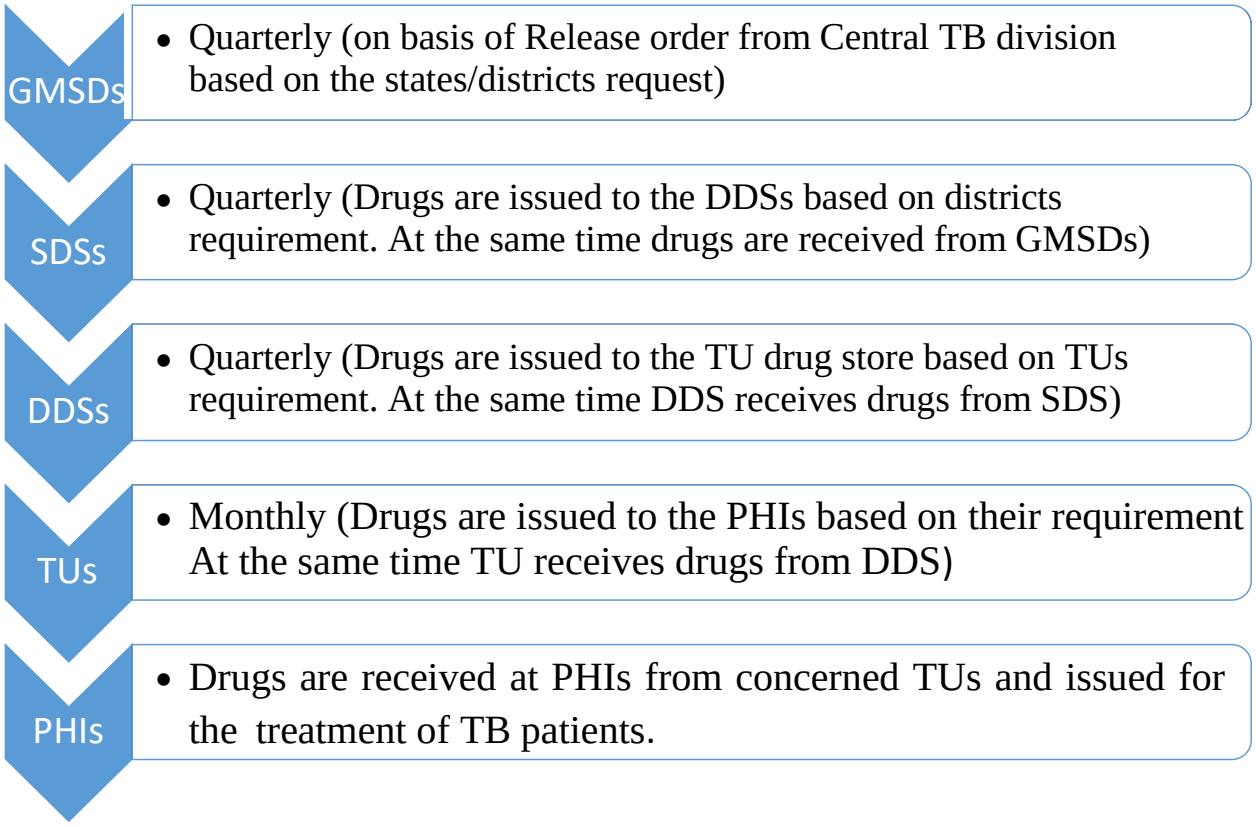
REPLENISHMENT OF SDS STOCKS

The state shall submit their requisition to CTD for the replenishment of SDS(s) stocks.

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

The above requisition is carefully validated and reviewed by CTD, culminating in the preparation of CTD-RO through Nikshay Aushadhi, for the replenishment of SDS(s) stocks for the next quarter. The detailed procedure of issue of drugs to the SDSs/DDSs is given in the 'Receipt/Issue of drugs' chapter.

Flow of Drugs



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

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

Thus, 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). Thereafter, every month, as per the monthly PHI report, Drugs are supplied with stock from the TU which helps to maintain the reserve stock for a month 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, it needs to have a reserve stock of two months at the beginning of the quarter. This will ensure a continuous supply of drugs.

To ensure sufficient stock of all drugs, as per stocking norms, at PHI / TU, DTC needs to have a reserve stock of three months at the beginning of the quarter.

Once the reports/requisitions are received by SDS from DTCs through Nikshay Aushadhi, it takes around 10 days for SDS to process the requirement (from all districts). The State Drug Stores should have at least a reserve stock of 3 months of consumption of the state at the beginning of the quarter.

The regular process of supply of fresh stock of drugs from the GMSD/CMSS warehouses to the SDSs begins only when the states submit their quarterly reports/requisition to CTD through Nikshay Aushadhi. The replenishment of drugs from CTD to SDSs through Release Orders takes around 15-20 days.

5. Reporting and Monitoring

(a) Reporting: -

The regular process of supply of new stock of drugs to the districts / SDS begins only when the districts submit their requirement. The request of the stocking units is to be submitted as per the schedule mentioned at Table No. 1 on page 14.

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 at the earliest possible time. Respective states are also expected to make arrangements for transportation of drugs from SDS to District Tuberculosis Centers (DTCs) and onwards.

The state requests are analyzed 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 number of drugs at various levels is described in the stocking norms table.

Reports from Nikshay-Aushadhi on drug management:

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 Category : First Line Drug			
TB Sub Category : 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 Category : 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

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****End of Report****

Stock in Hand Report (2nd Line Drugs boxes)

Report Date and Time :
01/02/2019 13:40
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	Batch No.	Expiry Date	Supplier Name	Active Stock Qty.(in No.)
TB Category : --						
TB Sub Catgeory : --						
1	Conventional MDR TB Regimen Type A (30-45 Kg) [RRA2]	Patient Wise Boxes	1860013760	Jul/2019	-	4
TB Category : Second Line Drug						
TB Sub Catgeory : Conventional Mdr Tb Regimen						
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 H Mono/Poly Drtb						
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 Tb 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

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****End of Report****

Stock in Hand Report (2nd Line Loose Drugs)

Report Date and Time :
01/02/2019 13:45
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	Batch No.	Expiry Date	Supplier Name	Active Stock Qty.(in No.)
TB Category : Second Line Drug						
TB Sub Catgeory : Loose_Drugs						
1	Clofazimine 100mg [PC40]	Tablet	CC1726	Nov/2019	Sangrose Laboratories	310
2	Ethambutol 400 mg [PC45]	Tablet	AS8C4311	Apr/2021	Lupin Ltd	1200
3	Ethambutol 800 mg [PC10]	Tablet	17007	Aug/2020	Ms Cadila Pharmaceuticals Ltd	300
4	Ethionamide 250 mg [PC20]	Tablet	NEA742A	Sep/2021	Macleods Pharma Ltd	80
5	Inj Kanamycin 500 [PC17]	Vial or Kit	DKN743A	Jul/2019	-	206
6	Isoniazid 300mg [PC11]	Tablet	VQ642	Nov/2021	-	2340
7	Linezolid 600 [PC38]	Tablet	BLN702A	Jun/2020	Macleods Pharma Ltd	130
8	Linezolid 600 [PC38]	Tablet	BLN704A	Sep/2020	Macleods Pharma Ltd	300
9	Moxifloxacin 400 [PC39]	Tablet	BT1702117A	Jan/2021	-	600
10	Pyrazinamide(500) [PC8]	Tablet	PRBBH0023	Jun/2021	-	90
11	Pyrazinamide 750mg [PC23]	Tablet	T180660	May/2021	Micron Pharmaceuticals	180
12	Pyridoxine 100mg [PC26]	Tablet	2BP2C008	Jul/2019	Macleods Pharma Ltd	1800
13	Pyridoxine 100mg [PC26]	Tablet	2BP2E004	Apr/2020	Macleods Pharma Ltd	2880
14	Pyridoxine 100mg [PC26]	Tablet	2BP2E009	Jun/2020	Macleods Pharma Ltd	1620
15	Pyridoxine 100mg [PC26]	Tablet	2BP2E016	Sep/2020	Macleods Pharma Ltd	3300
16	Pyridoxine 100mg [PC26]	Tablet	EPA6720A	Jul/2019	-	600
17	Pyridoxine 100mg [PC26]	Tablet	WBA36009	Oct/2019	Macleods Pharma Ltd	390

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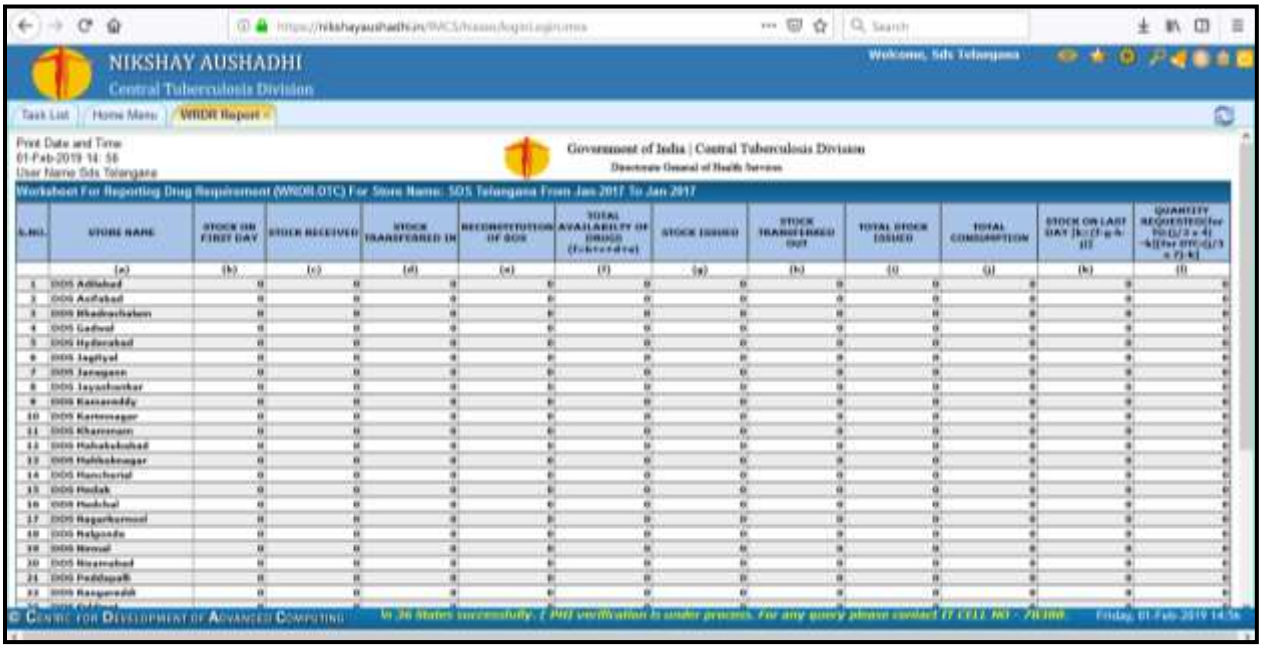
****End of Report****

PREPARATION OF QRDL REPORT -



5 (B) 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.

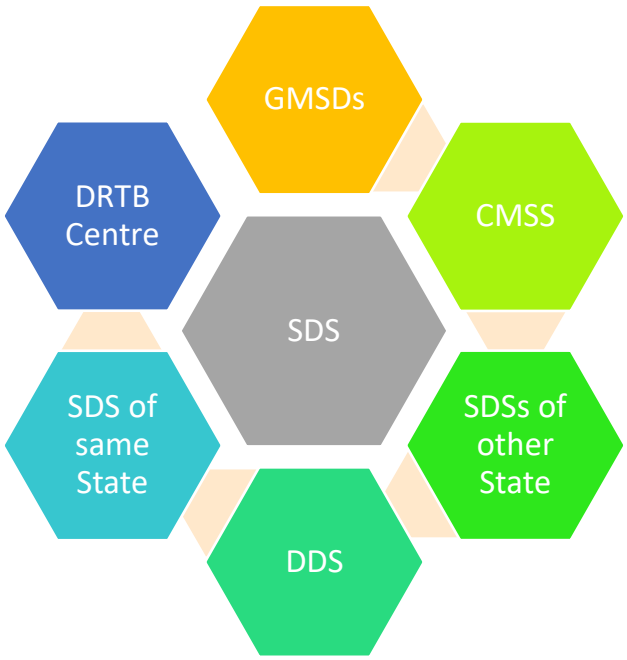
RECEIPT AND DISPATCH OF DRUGS

(A) RECEIPT OF DRUGS

This section deals with procedures to be followed for the receipt of drugs at the Drug Stores .

Outline

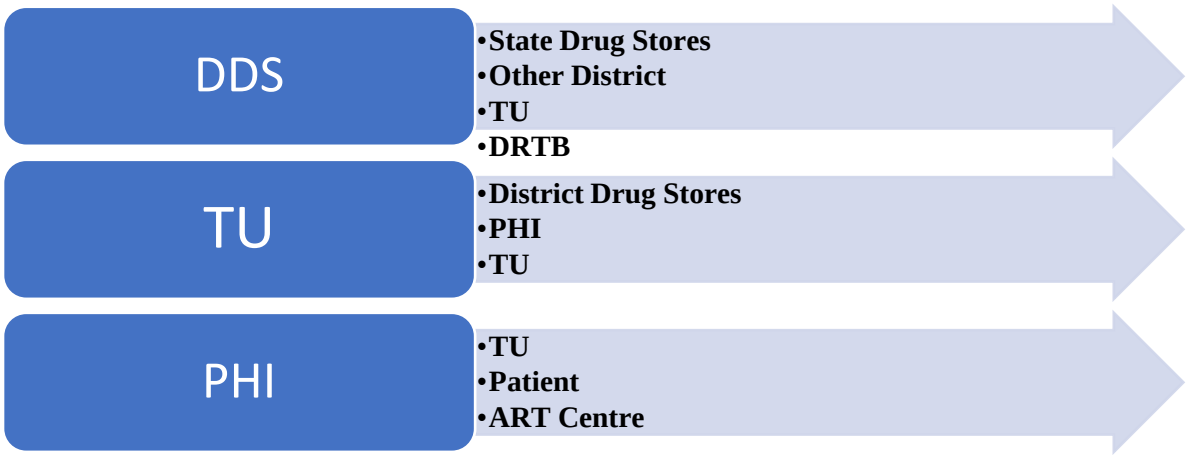
SDS' may receive drugs from multiple sources including:



- GMSDs & CMSS shall be the primary stocking point for receipt of anti-TB drugs from the suppliers and distribution to SDSs across the Country
- Transfers from SDSs of another State is based on the instructions issued by the CTD to correct stock imbalances or risk of expiry observed in the state
- Transfer from DDS/ DRTB / other SDSs (in the same state) are a direct consequence of instructions issued by the STO to correct stock imbalances observed within the state
- Return from DDS / N-DRTB In case of default / death/ treatment stopped patients

- GMSD- Government Medical Store Depot
- DDS – District Drug Store
- SDS – State Drug Stores
- CMSS - Central Medical Services Society
- DRTB Centre – Drug Resistant Tuberculosis Centre

Likewise, DDS, TUS & PHI to receive drugs from parent stores and in under few circumstances, return from sub –stores:-



Procedures to be followed by Pharmacist on receipt of drugs from the GMSD(s) /CMSS(s) /Drug Stores); have been recommended below:-

Availability of Authorisation Document

Ensure copy of Authorised document issued by the Central TB Division, is received before or along with the consignment. The RO serves as an authorization document, enabling the SDS to receive the consignment of drugs from GMSDs and CMSSs. and Drug Transfer Advice (DTA) in case of SDS of other State, enabling the SDS to receive the consignment of drugs.

Transmission Documents to be checked

Ensure that a complete set of transmission documents (including the Issue Voucher, 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

Visual Inspection*

Check the contents of the incoming consignment to ensure conformity with RO / DTA and specifications as per the transmission documents.

Shortages / Damages*

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

Acknowlegment

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

Recording & Reporting*

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

Note:

**Visual Inspection :-*

i. *The check shall be limited to visual inspection and count of the number of cartons received and matching the same with the Issue Voucher and Challan. The Storekeeper will not ordinarily open sealed cartons unless the seal and/or exterior suggest damage or shortage or there have been frequent shortages observed in the recent past.*

ii. *In case, where the GMSD/CMSS has opted to make part shipments, the Storekeeper shall record details of drugs received and the balance quantity pending supply. The Storekeeper shall follow-up closely with the supplier.*

**Shortages and/ or transit damages*

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

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

**Recording and Reporting*

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 & NA and highlight the same.*

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

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

Intra-State Transfer/ Returns of Drugs from districts / DRTB Centres / NDRTB Centre

- The STO may authorize returns/ transfers from DTCs or multiple SDSs within the state or DRTB Centres, to adjust stock imbalances and/or ensure the timely utilization of close to expiry drugs.

- In such cases, a formal DTA should be generated by the STO for the purpose and e-mailed/ faxed to the transferor/ sending unit and the transferee/ recipient unit.

- The Storekeeper of the transferor/ sending unit shall generate a SIV/DIV and arrange for the dispatch of drugs as requested.

- The Storekeeper of the recipient unit shall follow the steps detailed at previous pages on the receipt of drugs / transferred from other SDSs or DTCs within the state, with the exception that the authorization document in this case shall be the DTA.

- Acknowledgement of drugs received should be made by signing the SIV or DIV, as the case may be. Acknowledged copies of the SIV/ DIV should be sent to the STO, as well as the transferring SDS/ DTC.

Recording in NIKSHAY AUSHADHI

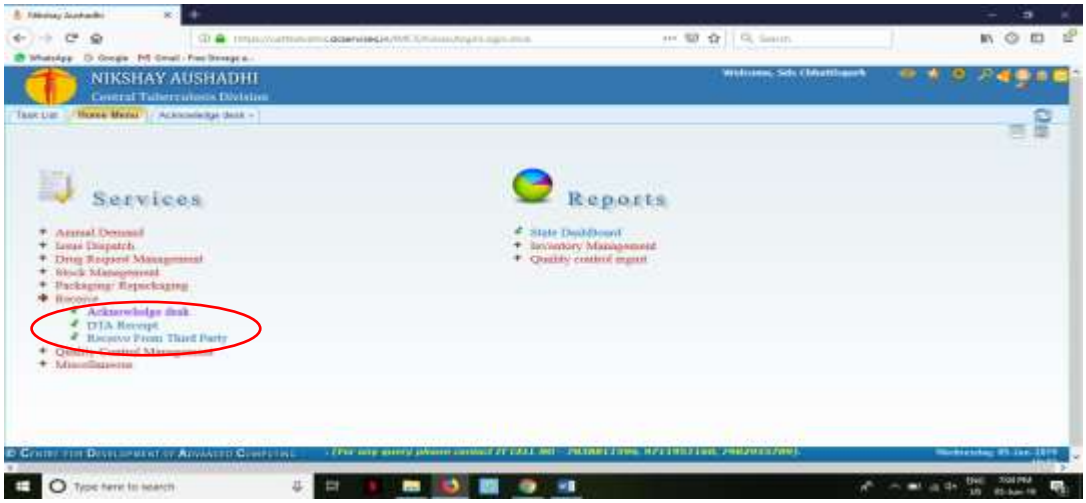
The pharmacist shall follow the following steps to record the drugs received from GMSDs and CMSSs :-

- Login in Nikshay Aushadhi :

  https://www.nikshayaushadhi.in/IMCS/hissso/loginLogin.imcs

- The storekeeper to follow following path

Home Menu→ Services→ Receive



- Three menu will pop-up

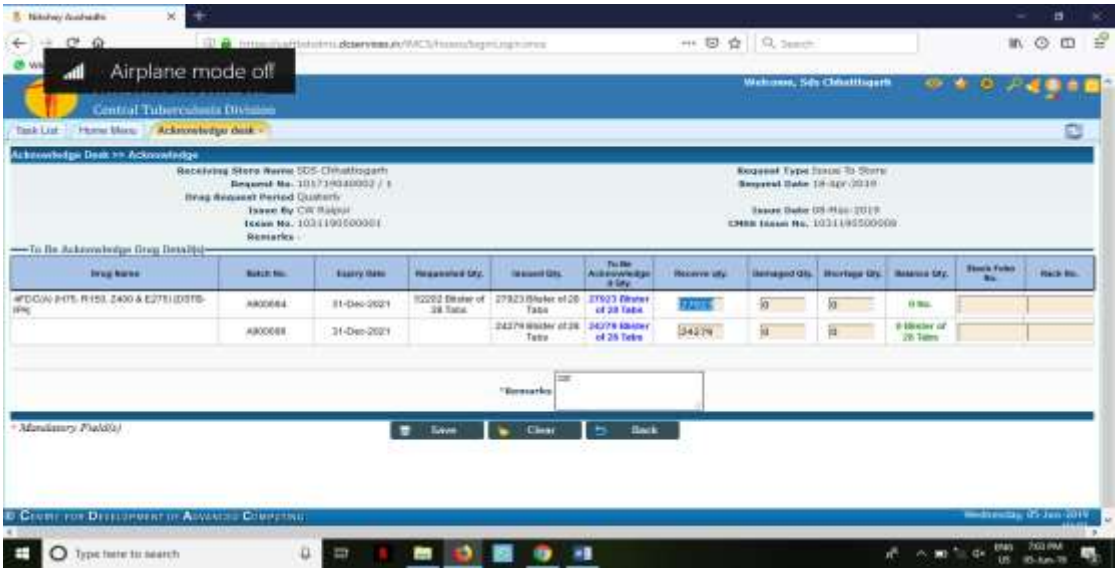
  I. Acknowledge Desk - For acknowledgment of drugs received against CTD-RO/ Issue Voucher

  II. DTA Receipt - For acknowledgment of drugs received against CTD-DTA

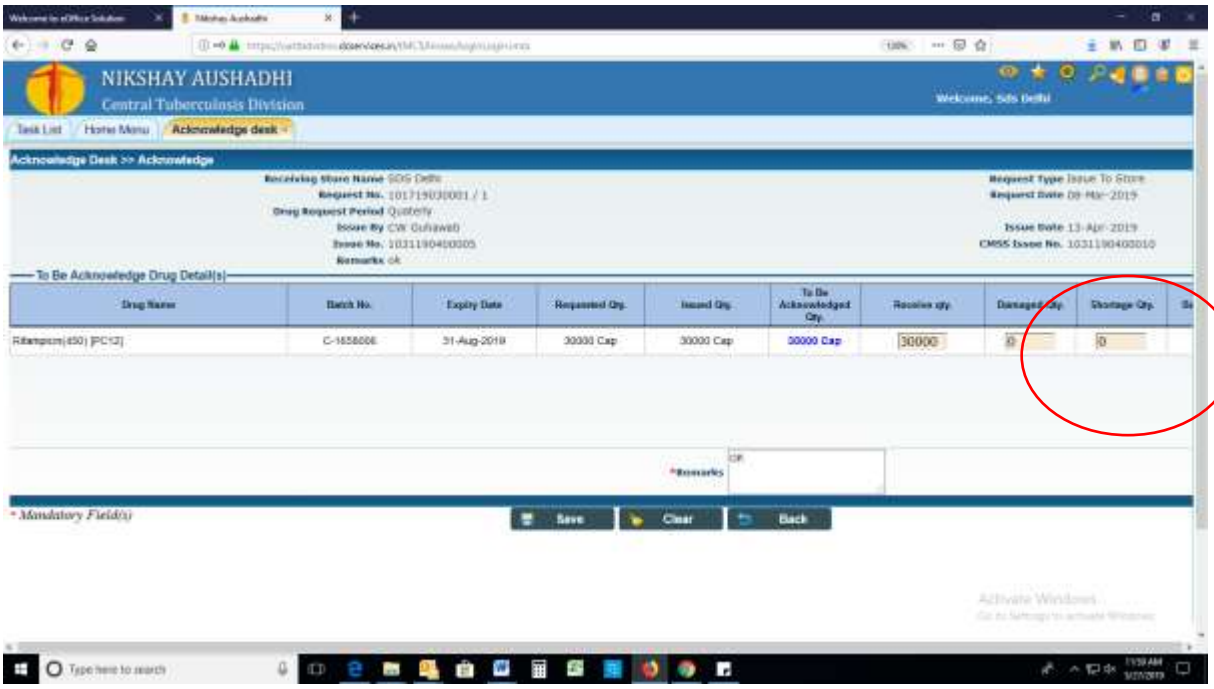
  III. Receive from Third Party

Acknowledge Desk:- This process is used to record receipt of drugs in Nikshay Aushadhi, which are received against Release Order issued by CTD / Issue Voucher issued by parent store or returned from sub-stores. The pharmacist to follow following mentioned steps :-

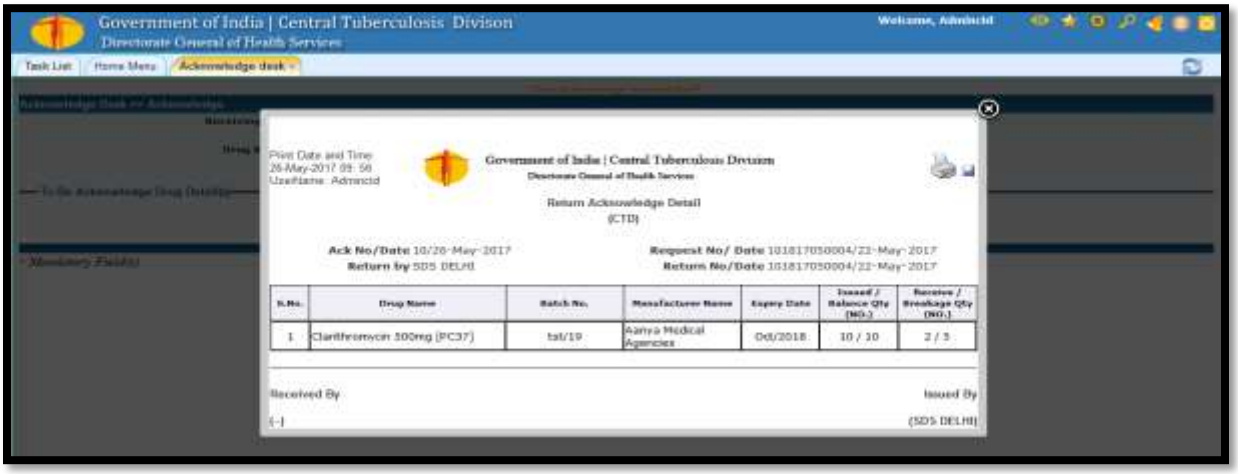
1. Select Request Type and click on Acknowledge Button.
2. Window shall be opened and requisite information to be filled ; received Quantity, Damage Quantity and Shortage Quantity



3. In case of partial supply, the storekeeper shall only enter the quantity received and balance quantity will be reflected in the window and the acknowledgment shall remain pending for balance stock.



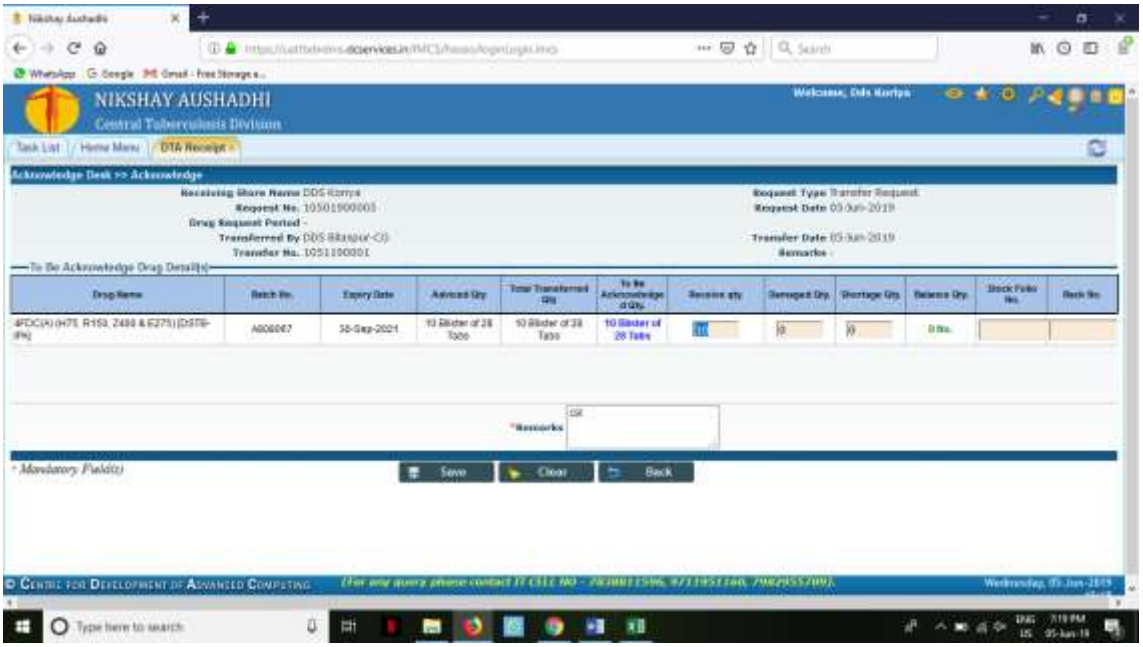
4. Click on save Button.
5. Voucher is generated



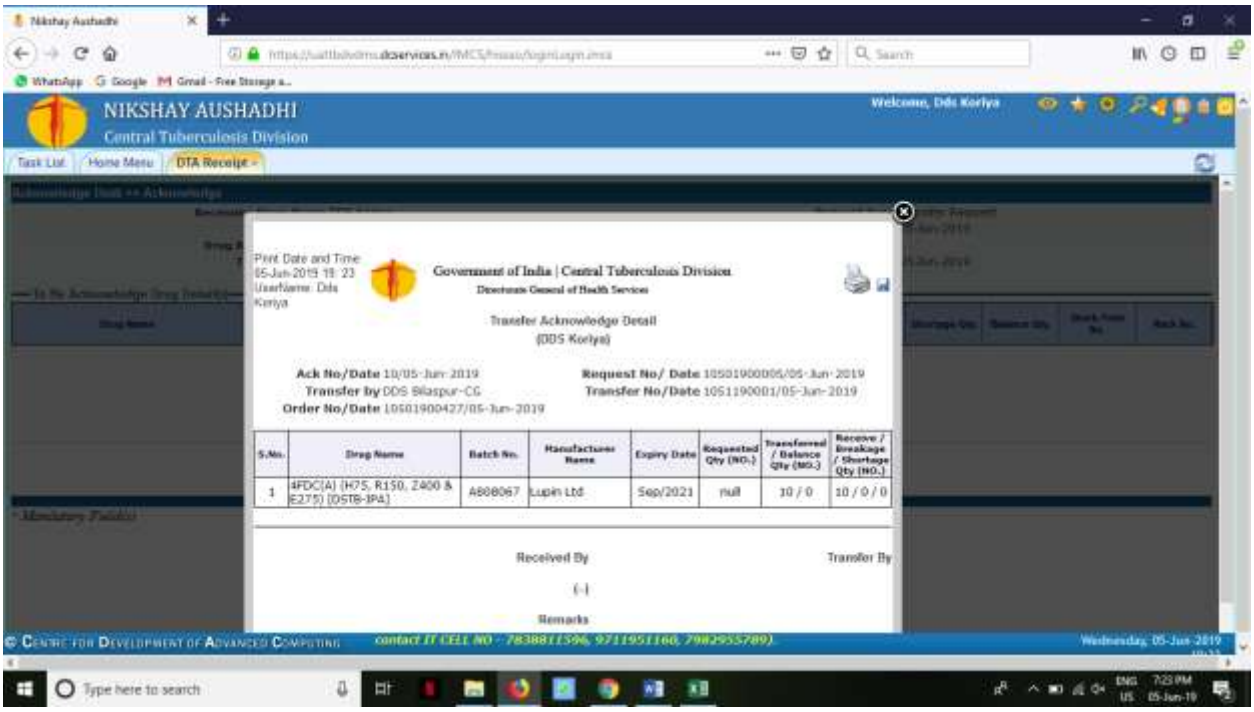
Voucher Generated

DTA Receipt :- This process is used to record receipt of drugs in Nikshay Aushadhi, which are received against DTAs issued by CTD / issued by parent store to correct stock imbalances in sub-stores. The pharmacist to follow following mentioned steps :-

1. Select Request Type and click on Acknowledge Button.
2. Window shall be opened and requisite information to be filled ; received Quantity, Damage Quantity and Shortage Quantity

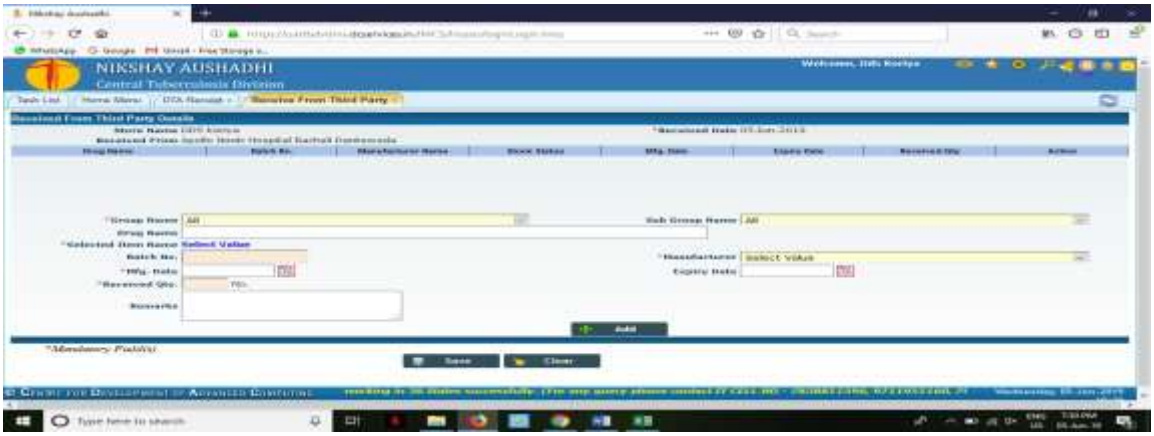


3. In case of partial supply, the storekeeper shall only enter the quantity received and balance quantity will be reflected in the window and the acknowledgment shall remain pending for balance stock.
4. Click on save Button.
5. Voucher is generated

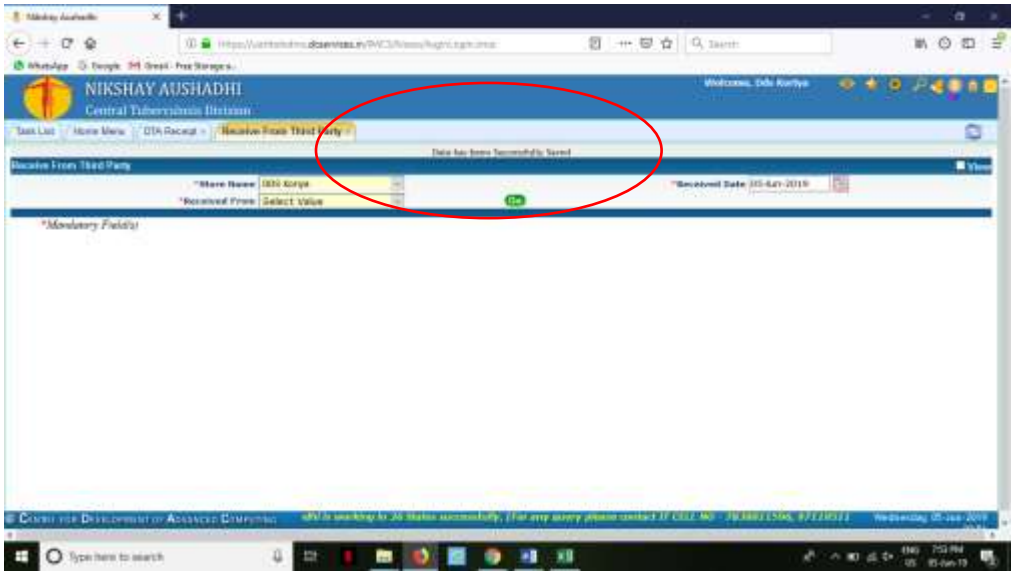


Receive from Third Party :- This process will be used when a store receive any drug or commodity from third party as donation. The pharmacist to follow following mentioned steps :-

1. Select Store, receive date and select third party name and click on GO Button.
2. Window shall be opened and requisite information to be filled ; Drug name, batch no., manufacturer name, manufacture date, expiry date , received Quantity and remarks, if any



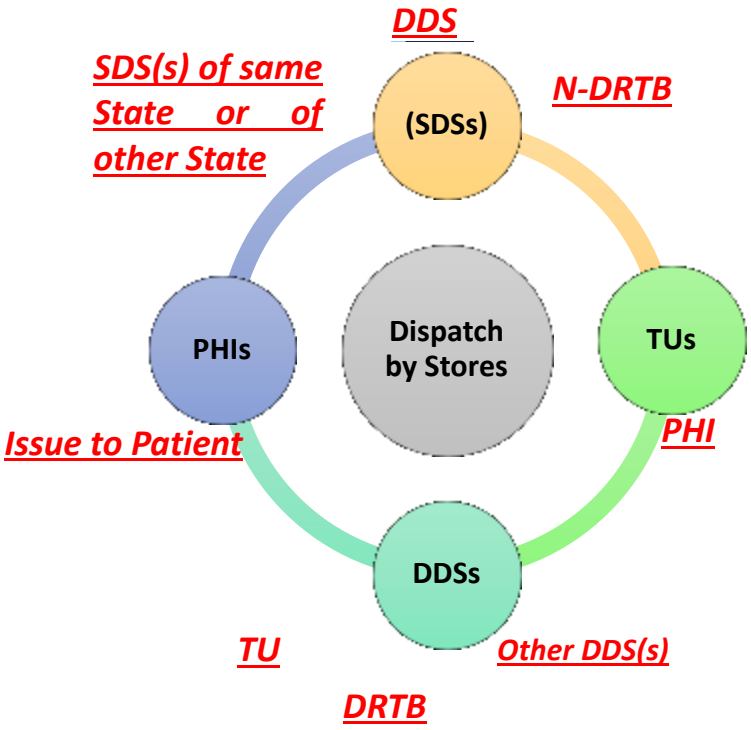
3. Click on Add and then add other drug details, if any
4. Click on SAVE button
5. Drugs updated



(B) Issues/Dispatch by State Drug Stores

GLIMPSE

Store may issue drugs to multiple sources including:



- Dispatch of drugs shall be determined by the STO/DTO or officer in-charge (authorized by the STO/DTO for the purpose), on the basis of analysis of QRPML, ADRs and Expiry analysis.
- Transfers to SDSs in other states, if any, shall be made on the basis of instructions (DTA) from CTD.
- Interstate SDS transfers: Between multiple SDSs within the state on the basis of instructions (DTA) of STO.
- Implementing DDSs shall be linked to the most convenient SDS (in terms of proximity and transportation arrangements), in the case of TU/ PHI, shall be linked to the most convenient DDS / TU respectively.

- ***SDS-*** *State Drug Stores*
- ***DDS*** *–District Drug Store*
- ***STO*** *–State TB Officer*
- ***N/ DRTB – Nodal / Drug resistant TB centre***
- ***QRPML-*** *Quarterly Report on Programme Management & Logistics*
- ***ADRs*** *–Additional Drug Request*

Procedures to be followed by Pharmacist to dispatch drugs to DDS /SDS within State / SDS of other State; have been recommended below:-

Routine Quarterly Supplies

- Quarterly replenishment of drug stocks with districts shall be based on the QRPMLs
- Information provided in the QRPML, shall be analysed by the pharmacist to help determine the drug requirement of districts for the next quarter.
- Release of quarterly supplies to DDSs based on analysis, followed by the approval of the concerned officer-in-charge
- Steps to be followed are appended below via table A

Supplies against Additional Drug Requests (ADRs)

- Sometimes, the quarterly supply of drugs 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/TU/PHI is required to prepare and submit an ADRs to the SDS/DDS/TU, providing details in support of the supplementary requirement.
- The ADR shall be carefully reviewed and validated by the concerned officer-in-charge, prior to approval.
- Same steps to be followed as indicated in below table,with the exception that the authorization document for this transaction shall be the ADR

Transfer to other SDSs /DDSs in the same State

- The quarterly review cycle by concerned officer-in-charge may suggest benefit from the transfer of temporarily excess drugs stocks available at any one SDS /DDS to the other(s), within the same state.
- Transfer as above shall be done through the means of DTA, generated by STO /officer-in-charge.
- Same steps to be followed as indicated in below table,with the exception that the authorization document for this transaction shall be the DTA

Transfers to SDSs in other States

- The quarterly review of state level QRPMLs carried out by CTD may suggest benefit from the transfer of drugs across SDS in different states to adjust stock imbalances and/or to ensure the timely utilization of close to expiry drugs.
- Transfer as above shall be done through the means of DTA generated by CTD.
- Same steps to be followed as indicated in below table,with the exception that the authorization document for this transaction shall be the DTA

The Storekeeper shall perform the following activities for releasing drugs to sub-stores

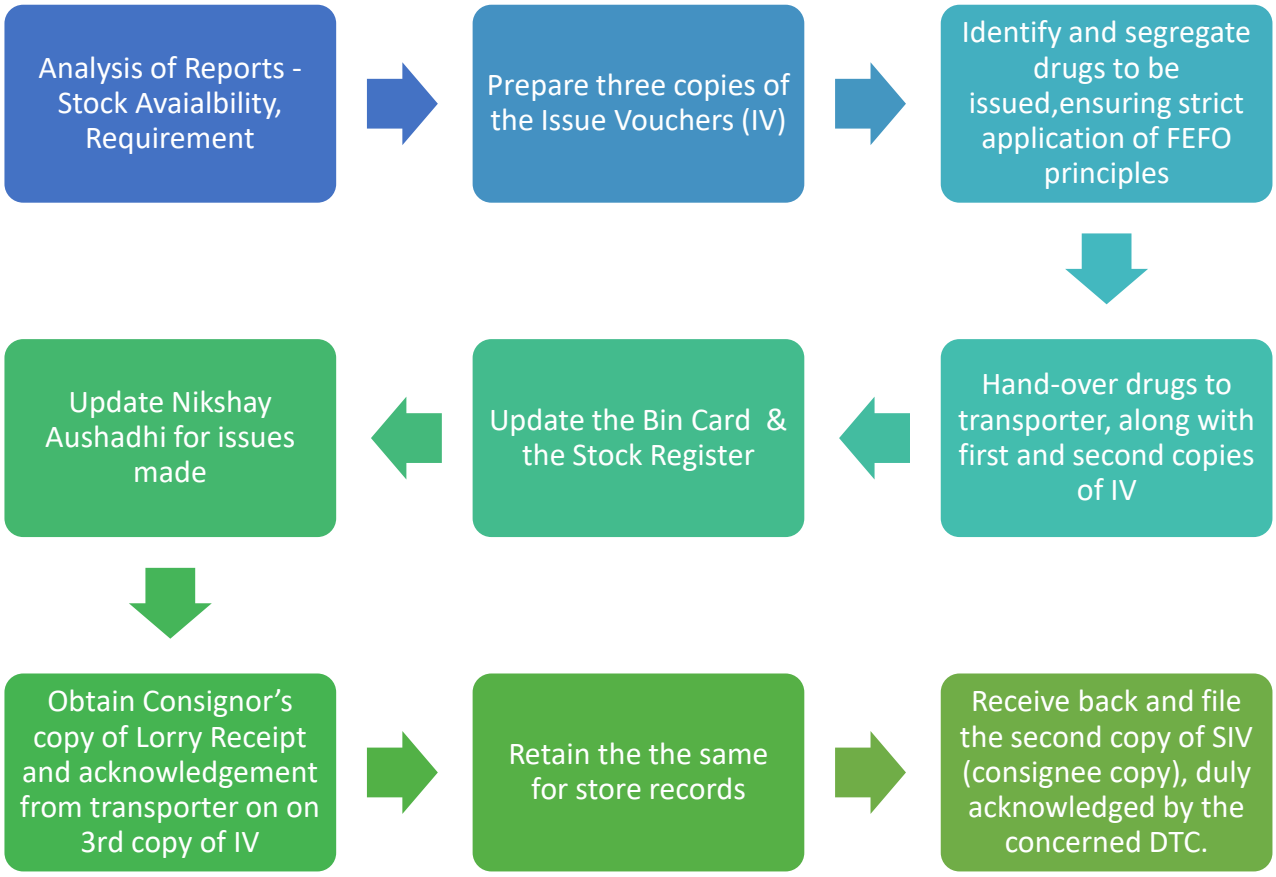


Figure 1 Detailed Step

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

Issue to patient

Patients to receive drugs for the treatment of drugs sensitive TB or drug resistant TB by DOTs Provider or Treatment Supporter as per the regimen prescribed by the doctor. The DOTs Provider or Treatment Supporter shall receive drugs from PHI. PHIs shall issue drugs on monthly basis against the unique Notification ID generated by Nikshay through Nikshay Aushadhi.

In certain circumstances, when a patient enrolled for the first time, he may not have Notification ID available with him during the receipt of medicines. In such cases, PHI to issue drug without Notification ID, which is strictly limited to one time use only. During his/her second visit, availability of Notification ID is mandatory.

In certain cases, Isoniazid is required to be given to the household contacts (less than 5 years of age) of TB Patient for Chemoprophylaxis.

Issue to ART Centre

Drugs which are required to be issued to ART Centre for the TB-HIV patient under collaboration of TB and NACO, will required to be issued through Nikshay Aushadhi in order to capture the stock being consumed by these ART centres. Programme is in integration NACO and in future Nikshay Aushadhi shall have direct request from ART Centre through their system and accordingly, drug shall be release.

Return from Sub-Stores

In case of default/death/transferred-out/treatment stopped patients, unconsumed strips /boxes/loose drugs/jars shall be brought back from Treatment centre to PHI to TU to DTC within the shortest possible time. The unconsumed box returned to the store should be updated in Nikshay Aushadhi. All loose drugs shall be accounted for in the Stock register and Nikshay Aushadhi at the DDS and same will be issued as per FEFO principles to either for hospitalized patients / DR TBC / repackaging into monthly Type boxes.

Recording in NIKSHAY AUSHAHDI

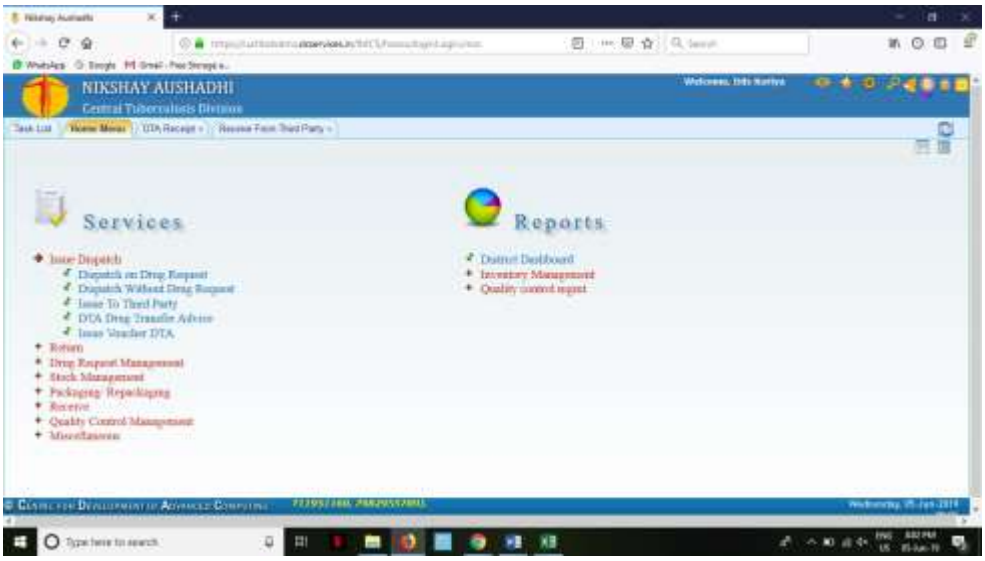
The pharmacist shall follow the following steps to record the drugs issued to sub-stores :-

- Login in Nikshay Aushadhi :

  https://www.nikshayaushadhi.in/IMCS/hissso/loginLogin.imcs

- The storekeeper to follow following path

  Home Menu→ Services→ Issue/Dispatch



- **Issue of drugs – in case of r<u>outine quarterly supplies or Supplies against Additional Drug Requests (ADRs)</u>**

    I. Dispatch on Drug Request

    II. Dispatch Without Drug Request

- **Issue of drugs - <u>Transfer to other SDSs /DDSs in the same State</u>**

    I. DTA Drug Transfer Advice

    II. Issue Voucher DTA

- **Issue of drugs to patient**

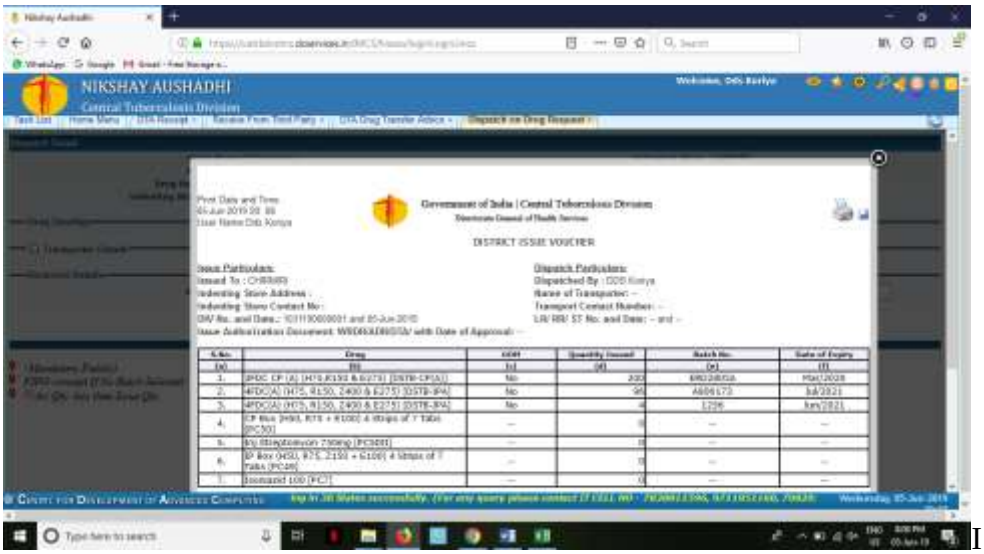
- **Issue to Third Party**

<u>Dispatch on Drug Request: -</u> This process is used to record drugs issued or dispatched to district drug store in Nikshay Aushadhi, against the request generated through Nikshay Aushadhi. **The pharmacist to follow following mentioned steps :-**

1. Select Store name.
2. Select drug request no.
3. Window shall be opened and requisite information to be filled
4. click on save Button

Dispatch desk

5. Issue Voucher is also generated.



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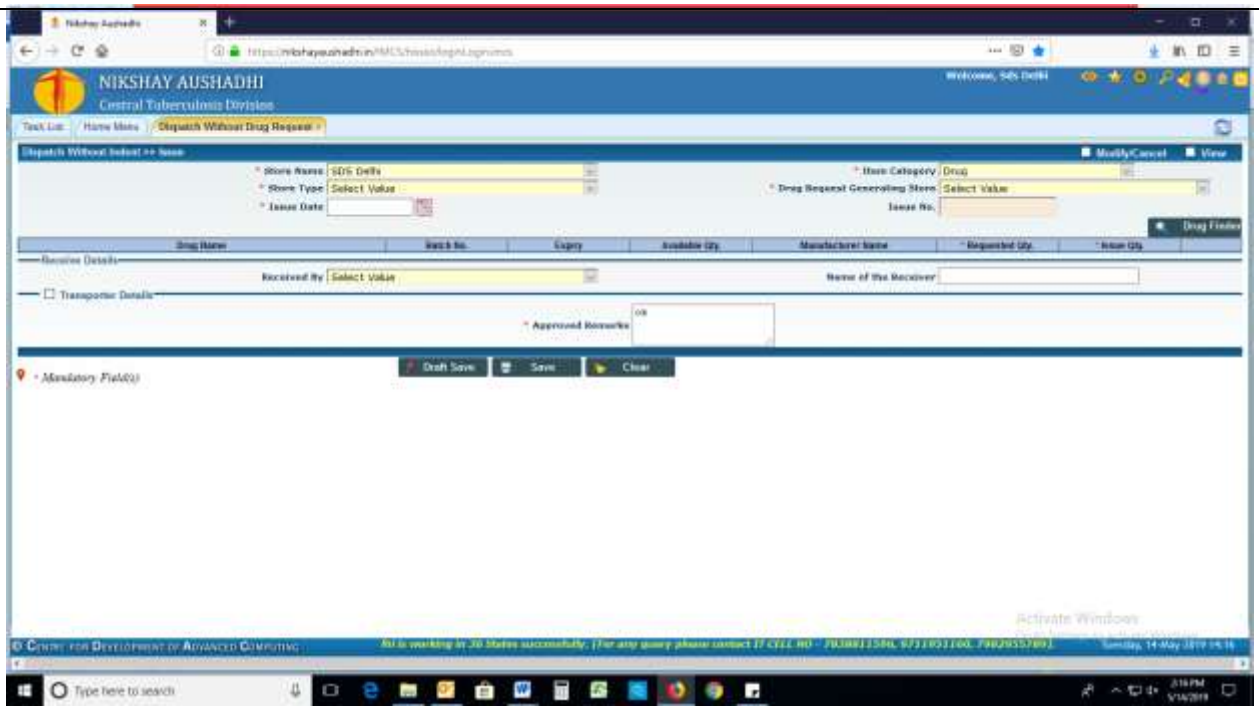
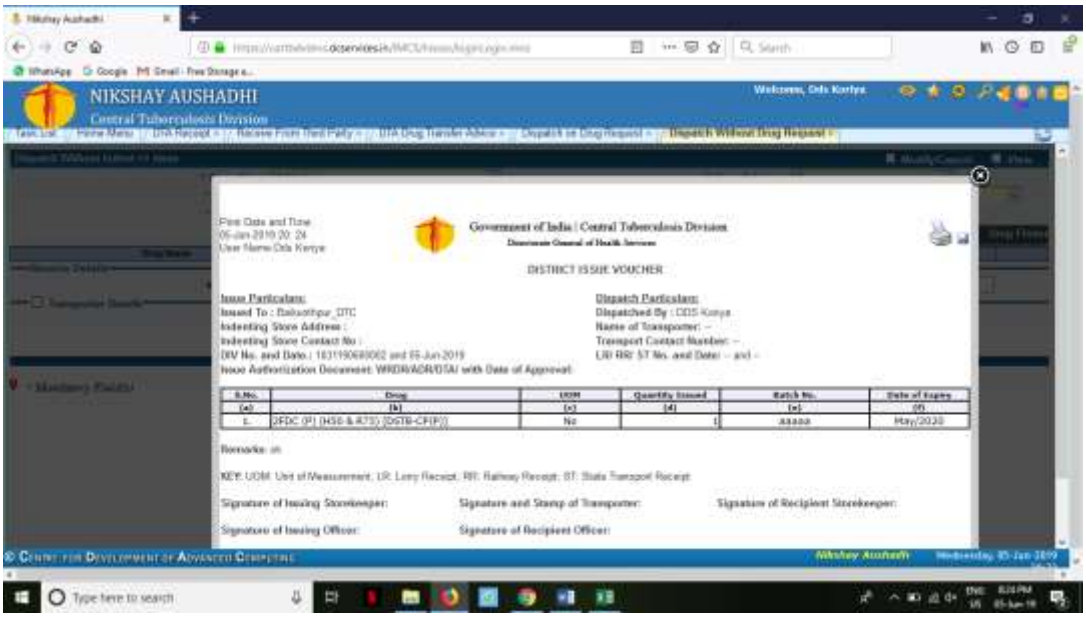
Dispatch on without Drug Request: This process is used to record drugs issued or dispatched to district drug store in Nikshay Aushadhi, without any request received from sub stores through Nikshay Aushadhi. **The pharmacist to follow following mentioned steps :-**

1. Select Store name.
2. Select drug request no.
3. Window shall be opened and requisite information to be filled
4. click on save Button



Dispatch desk

5. Issue Voucher is also generated.

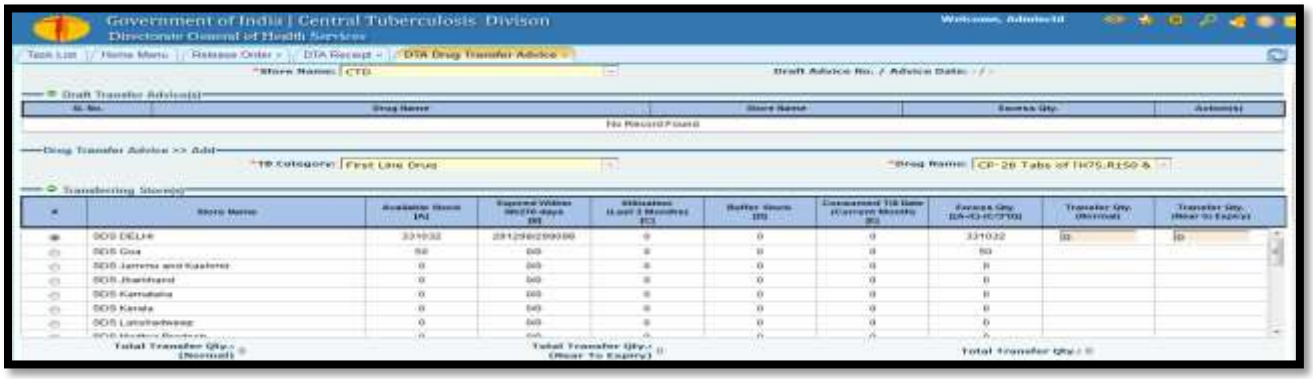


DTA Drug Transfer Advice: **Movement/Transfer/least expiry drugs are moved from one store to other store, a process is created called DTA drug Transfer Advice. This Process is usually done by , CTD/HQ level for SDS to SDS Level, SDS level uses for DDS to DDS level and**

DDS transfers drugs from TU to TU only. TU and PHI level stores cannot transfer drug through this process.

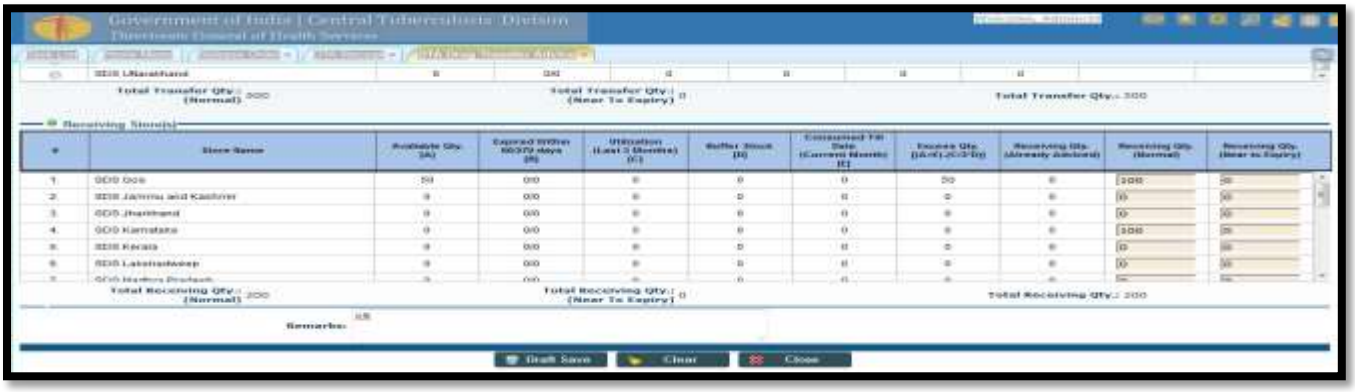
In this process, the CTD/SDS/DDS generate the advice as per the availability/shortage or least expiry drugs available in one store to other needy/shortfall drugs as desired by the both stores (Issuing and receiving stores). **The pharmacist to follow following mentioned steps :-**

1. Select the store name from which drugs transfer to other stores name
2. Enter the transfer quantity of drugs from which warehouse they are transferring.



Transferring store

3. Enter the receiving quantity for the store the drugs will get transferred to.



Receiving store

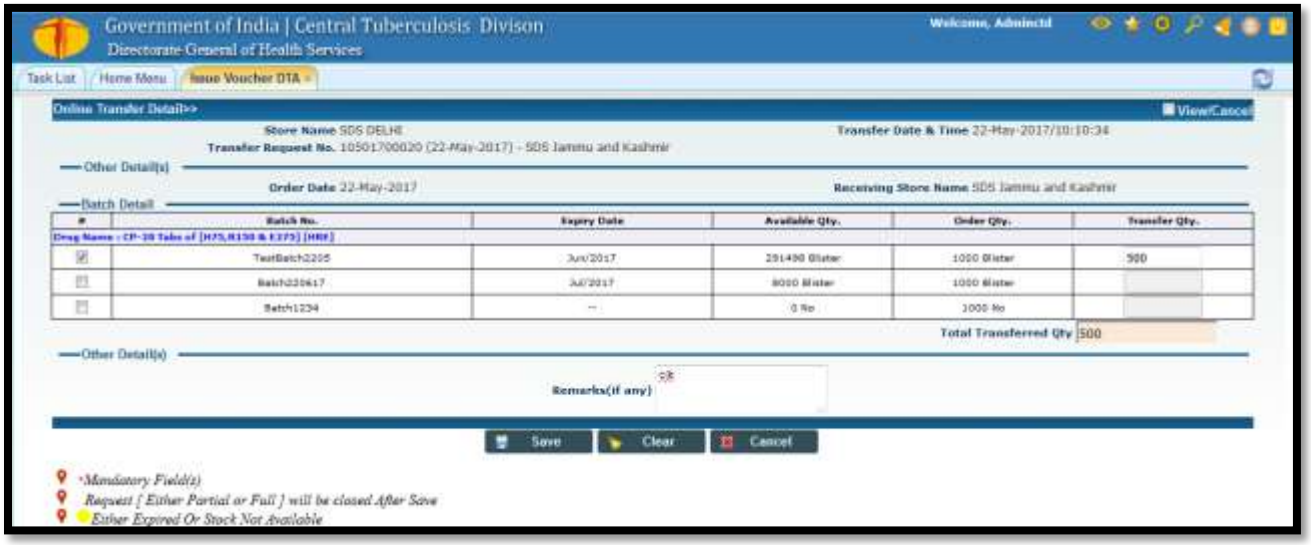
4. Click on Draft save Button.

5. Then click on Final save Button.

Voucher Generated

Issue Voucher DTA: Once the advice has been generated by the CTD/SDS/DDS store through Drug Transfer Advice process, an issue voucher is made by the issuing/Transferring store in favor of receiving store w.r.t the transfer order number. **The pharmacist to follow following mentioned steps :-**

1. In Store Name combo Store Name must be mapped with the application
2. Select Transfer Request No and click on Go Button.



Online Transfer Detail Desk

3. Fill transfer Quantity and click on Save Button.
4. Voucher is getting generated.

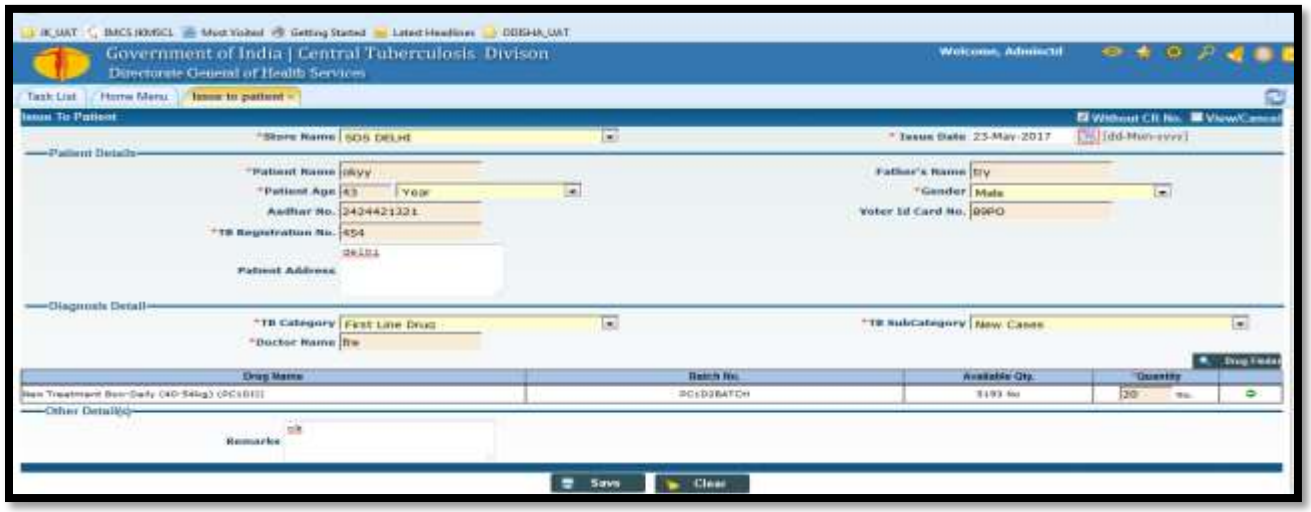
Voucher generated

Issue To Patient: Patient shall come to PHI – DOTs Provider or Treatment Supervisor will collect medicine from PHI using Patient Nikshay ID on monthly basis. **The pharmacist to follow following mentioned steps :-**

Scenario 1 - Patient with Nikshay ID :-

1. Select Store Name.
2. Enter the Notification ID

3. Following details will appeared with auto populated detail from Nikshay



Issue to Patient Desk

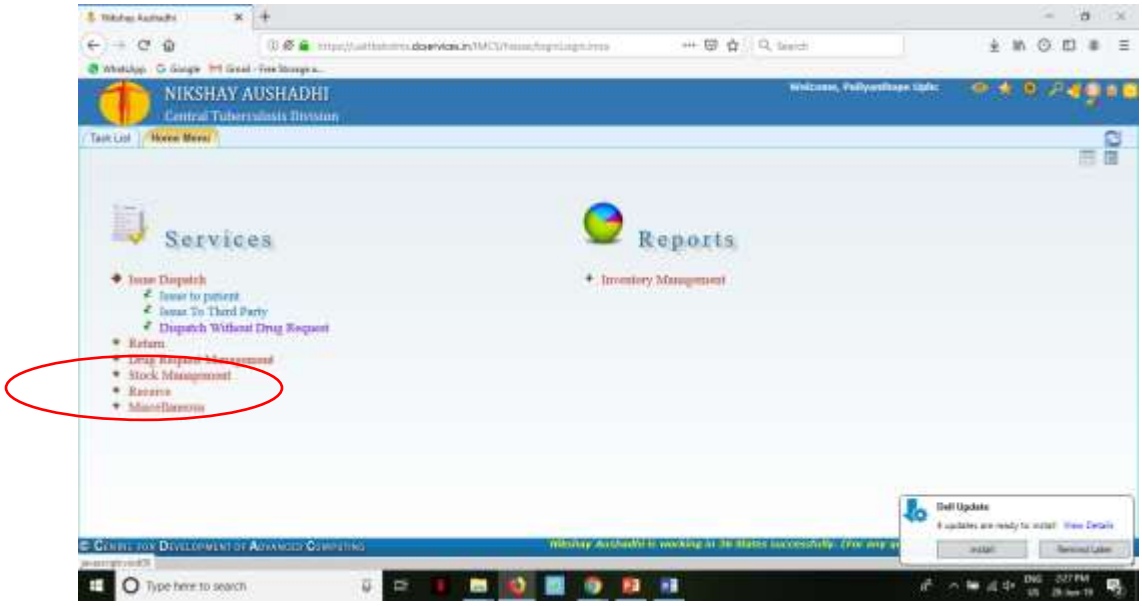
4. Click on Drug Finder.
5. Select Drug Name and fill drug quantity then click on ok button.
6. Click on Save Button.

Voucher Generated

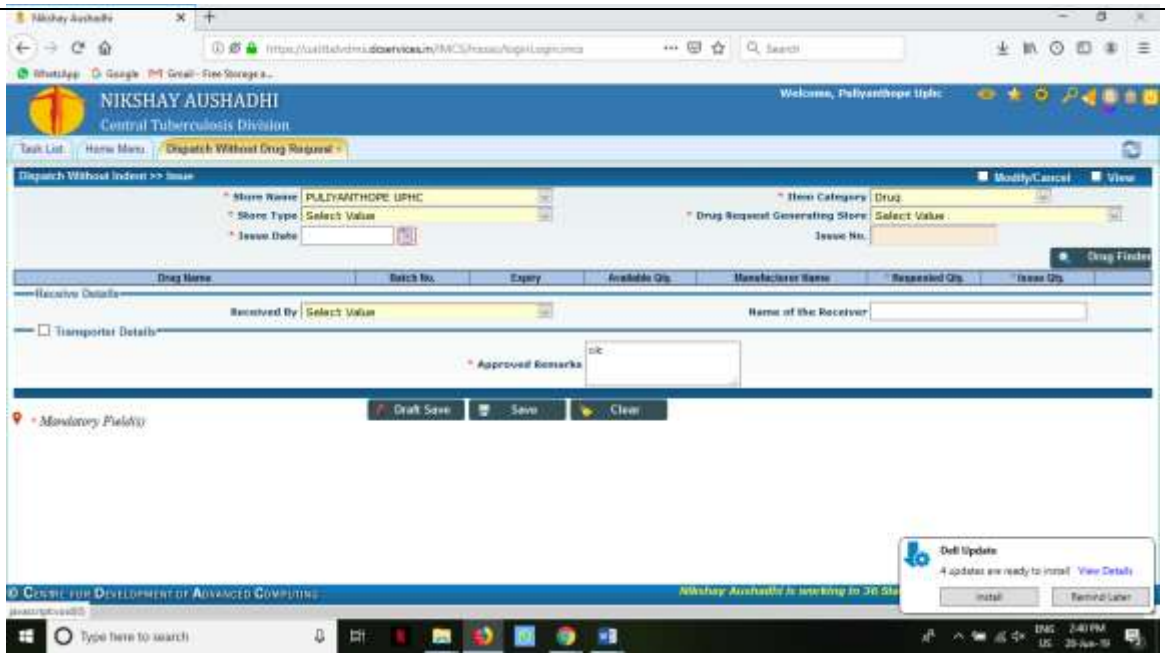
Scenario 2: *In case, patient without Notification ID, above steps will be followed, except at step 3 ; details need to be filled by the pharmacist.*

Issue to Art Centre

Home Menu→ Services→ Issue/Dispatch➔Dispatch without drug request

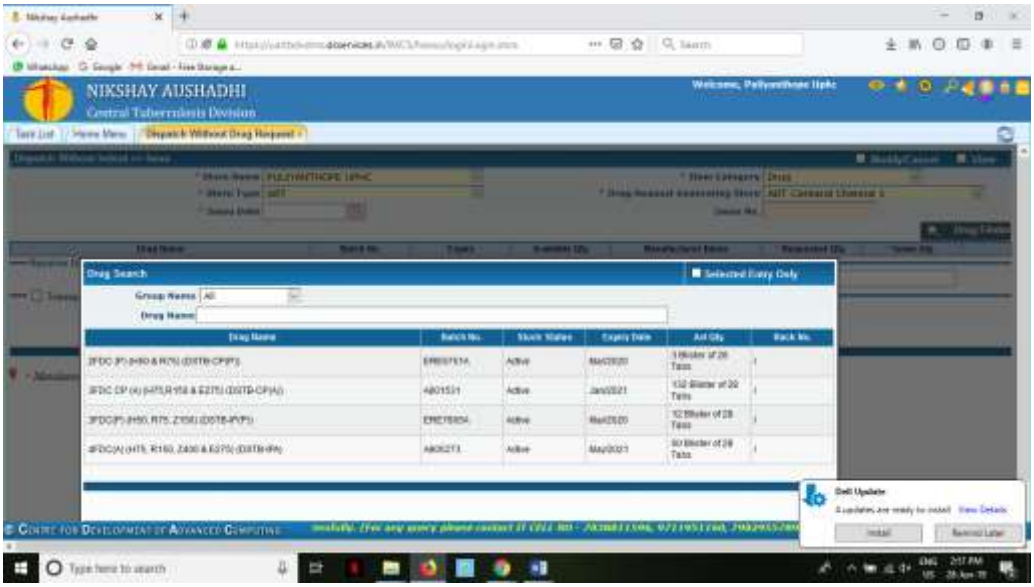


- On click following window will be shown :-



- Select desired details :- Store name, Item Category, receiving Store type & name, issue date and Issue No (manual)

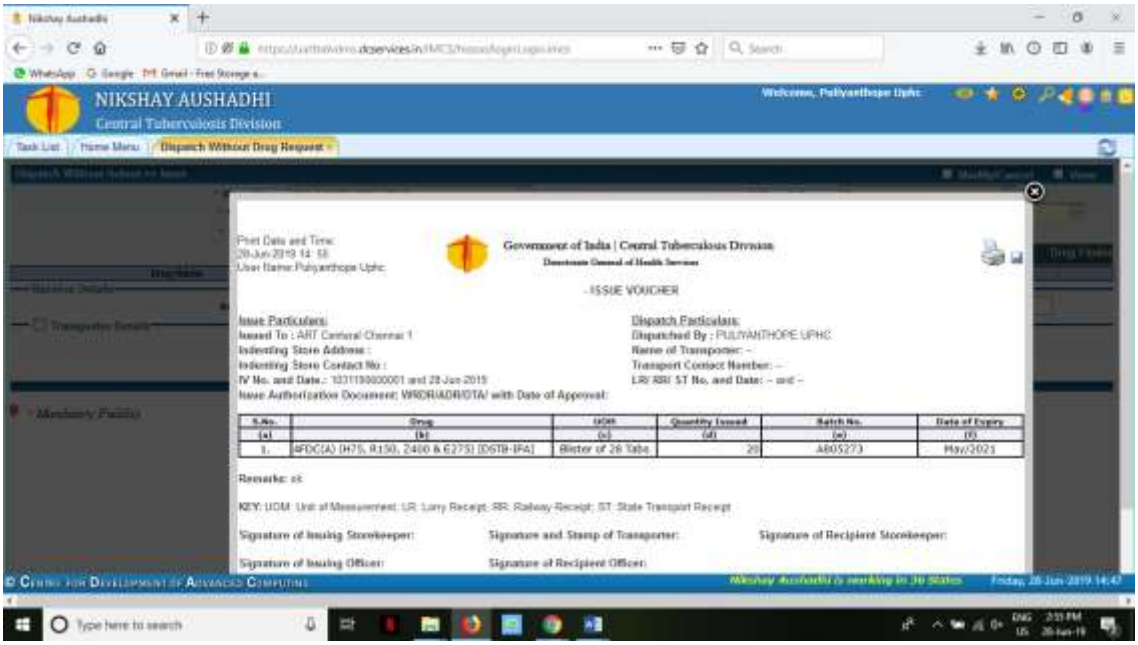
- Click on Drug Finder



- Select drug , enter drug required quantity, select from available batches / expiries and click on button ‘ok’.

- Add if any other need to be issued , repeat same step as ‘6’ and lastly click on Close
- Add receive details and transporter details
- Enter remarks and click on save

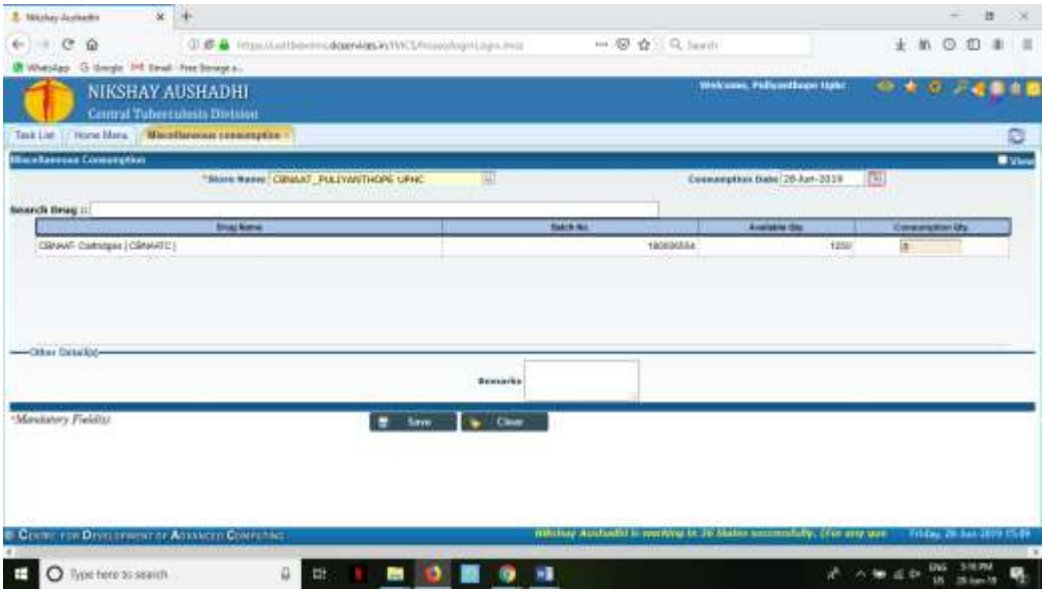
- Voucher is generated



Consumption of Cartridges at CB-NAAT site and Isoniazid for Chemoprophylaxis

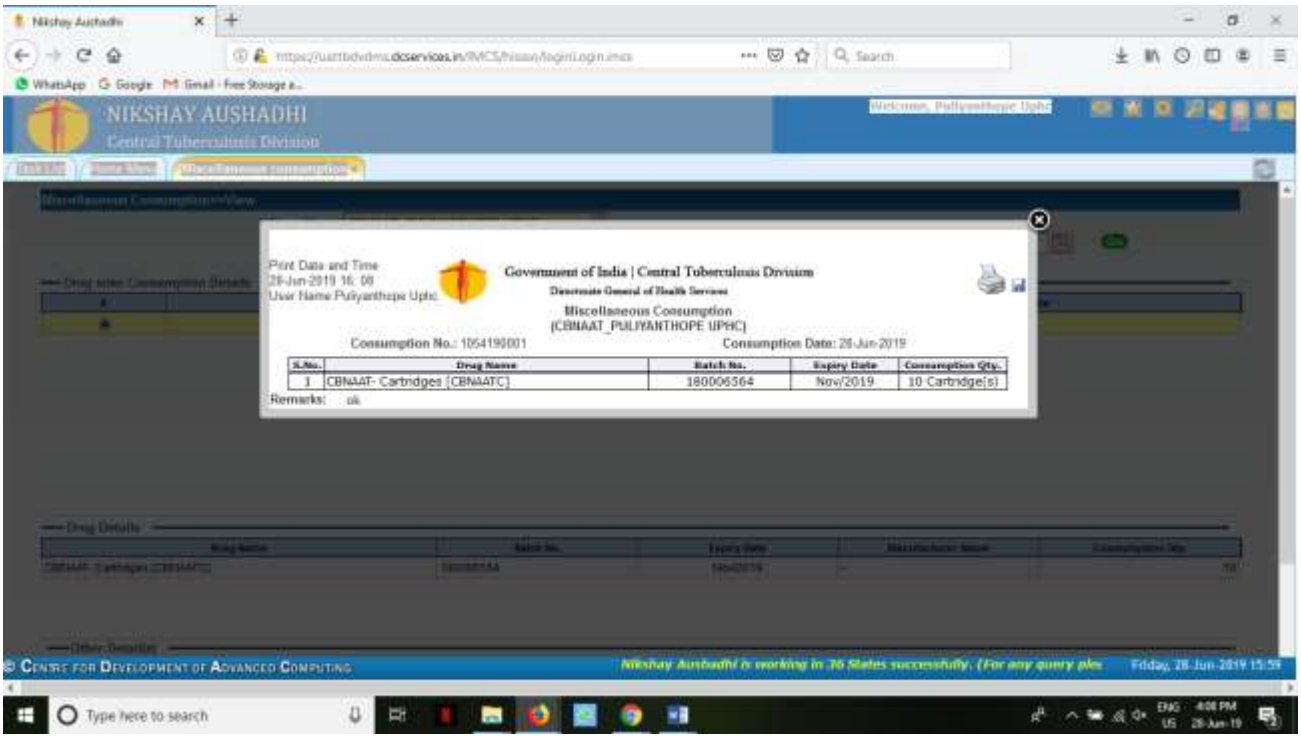
For cartridges

- **Select Store name – CBNAAT-Site**



- **Enter the no. of cartridges consumed**

- **Click Okay, voucher will be generated**



For Chemoprophylaxis

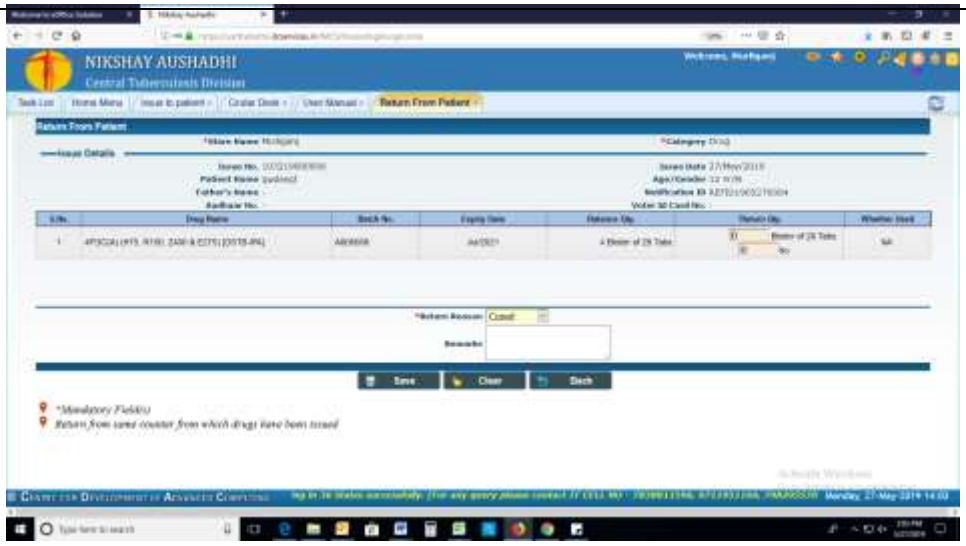
- **Select Store name – PHI**
- **Enter the quantity of Isoniazid issued for chemoprophylaxis**
- **Click Okay, voucher will be generated**

Return: This process is used to record drugs received back from patient and retuned to parent stores in Nikshay Aushadhi. It includes two steps:-

1. Return from Patient – to be used only by PHI to record drug received back from patient
2. Return Request Desk – to return drugs to TU/ DDS/SDS

1. **Return from Patient**

- Enter Issue Voucher No. (voucher generated at the time of issuing drug to patient)

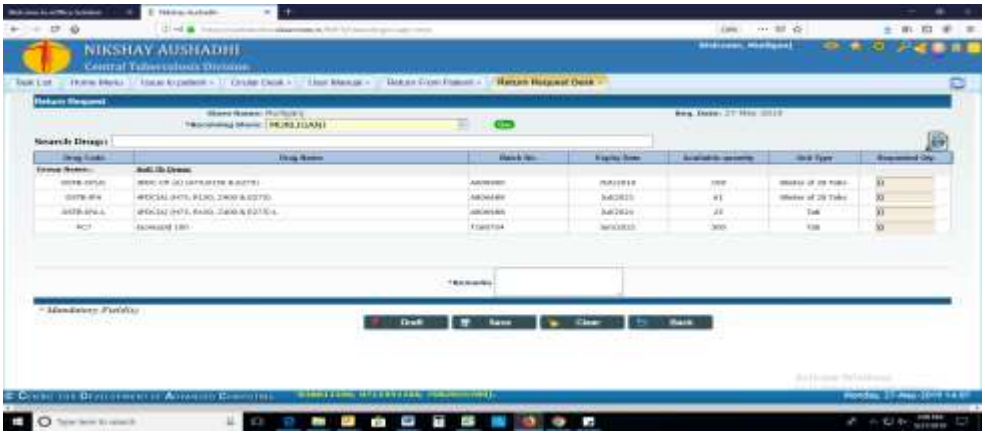


- Fill no. of tablets/strips/box/jar returned from a patient
- Drugs will be updated in the Nikshay Aushadhi

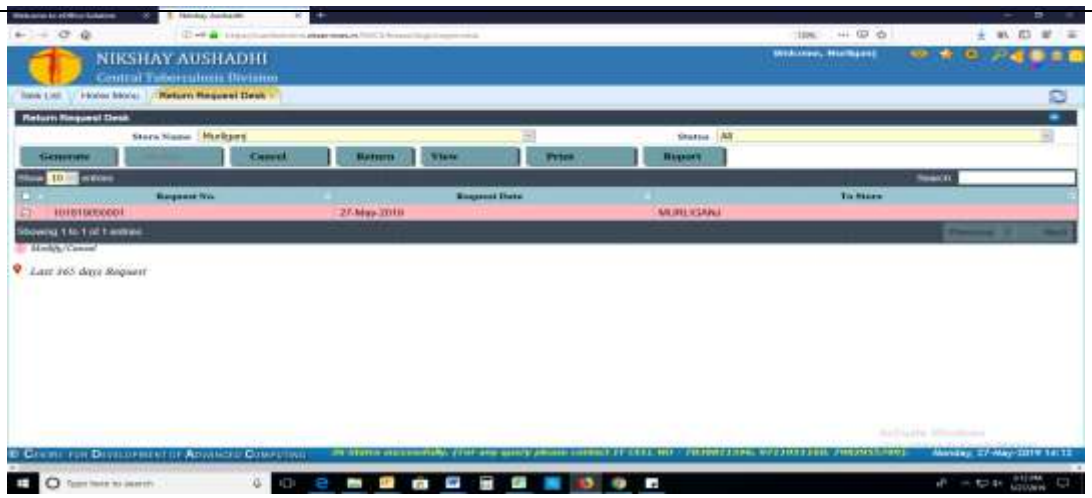
2. Return Request Desk

Steps to be followed :-

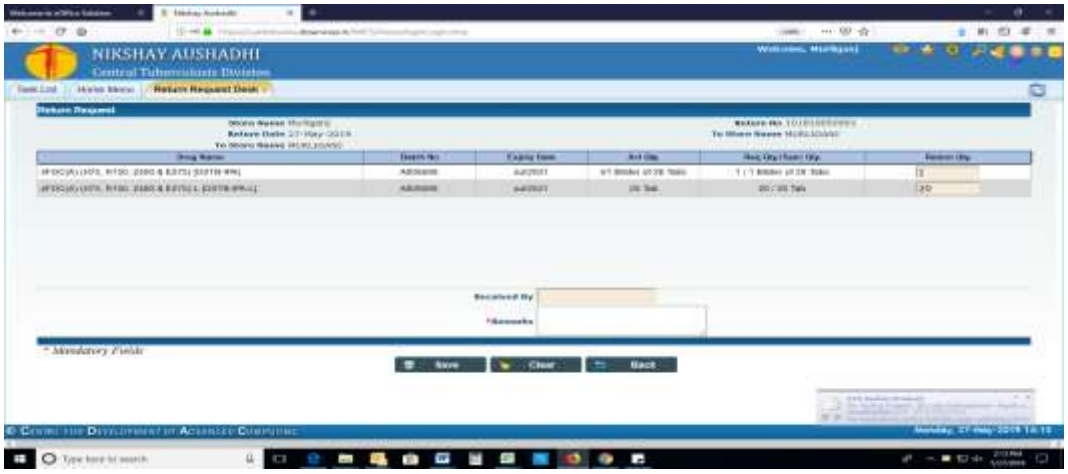
- Click on generate
- Select receiving store and Click on Go
- Fill details –drug quantity to be returned



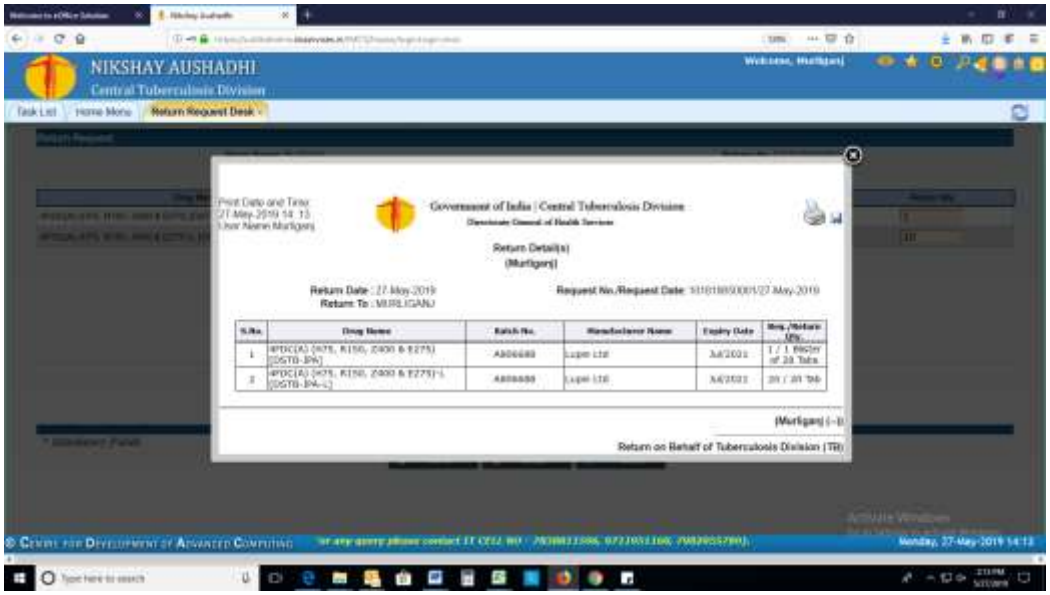
- Click on save
- Return to main menu



- Select request no. and click return



- Confirm retuned quantity and click on save
- Drugs retuned to parent store and voucher generated



Quality Assurance

OVERVIEW

Procurement of good quality anti TB drugs and ensuring quality of drugs till consumption point is one of the prime objective of RNTCP.

To ensure quality and efficacy of anti TB drugs, a comprehensive RNTCP Quality protocol has been developed and is being followed during the procurement mechanism and supply chain management of drugs up to the consumption points. Simultaneously, quality assurance of anti TB drugs has also been aligned with Nikshay Aushadhi application for easy reporting and recording from Central to the peripheral level.

RNTCP Quality Assurance under RNTCP → **Mandatory Pre-dispatch Inspection** + **Post-dispatch Inspection as per RNTCP Protocol**

RNTCP QUALITY ASSURANCE PROTOCOL – DURING PROCUREMENT MECHANISM

Procurement of anti TB drugs is always done through a Govt. authorized procurement agency and in accordance with quality protocols laid down in technical specifications of anti TB drugs. Quality parameters include procurement of drugs through WHO GMP certified / WHO pre-qualified suppliers only or suppliers found eligible as per Global Fund quality assurance guidelines. Further, there is mandatory pre-dispatch inspection of drugs prior to dispatch to RNTCP consignees by independent laboratories hired by the procurement agencies.

RNTCP QUALITY ASSURANCE PROTOCOL – POST PROCUREMENT

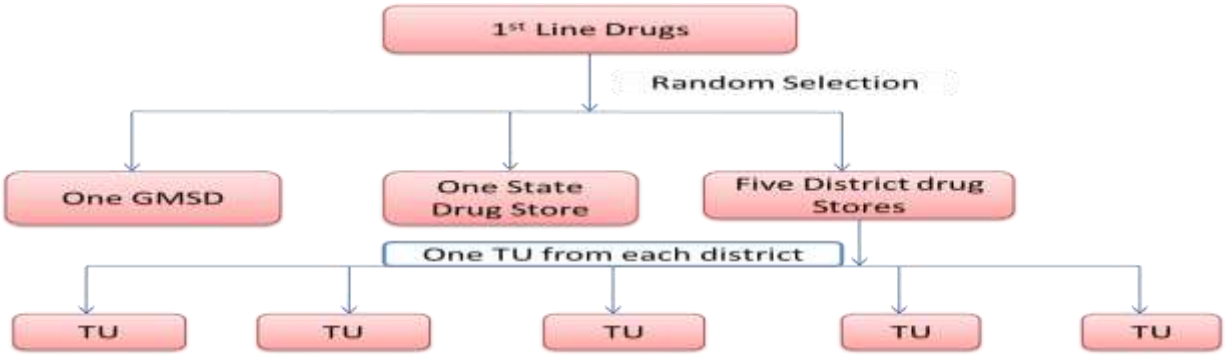
To ensure quality and efficacy of drugs up to consumption points, an additional quality protocol mechanism has been developed by the programme wherein samples of anti TB drugs lying at GMSDs, states, districts and TUs are being picked up by an independent lab hired by the programme, following RNTCP quality protocol.

RNTCP QA METHODOLOGY – POST PROCUREMENT

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

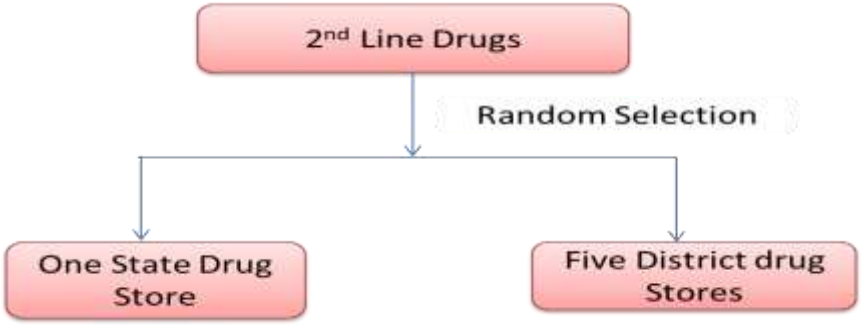
Each quarter, drug samples are being collected from selected zone as per direction of the Central TB Division. Drug sample collection protocol for 1st and 2nd line drugs is summarized below in tabular form:

a) 1st line Drugs



1. One GMSD, selected randomly.
2. One SDS, selected randomly.
3. Five District TB Centers (DTCs), selected randomly.
4. Five districts which have been selected for sample submission of 1st line drugs shall also ensure submission of same drug samples on randomly selected at least one TUs from respective districts, based on the stock availability.

a) 2nd line Drugs



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

GUIDELINES FOR COLLECTION OF DRUG QUANTITIES FOR TESTING

Central TB Division will issue directions every quarter to concerned GMSDs and states for collection of drug samples as per RNTCP QA protocol. Directions will be accompanied with name of drugs and number of batches to be collected from respective drug stores.

Generally, at least two batch numbers of drug samples, selected randomly, shall be sampled for testing from GMSDs, State and districts drug Stores. From TU, only one batch number of drug may be sampled. In case of stocks shortage, sample will not be taken from TU.

QUANTITIES AS PER FORMULATIONS TO BE COLELCTED FOR TESTING

Sl. No.	Formulation	Quantity for collection
1	Tablet	10 strips
2	Capsule	10 strips
3	Injectable	80 vials
4	DSTB-IP / (A) 4FDC	8 Blister Strips
5	DSTB-CP (A) / 3FDC-A	8 Blister Strips
6	DSTB-IP (P)/ 3FDC-P	8 Blister Strips
7	DSTB-CP (P) / 2FDC-P	8 Blister Strips

The following officials shall be responsible for collection of drug samples:

i) From GMSD : STO / official authorized by STO
ii) From SDS : STO / official authorized by STO
iii) From DTCs & TUs : DTO / official authorized by DTO

PROCEDURE FOR COLLECTION OF DRUG SAMPLES:

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

1. As far as possible, the officer in-charge should draw drug samples, from original, unopened boxes /containers/ packs.

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:

   (1) Drug name
   (2) Quantity
   (3) Batch No.
   (4) Date of Manufacturing
   (5) Date of Expiry
   (6) Supplier Name
   (7) Procurement Agency
   (8) Manufacturing License No.
   (9) 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 sealed sample to the laboratory.

5. A copy of the covering letter should also be sent to Central TB Division.
6. Sample quantities collected should be such that the samples collected can be analyzed twice (as indicated above, by dividing into two equal batches).
7. 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.
8. Record the quantities issued to testing laboratories in Stock register and Nikshay Aushadhi

QUALITY ASSURANCE REPORT

The contracted laboratory shall share drug quality reports as per the defined timelines to Central TB Division. The stipulated time is about 20 days for parenteral formulations & about 15 days for others drugs (capsule / tablets).

Once quality reports of drugs are shared by contracted laboratory, same shall be shared further with the states. The sealed drug samples may be opened and used in case the lab report indicates acceptable quality. However, in case of drug sample declared as sub-standard, necessary action shall be taken by the Central TB Division. Central TB Division shall communicate the State about the sub-standard drugs and update the reports in Nikshay Aushadhi. Consequently, said batches which are declared sub-standard shall be segregated in the Nikshay Aushadhi.

PRECAUTIONARY MEASURES IN CASE OF SUB-STANDARD DRUGS

1. Stocking units down the line shall immediately be instructed to stop further consumption and issues from the batch declared substandard.
2. Specific instructions shall be given to stocking Units / DOTS Centres, to replace, unconsumed drugs of substandard batch from boxes / drugs allocated to patients, with drugs of different batch.
3. Unconsumed / unused substandard drugs shall be labelled ‘substandard’ and carefully segregated in stores, in such a way that there is no possibility of their being reissued to patients.
4. Detailed record shall be kept of segregated substandard drugs taken
5. All further necessary action for declared substandard drug shall be taken by CTD with concerned procurement agencies.

REPEAT TESTING

The following procedure is to be followed in case of declared sub-standard drug:

1. Laboratory Report suggesting substandard drug 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 concerned GMSD/ SDS/ DTC /TU for dispatching the sample retained in sealed condition, for another round of testing to CDL, Kolkata.

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

In case repeat testing confirms substandard quality of drugs, CTD shall send a copy of the report to Procurement Agency for further necessary action.

RECORDING AND REPORTIN IN NIKSHAY AUSHADHI

Consequent upon direction of Central TB division, all concerned officials shall ensure collection of drug samples as per the RNTCP protocol within the stipulated time.

Respective stores shall record all details of drugs collected for quality assurance in Nikshay Aushadhi application under Quality Control management option.

Path 1:- (For Drug sampling as per RNTCP QA protocol)

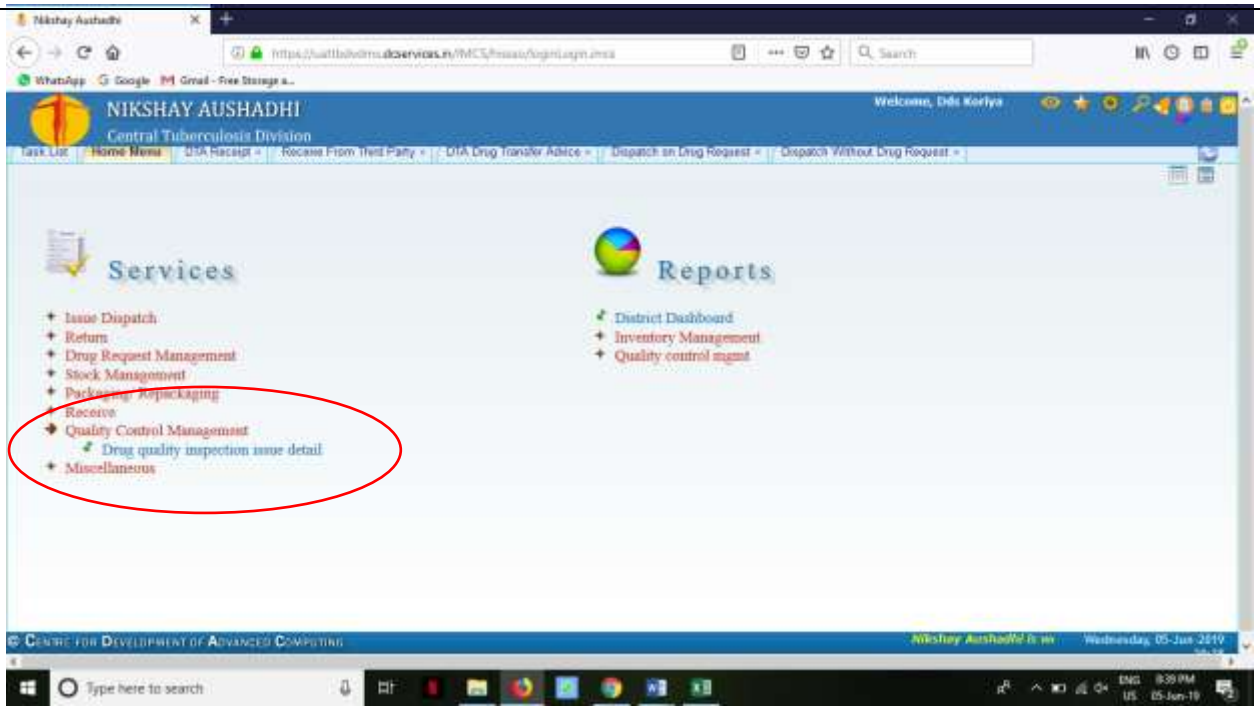
(REPORTING FORMAT FOR CTD LEVEL IS UNDER DEVELOPMENT)

QUALITY ASSURANCE AT STATE LEVEL

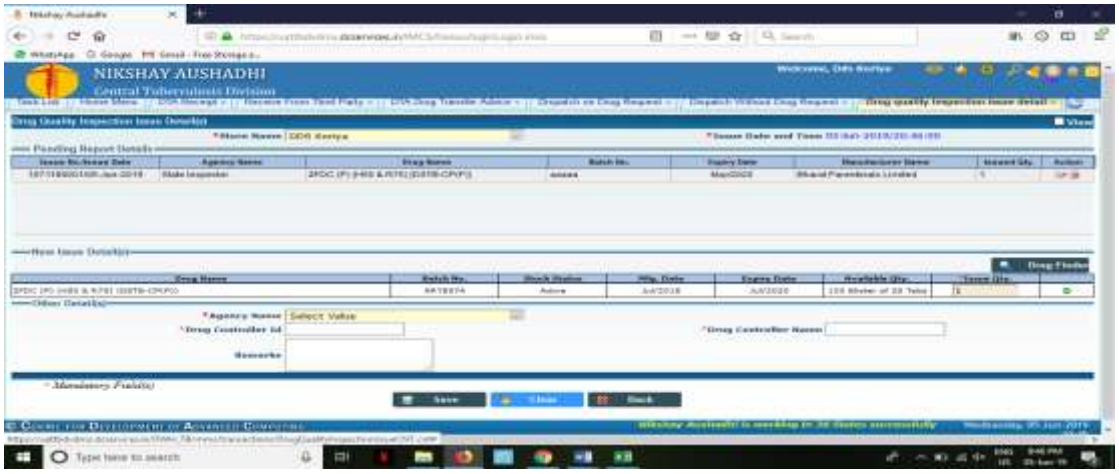
There may be instances that anti TB drug samples may also be picked from state/district/TU drug stores by authorized representatives / officials of states like drug inspector or may be from any regulatory / competent authority like CDSCO (Central Drugs Standard Control Organization).

Accordingly, recording and reporting of samples picked by authorized officials at State/District/TU drug stores has been included in Nikshay Aushadhi application. The respective drug store shall record all the details of sample picked by any authorized officials / representatives in Nikshay Aushadhi application under Quality Control management option.

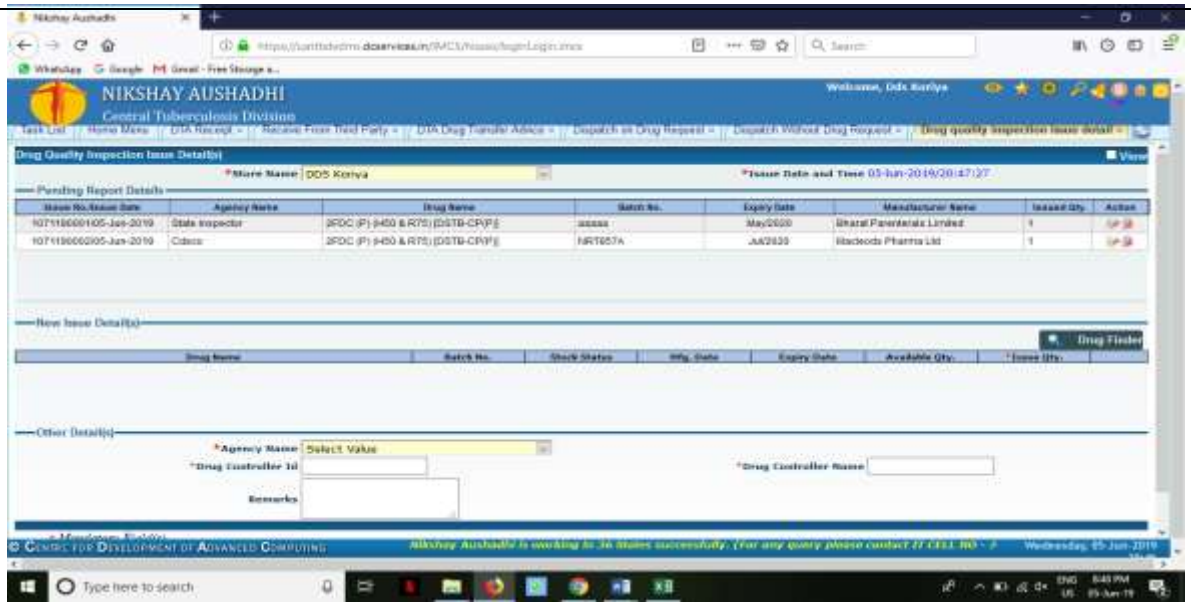
Path 2 :



1. Select drug quality inspection issue detail
1. Following dialogue box will appear – select drug finder
2. Select drug and batch number required for testing and enter the quantity
3. Same quantity of drug and batch number selected at Sr. No.2 will also be recorded in Nikshay Aushadhi and this quantity have to be retained at respective drug store in sealed condition till further instructions from Central TB division.
4. Click Ok and add other drug, if any
5. Click Close
6. Enter desired details- agency name, drug controller name and ID



7. Click on SAVE button, following details will appear :-



Post receipt of quality reports by state / respective drug stores, the same should be shared with Central TB Division immediately through email and Nikshay Aushadhi application for information and necessary action.

In case of drug sample declared as sub-standard by testing agency, necessary directions shall be issued by the Central TB Division for retesting of that particular drug and batch number from the retained sealed sample at respective drug stores.

EXPIRY MANAGEMENT

This section of the manual deals with procedures to be followed for the management of short expiry drugs and immediate steps in dealing with the same so as to ensure their utilization within their shelf-life.

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

Overview

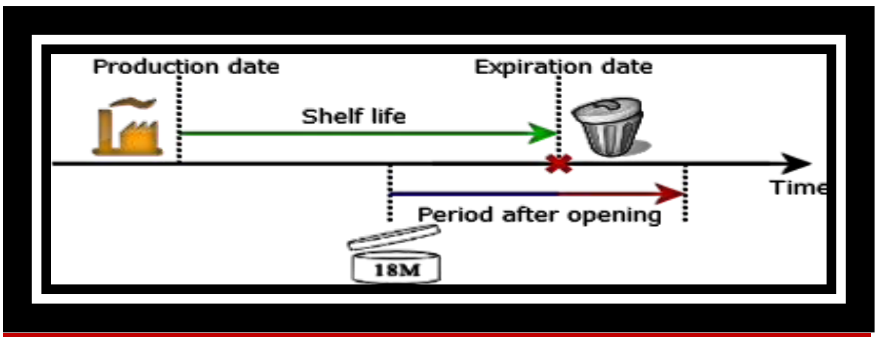
The storekeeper is expected to incorporate appropriate tools to periodically monitor controls over the expiry position of drugs held in stocks mainly through storage of drugs of a particular description at one place, expiry-wise stacking and marking expiry dates on cartons/drug boxes with marker pens.

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

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

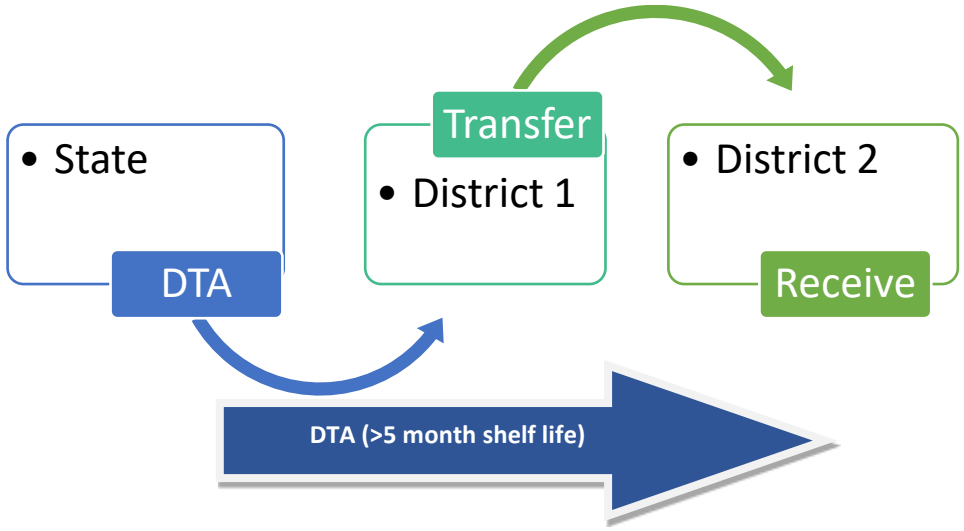
Shelf-life of Anti-TB Drugs

The shelf-life of Anti-TB drugs range from 2-5 years after which the chances of losing efficacy and side-effects thereof increase rapidly. Hence, it is important to ensure that appropriate steps are taken as soon as the drugs reach the critical stage, to ensure their usage well within their shelf-life. In case of direct supplies from Manufacturer /supplier, Pharmacist may check for availability of 5/6 th of shelf life at the time of receipt of drug at their respective stores.



Issue of short-expiry drugs to other districts

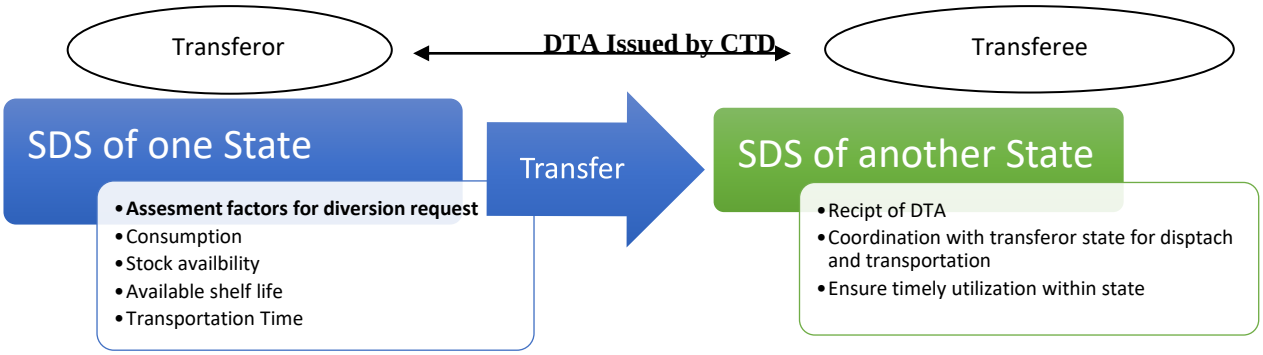
As soon as a decision has been arrived at by the State as regards the quantity of drugs to be issued & diverted, immediate steps for preparation of Drug Transfer Advice shall be taken.



Necessary transportation & logistics arrangements shall be made for diversion from one DTC to other DTC or State Drug Stores. Once the DTA is finalized, based upon requirement & utilization assessment of each district, the DTOs need to accept these drugs. Ideally **at least 5 months shelf life** should remain before the drugs are diverted from one district to another district.

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

Diversion of short-expiry drugs from the State



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

However, it may not be always logistically convenient & feasible to divert drugs from one state to other and ensure utilization in that state. In case the drugs to be diverted are scattered across the state, it becomes all the more difficult and information pertaining to such drugs may not be fully reliable. The drugs to be diverted would need to be transported back to State Drugs Stores from all the DTCs. States shall need to gather accurate inventory & available shelf life of such drugs and make reasonable assessment of transportation time from District TB Centres to State Drug Stores.

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

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

Barcode Interface

BARCODES IN ANTI TB DRUGS

For ensuring better inventory, tracking and supply chain management, bar coding on primary and secondary packaging of drugs has been adopted by the programme.

As per programme technical specifications of drugs, all primary and secondary packaging of drugs should have bar codes imprinted / labelled on them and should contain all requisite information as per guidelines issued by Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi or any Govt. competent authority, as modified from time to time.

The important information which shall be incorporated in bar codes are:

1) Product Name/content
2) Product Strength
3) Batch Number
4) Date of Manufacturing
5) Date of Expiry
6) Manufacturer Address
7) Manufacturer License number
8) Storage conditions requirement

USE OF BARCODES THROUGH NIKSHAY AUSHADHI MOBILE APPLICATION

Nikshay Aushadhi software has an in-built feature of tracking drug stocks with the help of barcode. In addition to barcodes available on anti TB drugs procured by the programme, barcode is also used in managing and tracking the inventory of 2nd line boxes being prepared at State / district levels. For 2nd line boxes, barcode generated by Nikshay Aushadhi application is labelled / affixed on boxes.

Android based Nikshay Aushadhi application can be downloaded from Google Play Store in Tablet computers or mobiles. The programme has also provided tablet computers to states to ensure strengthening of inventory management by adopting bar code mechanism.

PROCEDURE:

To scan a barcode, click on '**Scan**' button.

Place the barcode inside the scan area and scan the barcode from the scanner.

The system will show details of the drug

Once the required information is populated in Nikshay Aushadhi application after scanning bar code, user has to check the information and save the same for further action. Simultaneously, inventory management in Nikshay Aushadhi using barcoding may be used for acknowledgement, receipt and issues of drugs.

ADVANTAGES OF BAR CODE

1. Entering data using bar coding is fast & reliable
2. Significantly reduces human error and increase efficiency
3. Identification of product information

Infrastructure

(1) Location, Space and Storage Arrangements

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

STATE/DISTRICT DRUG STORE

LOCATION

- **Access** :The SDS should be located on a wide road, providing easy access to transportation vehicles throughout the year and 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

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

(II) Specifications for drug stores:-

i. The Drug Store should preferably comprise one large room. Where multiple rooms already exist, they should be contiguous or proximate to each other
Preferably separate space for storage, handling and re-packing of Patient Wise Boxes.

ii. An Ideal store to have:Ceiling height of at least 5 meters, a lockable door, at least one window with grill,(wire meshing / glass shield), proper lighting, an even-level, 'pukka' floor, plastered walls and ceiling with whitewash without any kind of seepage in the room.

iii. In case of a situation where separate room for storing 2nd line drugs is not possible, an attempt to demarcate and enclose a specified area for storing 2nd line

drugs should be made within the larger store to ensure required temperature control for 2nd line drugs.

iv. Architects should be consulted for suitable modifications in the existing drug store/construction of a new drug store for the same.

v. A signage board with instructions in local language should to be put near the entrance of the store to remind the concerned officials regarding good storage practices.

vi. Ideally, Vacuum de watered flooring (VDF) should be used for the Drug Stores. However depending on the feasibility, such flooring may be done at the State Drug Store level.

vii. In case it is feasible at the State Drug Store level, separate areas should be demarcated for receiving and dispatching the drugs.

viii. Contract for Pest Control should be entered into by the State to ensure drug stores free from pests, rodents etc.

ix. Fire extinguisher with AMC should be in place.

2. Shelves, Racks & Storage Arrangements:

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

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

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

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

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

vi. Rows & Columns, where drugs are stored should be defined and locations to be assigned a unique identification number.
In future, if the State Drug Store of a particular state has to handle large volume of drugs and occupies larger space, Isle space (between the two racks across the storeroom) can be of 3 metres. In such situation, material handling equipment shall be required.

3. Stacking Arrangements:

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

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

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

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

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

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

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

4. Control of Humidity and Temperature:

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

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

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

b. **Packaging:** The cartons/drug boxes should not be opened unless necessary.
c. **Circulation:** Use fans to circulate fresh air from outside.

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

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

iv. **Control of temperature:-** The 2nd Line/1st Line FDC Anti-TB Drugs should preferably be stored below **25^0 C**. In the area specified for storing 2nd Line Drugs, temperature of about **20^0 C** should be maintained with the help of Air-Conditioners (Tonnage would depend on size of the room).

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

The purpose of information provided in the above sub-paras is to emphasise that the drugs should be stored in cool & dark place for proper efficacy. Experimental data/literature review also reveals that these drugs loose their efficacy beyond **6 months** if exposed to stressful storage conditions of **$40^0 \pm 2^0$C** temperature and humidity of **75% ± 5** % RH.

Staffing Requirements

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

Overview

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

1. Pharmacist
2. Store Assistant

3. Helper(s)

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

Staff/ Reporting	**SDS**	**DTC**	**TU**	**PHI**
1. Staffing Requirement:				
a) Pharmacist	Required	Required*	Required*	Required*
b) PSM – State Coordinator	Required	Not Required	Not Required	Not Required
c) Store Assistant	Required	Required*	Not Required	Not Required
d) Watchman/ Helper(s)	Required	Not Required	Not Required	Not Required
2. Store staff Reporting to	Deputy STO/ Second Medical Officer	DTO/ MO In-charge	MO In-charge	MO In-charge of PHI

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

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

Post – Pharmacist
Essential Qualification – Degree / Diploma in Pharmacy

Preferential Qualification –

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

Job Specification / responsibilities –

1. Handling of drug stores in the State Drug Stores including Receipts & Issues
2. Recording & reporting of drug stocks at the stores
3. Reconstitution / Repacking of Patient Wise Boxes.
4. Assistance to State in consolidation of district quarter reports& analysis of stock reports.
5. Preparation of State level quarter reports.
6. Data entry in NikshayAushadhi 'web based software for Drug Logistics'.
7. Communication with State/District & Central TB division officials.
8. Assistance in imparting drug logistics trainings to district level pharmacists.
9. Possible visits to districts on issues relating to drug management.

10. Any other job assigned as per programme need.

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

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

Job Specification / responsibilities –

1. Assist Pharmacist in all of the above activities.
2. Any other job assigned as per programme need.

Helper

Stores may hire additional helper for preparing SLD boxes; only cases where boxes prepared monthly are more than 3000.

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.

Management of Second Line Anti TB Drugs

A comprehensive Drug Logistics Management System has been developed and implemented at various levels for RNTCP 2nd Line drug supplies. This chapter outlines the guidance regarding procedures for inventory management of second-line drugs used in the treatment of drug-resistant TB.

12.1 Overview of drug distribution flow

All drugs used in the various DR TB regimens shall be supplied through a centralized procurement system at Central TB Division, MoHFW, GoI. Supplies of the second-line drugs shall be from the respective Government Medical Store Depot (GMSD)/ Central Medical

Services Society (CMSS) to the state drug store (SDS). An advance intimation of all drug supplies shall be communicated to the States for SDS to make available requisite space in the drug store. The State/ SDS shall be supplied only loose form of second-line anti-TB drugs (SLD). On receipt of drugs, the SDS shall acknowledge the receipt to CTD.

The SDS shall repack the loose drugs into one-monthly patient-wise boxes for shorter, longer MDR/RR TB and for H mono/poly DR TB regimen and supply to districts for treatment. SDS shall be preparing 'standardized drug boxes' for standard regimen and supply to districts, namely for shorter MDR/RR TB regimen, all oral longer MDR TB regimen and all oral H mono/poly DR TB regimen.

The composition of Shorter Regimen, all oral longer MDR TB regimen and all oral H mono/poly DR TB regimen is given below –

Regimen class	Intensive/First phase	Continuation/Second phase
H mono/poly DR TB (R resistance not detected and H resistance)		
All oral H mono-poly DR TB regimen	(6) Lfx R E Z X	
MDR / RR TB		
Shorter MDR TB regimen	(4-6) Mfxh Km* Eto Cfz Z Hh E X	(5) Mfxh Cfz Z E X
All oral longer MDR TB regimen	(18-20) Bdq(6) Lfx Lzd# Cfz Cs X	

**If the intensive phase is prolonged, the injectable agent is only given three times a week in the extended intensive phase. 1*

 # Reduce Lzd to 300 mg/day after 6 to 8 months.

In addition to the above, the conventional MDR/XDR-TB regimen already initiated would continue to be supplied, till the State/ District fully transitions to the above regimen. All new patients after implementation of 2019 guidelines would only be placed on the regimen as per the guideline 2019.

Modification/ change in regimen may be required during the course of treatment based on the decision of N/DDR TBC. In such patients, the supply of the monthly box would be as per the regimen-class to which the patient is reclassified to.

The drug box preparation would preferably be done at the SDS level. However, there may be circumstances when the drug box preparation is required to be done at the district level, e.g. unpacking of unused/partially used boxes and preparation of fresh drug box. Whenever the

state has built the capacity of districts, exercise of preparation of patient-wise boxes shall be conducted at DDS under the guidance and supervision of DTO. SDS shall supply additional quantity of SLDs to districts for necessary modifications which will be done at district level.

For meeting the Drug requirement for treatment initiation at N/DDR TBC and box modification at district level, SDS shall supply monthly patient wise boxes & loose SLDs to all N/DDRTBC.

Modification/ change in regimen may be required during the course of treatment based on the decision of N/DDR TBC. In such patients, the supply of the monthly box would be as per modified regimen requirement.

For regimen containing Bedaquiline (Bdq), the patient will be initiated on treatment through a fresh bottle containing full course of requirement. On discharge, the patient will carry the bottle containing Bdq and hand it over to the treatment supporter under supervision/guidance of the senior DR TB/TB-HIV supervisor. Seven days supply of the component drugs of the regimen will also be handed over to the patient/attendant on discharge from the N/DDRTBC. The bottle will remain under custody of the treatment supporter till the patient completes the treatment course, while the Type A box containing remaining drugs will be issued on a monthly basis.

For maintaining inventory of Bdq and its accountability, once BDQ bottle is issued to patients from N/DDR TBC, this will be taken as issue/consumption for recording and reporting under Nikshay and Nikshay-Aushadhi. The patient discharge information shall be communicated to concerned DTO/District/DDS for ensuring continuous supply of the patient's drug requirement.

1.2 Constituents of patient-wise Monthly box

The constituents of the monthly patient-wise box for DR TB patients is detailed in Annexure 17. The patient on shorter MDR TB regimen shall be put on Type A and Type B monthly boxes during intensive phase (IP).

During the continuation phase (CP), the patient will be put on only Type A box for the entire duration. The patient on all oral H mono/poly DR TB regimen or all oral longer MDR TB regimen will be put on Type A box for the whole duration of treatment while Bdq & Dlm will be issued separately and stopped after 6 months.

These drug boxes will be prepared at the SDS or DDS for all standard weight bands. For <16 kg patient, boxes will be prepared from the loose drug provided.

It may be noted that in shorter MDR TB regimen if the intensive phase is prolonged, the injectable agent is only given three times a week in the extended intensive phase. Also, in all

oral longer BDQ containing regimen & DLM containing regimen strength of Linezolid may be reduce to 300 mg/day after 6 to 8 months.

Table 12.1 Drug boxes for standard DR TB regimen

Shorter MDR TB Regimen	
Type A Box (4-6 Months)	**Type B Box (5 Months)**
Moxifloxacin-High Dose (Mfx)[h]	Kanamycin (Km) [#]
Clofazimine (Cfz)	Isoniazid High Dose (H)[h]
Pyrazinamide (Z)	Ethionamide (Eto)
Ethambutol (E)	Pyridoxine (Pdx)
Pyridoxine (Pdx)	
All Oral Longer Bedaquiline Containing Regimen	
Type A Box (18-20 Months)	
Levofloxacin Lfx/ Moxifloxacin Mfx (High Dose) If modification required	
Linezolid (Lzd)-600/300*	
Clofazimine (Cfz)	
Cycloserine (Cs)	
Pyridoxine (Pdx)	
BDQ (Bedaquiline course will be handed over to the patient) **For 6 Months only**	
All Oral Longer Delamanid Containing Regimen	
Type A Box (18-20 Months)	**Type C/P Box (As per applicability) For 6 Months**
Levofloxacin Lfx/ Moxifloxacin Mfx (High Dose)	P1 (Peads.) Containing 8 Strips of DLM
Linezolid (Lzd)-600/300*	P2 (Peads.) Containing 2 Strips of DLM in 6th Month
Clofazimine (Cfz)	C1 (Adult) Containing 15 Strips of DLM
Cycloserine (Cs)	C2 (Adult) Containing 9 Strips of DLM in 6th Month
Pyridoxine (Pdx)	
H mono/poly DRTB Regimen	
Type A Box (6 Months)	

Levofloxacin (Lfx)
Ethambutol (E)
Pyrazinamide (Z)
Rifampicin (R)
Pyridoxine (Pdx)

1.3 Role of various drug stores in constitution of drug boxes

At State drug store level

SDS shall constitute drug boxes (Type A and B) for shorter MDR TB regimen, all oral longer MDR TB regimen and all oral H mono/poly DR TB regimen and supply to respective districts / N/DRTB centers. Loose drugs will also be supplied from SDS to DDS for modification and preparation of new boxes.

At District drug store level

When modification in regimen suggested by DR TBC, District drug storekeeper/Pharmacist shall take a call and prepare modified boxes from loose SLD supplied from SDS. The state shall provide necessary support for capacity building of DDS for carrying out entire exercise of preparing standardized/modified patient-wise drug boxes at DDS level. Dedicated full time District Drug store keeper/Pharmacist is mandatory to be recruited/ placed for successful decentralized system of preparation of drug boxes at DDS level.

The drug dosage for adult DR TB patient (>18 yrs) should be as per the weight bands while children (<18yrs) should be provided as per the dosage table of mg per kg body weight.

Patient initiated on all oral longer MDR TB regimen will receive monthly type A box and complete course of type C box (till the completion of Bedaquiline if it is a part of regimen) as per the regimen decided by N/DDR TBC prepared by DDS/SDS. Patient initiated on shorter MDR TB regimen will receive the monthly type A and type B box during IP and only type A box during Patient initiated on all oral H mono/poly DR TB regimen will receive the monthly type A box as per the regimen. Whenever oral regimens are modified during the course of treatment, DDS needs to ensure that the change in regimen should be incorporated in supply of subsequent boxes.

Drug Dosage of Adult DR-TB patient -

S.No	Drugs	16-29 kg	30-45 kg	46-70 kg	>70 kg

1	Rifampicin(R)[1]	300mg	450mg	600mg	600mg
2	High dose H (H^h)	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) [4]	250 mg	750 mg	1000 mg	1000 mg
6	High dose Mfx (Mfx^h)[4]	400mg	600mg	800mg	800mg
7	Bedaquiline (Bdq)	Week 0–2: Bdq 400 mg daily Week 3–24: Bdq 200 mg 3 times per week			
8	Linezolid (Lzd)	300 mg	600 mg	600 mg	600 mg
9	Clofazimine (Cfz)	50 mg	100 mg	100 mg	200 mg
10	Cycloserine (Cs)[4]	250 mg	500 mg	750 mg	1000 mg
11	Delamanid (Dlm)[4]	50 mg twice daily (100 mg) for 24 weeks in 6-11 years of age 100 mg twice daily (200 mg) for 24 weeks for >11 years of age			
12	Imipenem/cilastatin (Ipm / Cls)[4,5]	1000 mg imipenem/1000 mg cilastatin twice daily			
13	Meropenem(Mpm)[4,5]	1000 mg three times daily (alternative dosing is 2000 mg twice daily)			
14	Amikacin (Am) [2]	500 mg	750 mg	750 mg	1000 mg
15	Kanamycin(Km) [2]	500 mg	750 mg	750 mg	1000 mg
16	Ethionamide (Eto) [4]	375 mg	500 mg	750 mg	1000 mg
17	Na-PAS (60% weight/vol) [3,4]	10 gm	14 gm	16 gm	22 gm
18	Amoxyclav (Amx/Clv) (In child: WHO 80mg/Kg in 2 divided doses) [5]	875/125 mg BD	875/125 mg BD	875/125 mg (2 morning +1 evening)	875/125 (2 morning +1 evening)
19	Pyridoxine(Pdx)	50 mg	100 mg	100 mg	100 mg

[1]*For 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)*
[4]*Drugs can be given in divided doses in a day in the event of intolerance*
[5]*Not regularly supplied by the program. If needed for individual patients, may be procured at state/district level***Drug dosage for Pediatric DR-TB patients –**

DRUGS	Daily Dose (Pediatric)	DAILY DOSE (Adult)
Isoniazid1	7–15 mg/kg for patients less than 30 kg; max dose 300 mg daily	4–6 mg/kg once daily High –dose: 16–20 mg/ kg once daily

Rifampicin	10–20 mg/kg for patients less than 30 kg; max dose 600 mg daily	8–12 mg/kg once daily
Pyrazinamide	30–40 mg/kg for patients less than 30 kg; max dose 2000 mg daily	20–30 mg/kg once daily
Ethambutol	15-25 mg/kg once daily	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 months) 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 1000mg)	15–20 mg kg once daily
Amikacin	15–30 mg/kg once daily (Max 1000mg)	15–20 mg kg once daily
Capreomycin	15–30 mg/kg once daily (Max 1000mg)	15–20 mg kg once 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 co-infection) should also receive pyridoxine 5–10 mg/day

1.4 PACKING INSTRUCTIONS

- packaging of loose drugs into Type A & B boxes should be done under guidance of the STO/Medical Officer/Drug logistics In-charge at State level and district level;
- one monthly pouch of Cap. Cs & Tab. E each should be made from plastic bag with ziplock facility in which 1 gm. pouch of silica gel desiccant should be kept. In each Type A box, one pouch of silica gel desiccant of 4 gm weight should also be kept;
- each Type A & B box should be made using Nikshay Aushadhi. The boxes would be auto-numbered and same should be printed at SDS. The record of the serial no. of the box should

be maintained at the State, District & Sub-district (TU) Drug Stores. This would be of help while tracking a particular box.

- Labels for the boxes should be developed through the Nikshay Aushadhi Software only.:
    - item-wise name of drugs with quantity of each drug in the box;
    - batch no. & DOE of individual drugs;
    - DOE of boxes-expiry date of the drug having shortest expiry;
    - date of issue of the box from SDS;
    - serial number of the box;
    - storage instructions on the box for ensuring adequate precautions in storage of the drugs, especially at Treatment supporter level. Some suggested messages are: “store in a cool and dark place, preferably in a clean cupboard”; “do not expose to direct sunlight”; “keep away from children/unauthorized persons”; and or “box to be closed properly every time after withdrawal of drugs”.

Prototype of label is suggested in Annexure 18. The Nikshay Aushadhi software helps in preparing boxes by estimating number of boxes of required regimen that can be prepared from available stock. Label for prepared boxes to be printed directly from the system.

For each cycle of box preparation, a label which contains expiry-wise drug content of these boxes to be generated through the system. This label should be used to paste over the boxes prepared during that cycle only. Other steps include:

Barcoding and real time tracking system: Both first-line & second-line drugs provided under the programme are barcoded. The Nikshay Aushadhi software has an in-built feature of tracking drug stock with the help of barcode. The drug box label with barcode may be printed at state or district level as per the programme guideline and pasted over the boxes where it is prepared.

1.5 Drug management cycle of second-line anti-TB drugs

The management cycle of second-line anti-TB drugs comprises six elements, namely, drug selection; quantitative assessment of drug requirements; management of procurement; distribution protocol; assurance of drug quality; and ensuring rational drug use. Accurate demand forecasting of second-line anti-TB drugs, (correct quantification of drug needs for a specific period of time) is one of the elements guaranteeing an uninterrupted drug supply.

***Inventory management*:** Procedures for ongoing tracking and replenishment of the inventory of second-line anti-TB drugs at SDS and all subordinate stocking points ensures these are maintained at or close to the stocking norms presented below:

Table 12.2 Standard 1-month drug box for various DR-TB regimen

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 month	(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)

*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.

1.6 MONITORING OF DRUG DISTRIBUTION AND SUPPLY CHAIN MANAGEMENT

***Distribution from Centre to SDS*:** As mentioned in overview of this chapter, loose SLD shall be supplied to SDS directly from Centre. The regular process of supply of new stock of drugs to the SDS begins only when the state submits their requirement to CTD. 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 SDS pharmacist shall raise a request through Nikshay Aushadhi in the prescribed format available in the software. The request through Nikshay Aushadhi shall be verified by STO of all SDSs, in the state. The state shall facilitate in determination of drug stocks available with SDS (s) within the state. This requisition through Nikshay Aushadhi shall be submitted online to CTD by the state as per the reporting guidelines, by the 10thof every month / Qtr. In the event of more than one/ multiple SDSs within the state, all the requisition through Nikshay Aushadhi shall be forwarded to CTD within the timelines stated above. 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	07th of each subsequent month
TU to DTC	By 10 of the month after subsequent quarter
DTC to SDS / STO	By 12th of the month after subsequent quarter

STO to CTD	By 15th to 20th of the month after subsequent quarter

***Distribution from SDS to District*:** The SDS will supply drugs to the DTCs in the form of monthly patient-wise Type A and Type B drug boxes and loose second line drugs, every quarter. It shall review quarterly consumption report received from linked districts through Nikshay-Aushadhi and issue Type A & B boxes as well as loose medicines to the district. The DTC shall send the boxes to its implementing TU in a similar manner on quarterly basis and then monitor through the TU quarterly SLD requirement report. Buffer stocks of both Type A & B boxes of all weight bands shall be held at all levels as per stocking norms. The district will ensure arrangement for supply of monthly drug boxes from the respective TUs to PHIs and from PHIs to the Treatment supporters/center. The STS shall identify the Treatment supporter in consultation with MO-PHI and the patient. Considering further decentralization of services, SDS will supply loose oral SLD to the DDS for modification in regimen.

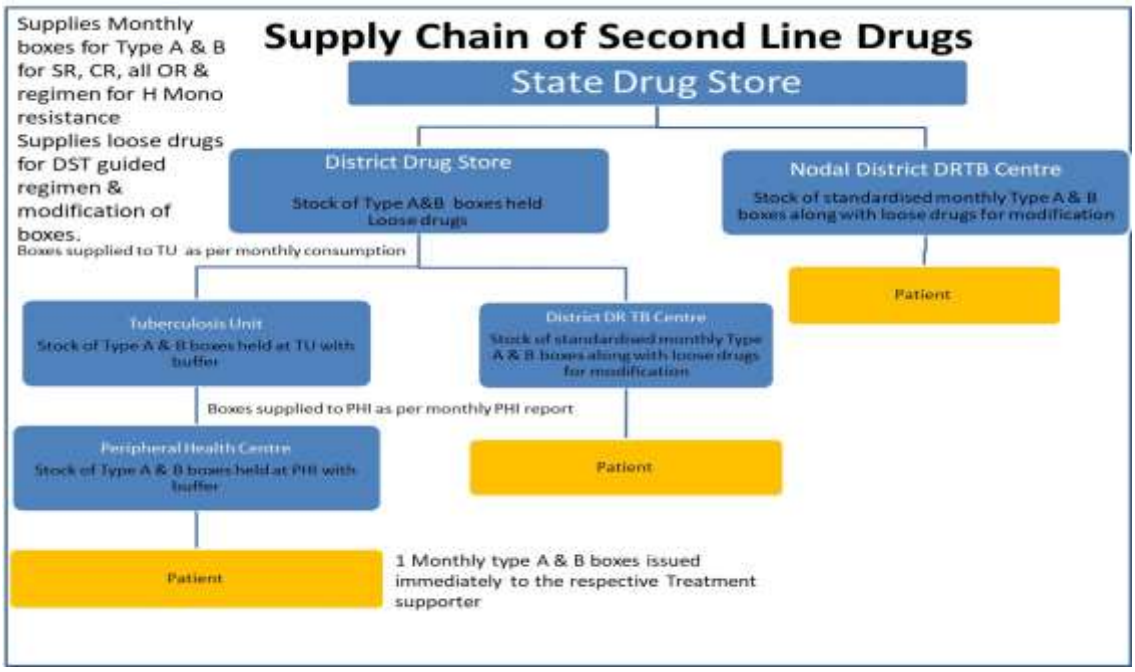
***Distribution of SLDs to N/DDR TBC*:** State shall issue standardized monthly patient wise boxes to N/DDR TBC from SDS. SDS shall also issue loose drugs for modification of regimen. Issuance of monthly Patient boxes and loose drugs to N/DDR TBC from SDS shall be based on the monthly stock statement/requisition submitted by N/DDR TBC, to ensure adequate stocks for a month of treatment, plus a buffer of one month. The patient would be initiated on treatment with the monthly patient wise box and on discharge from N/DDR TBC, patient shall be given the remaining drugs of the monthly patient boxes to cover the transit period. During this time, it is expected that the patient shall reach home for the ambulatory treatment and continue the therapy with the monthly IP box which has been issued to the respective treatment supporter. For patient put on Bdq treatment, Bdq bottle contains entire course of treatment for one patient which shall be earmarked for each enrolled patient and handed over to treatment supporter in supervision of District DR TB TB-HIV Supervisor.

***Distribution from DDS to TU drug stores*:** Buffer stock equivalent to two months will be kept at the TU. The drug boxes will be supplied from the TU to PHI every month. These will be transferred from the TU to respective PHI as per monthly consumption report submitted by PHI through Nikshay-Aushadhi.

Distribution from TU drug store to PHI: Buffer stock equivalent to two months will be kept at the PHI at the beginning of each month. The drug boxes will be supplied from PHI to Treatment centre/ Treatment supporter. All PHIs may not have reserve stock. Only PHIs where patient/s are initiated or on treatment will have reserve stock of second-line drugs.

Drug stock register (Annexure- 19) is to be maintained in the drug stores at all levels. Details such as drugs received, distributed and balance stock are to be entered in this register. Drug distribution mechanism is supported by Nikshay Aushadhi where drugs stock, dispatch and return of drug can be reported through tracking of the drug. The system is able to capture information log of boxes allotted to the patients who are provided by each health facility who is using this software for drug management purpose.

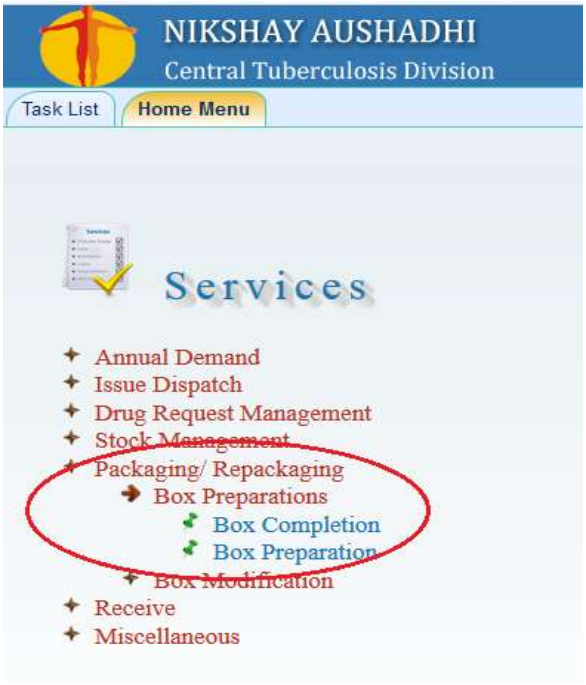
Flow chart of supply chain management of Second line drug is illustrated below: -



i. Box Preparation at State Drug Store:-

Steps for Box preparation on Nikshay Aushadhi portal is illustrated below:-

Path: Services→Packaging/Re-Packaging→Box Preparations→Box Preparation



This Process is used to prepare boxes.

1. Select Store Name as any SDS, TB Sub Category

2. Select Drug/ Box Name.

3. Click on Go Button.

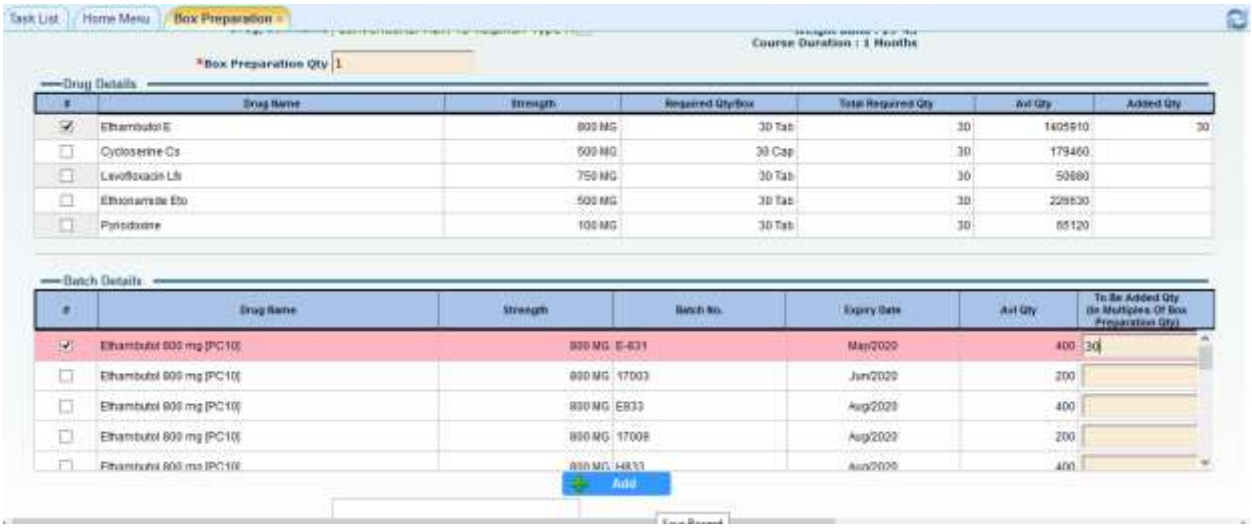
Illustration of operation on Nikshay Aushadhi is given below:-

4. Fill Box Preparation Quantity.

4. Select a drug by checking the checkbox from Drug Details table. On checking the checkbox, Batch details table will appear. Click on each checkbox to fill the To Be Added Qty (in multiples of Box Preparation Qty) certain validations will restrict user to fill to be added qty which are given as follows:

(a.) To Be Added Qty cannot be greater than the Avl Qty.

(b.) Sum of To Be Added Qty of all the filled textbox cannot be greater than the 'To be Used Qty' given in the drug details table.



Added Qty in the drug details gets calculated on the basis of the given formula:

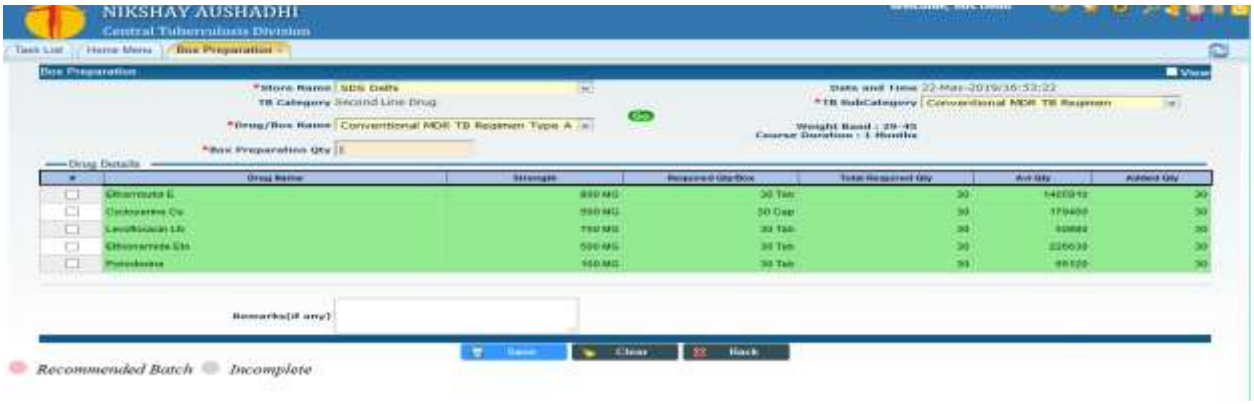
Added Qty =∑ ((Strength of the checked Batch Details* value filled in To Be Added Qty for the checked batch details) / Strength of the checked drug details.)

Note: If any strength in the batch details section is greater than the strength in batch details, then for the above calculation, it is considered equal to the strength in the drug details section.

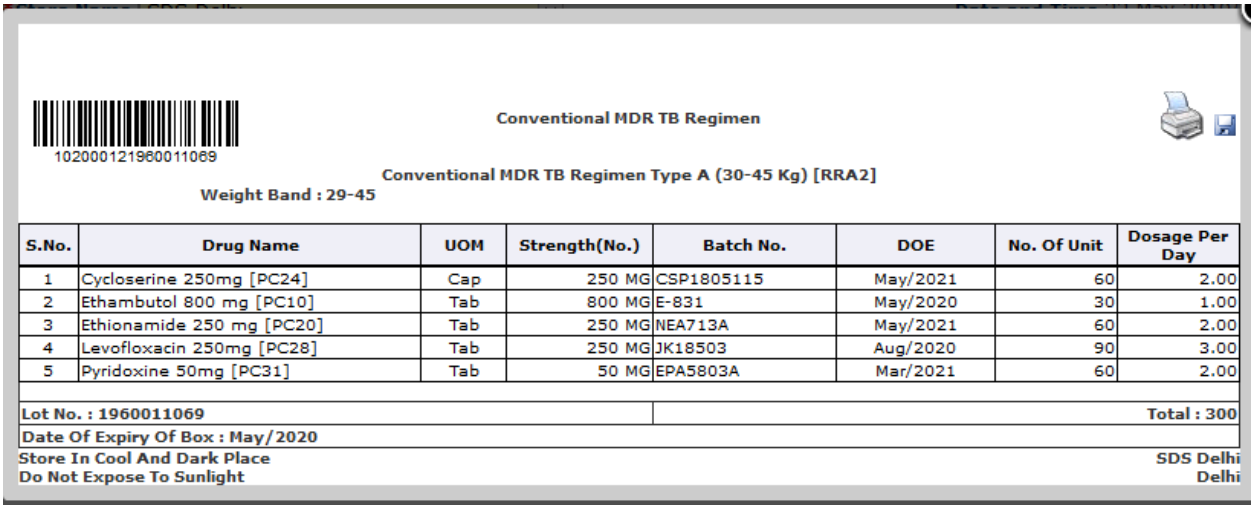
6. The first batch is highlighted with pink color which shows that it is the recommended batch and is to be used first since this is the batch with the nearest expiry among all the batches listed (not mandatory however an alert will be given to tell that the recommended batch has not been selected yet.)

7. Click on Add Button. The selected row in the drug details gets colored in green which means that the given drug has been successfully added.

8. Repeat steps **5-8**after adding one drug in order to fill more drugs in a box.



9. Click on Save. A voucher gets generated as shown below thereby ending the process.



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Conventional MDR TB Regimen

Conventional MDR TB Regimen Type A (30-45 Kg) [RRA2]

Weight Band : 29-45

S.No.	Drug Name	UOM	Strength(No.)	Batch No.	DOE	No. Of Unit	Dosage Per Day
1	Cycloserine 250mg [PC24]	Cap	250 MG	CSP1805115	May/2021	60	2.00
2	Ethambutol 800 mg [PC10]	Tab	800 MG	E-831	May/2020	30	1.00
3	Ethionamide 250 mg [PC20]	Tab	250 MG	NEA713A	May/2021	60	2.00
4	Levofloxacin 250mg [PC28]	Tab	250 MG	JK18503	Aug/2020	90	3.00
5	Pyridoxine 50mg [PC31]	Tab	50 MG	EPA5803A	Mar/2021	60	2.00

Lot No. : 1960011069 **Total : 300**

Date Of Expiry Of Box : May/2020

Store In Cool And Dark Place **SDS Delhi**

Do Not Expose To Sunlight **Delhi**

ii. Box Completion (In case of Incomplete Boxes)

In case of unavailability of certain drugs at State Drug Store, an incomplete box may be prepared by SDS and which will be completed later by adding the particular drugs. If some drug is unavailable at SDS but the same is available at DDS, SDS may prepare the incomplete box and issue the box to DDS for completion of box by adding the drug from its inventory.

Steps for completion of Patient wise monthly box at DDS are illustrated below:-

Path: Services→Packaging/Re-Packaging→Box Preparations→Box Completion

This process is used to add drugs in box if drugs are remaining in Box Preparation Process.

1. Select Store Name as SDS/ DDS TB Sub Category,

2. Select Regimen. On selecting the regimen those batches which are having incomplete boxes will get displayed within the Batch combo box. On selecting the batch from the combo box, Drug Details section will get displayed.

<u>The Criteria for making a complete box is:</u>

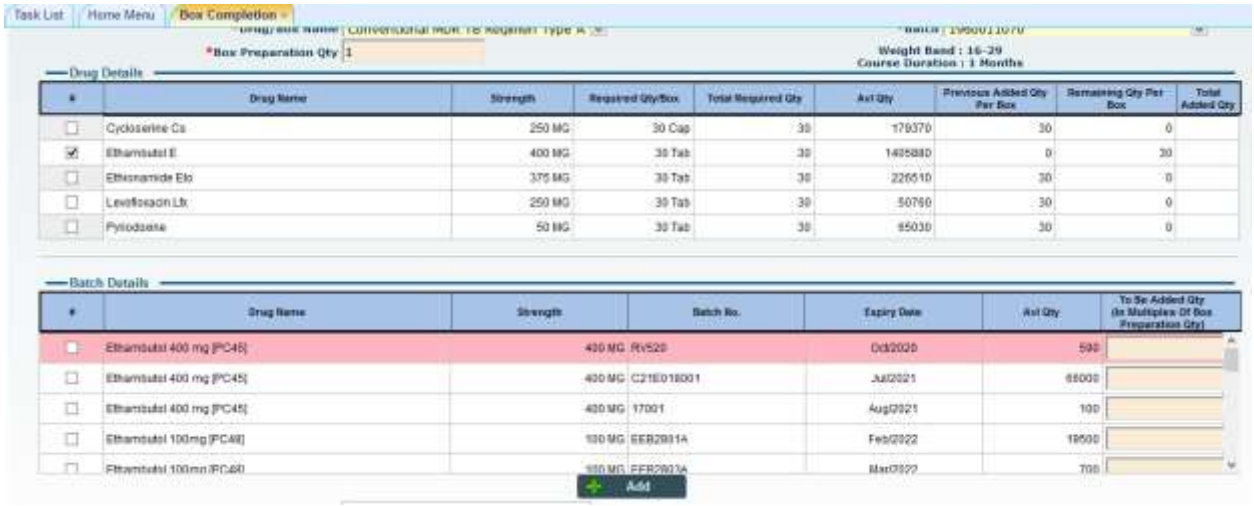
Added Qty per Box= Box Preparation Qty * Remaining Qty per Box

1. Select a drug by checking the checkbox from Drug Details table. On checking the checkbox, Batch details table will appear. Click on each checkbox to fill the To Be Added Qty(in multiples of Box Preparation Qty) Certain validations will restrict user to fill the to be added qty which are given as follows:

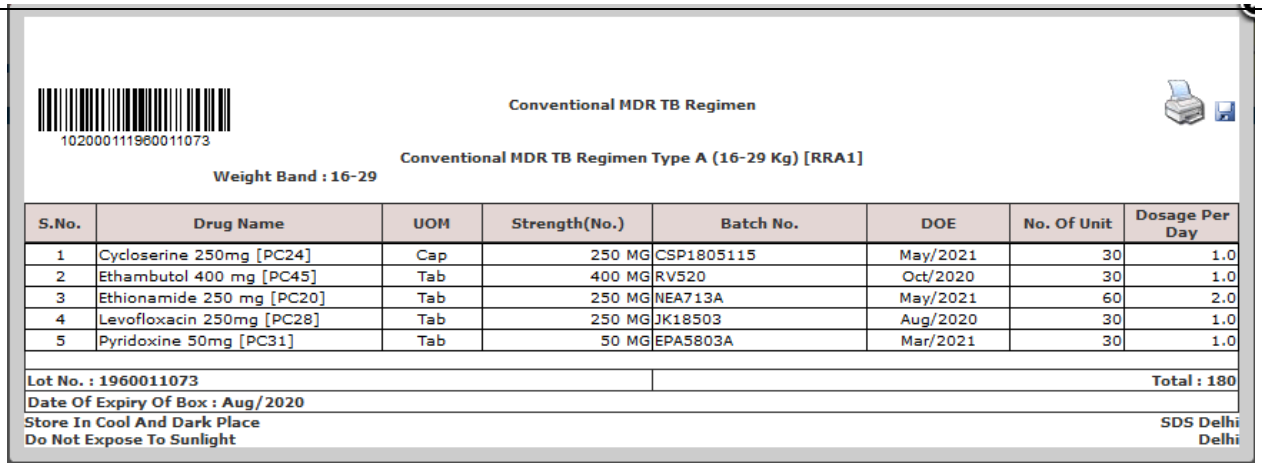
2. To Be Added Qty cannot be greater than the Avl Qty.
3. Sum of To Be Added Qty of all the filled textbox cannot be greater than the 'To be Used Qty' given in the drug details table.
4. To Be Added Qty can only be entered in the multiples of Box Preparation Qty.
5. Added Qty in the drug details gets calculated on the basis of the given formula:

   Added Qty per Box =∑ ((Strength of the checked Batch Details* value filled in To Be Added Qty for the checked batch details) / Strength of the checked drug details.)

   Note: If any strength in the batch details section is greater than the strength in batch details, then for the above calculation, it is considered equal to the strength in the drug details section.
6. The first batch is highlighted with pink color which shows that it is the recommended batch and is to be used first since this is the batch with the nearest expiry among all the batches listed (not mandatory however an alert will be given to tell that the recommended batch has not been selected yet.



7. Click on Add Button. The selected row in the drug details gets colored in green which means that the given drug has been successfully added.
8. Repeat steps **5-9** after adding one drug in order to fill more drugs to complete a box.
9. Click on Save. A voucher gets generated as shown below thereby ending the process.



102000111960011073

Conventional MDR TB Regimen

Conventional MDR TB Regimen Type A (16-29 Kg) [RRA1]

Weight Band : 16-29

S.No.	Drug Name	UOM	Strength(No.)	Batch No.	DOE	No. Of Unit	Dosage Per Day
1	Cycloserine 250mg [PC24]	Cap	250 MG	CSP1805115	May/2021	30	1.0
2	Ethambutol 400 mg [PC45]	Tab	400 MG	RV520	Oct/2020	30	1.0
3	Ethionamide 250 mg [PC20]	Tab	250 MG	NEA713A	May/2021	60	2.0
4	Levofloxacin 250mg [PC28]	Tab	250 MG	JK18503	Aug/2020	30	1.0
5	Pyridoxine 50mg [PC31]	Tab	50 MG	EPA5803A	Mar/2021	30	1.0

Lot No. : 1960011073 Total : 180

Date Of Expiry Of Box : Aug/2020

Store In Cool And Dark Place SDS Delhi

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1.6.2 Regimen wise Box Modification at District Drug Store

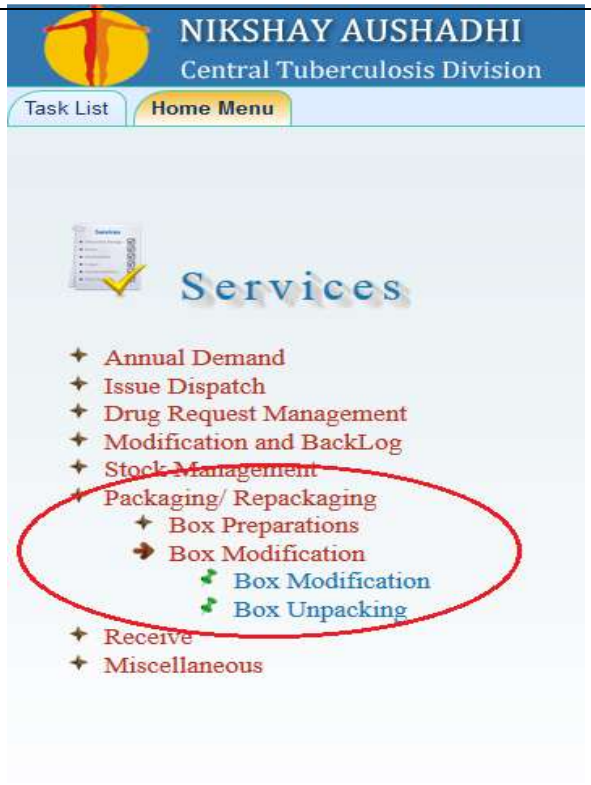
Scenario 1-Modification in regimen: If N/DDR TBC committee decides on modification of regimen, DDS shall prepare modified Type A or B boxes from available standard boxes using loose replacement SLD available at district level and arrange supply to treatment supporter. DTO needs to ensure that the drugs should be supplied as per the modified regimen for all subsequent months.

Scenario2-Extension of intensive phase: If IP of the patient is required to be extended; the respective N/DDR TBC committee shall inform DTO who will intimate the same to the MO-PHI and the respective TU. The PHI will release one-month drug box for MDR TB regimen or H mono/poly DR TB regimen to the respective treatment centre from where the patient is taking treatment. When the patient is switched to CP in case of shorter MDR TB regimen, the DTO shall intimate the same to the MO-PHI and the respective TU. On instruction of DTO, the PHI will release 1 Type A box only to the respective Treatment centre from where the patient is taking treatment. In the case of all oral longer MDR TB regimen, after completion of 6 to 8 months of treatment, the dosage of Lzd should be reduced to 300 mg as per the directives of N/DDR TBC. All patients must complete the monthly box before switching to subsequent box provided. In situations where the extension of IP is required, other drugs in the regimen will be given for extended period while newer drug like Bdq or Dlm should be given till the completion of 24 weeks only.

Scenario 3- Change in regimen: If DR TBC Committee decides to change the regimen then DDS shall arrange supply of new treatment regimen box from PWB/loose drugs supplied from the SDS and the unused drugs including Bdq container should be sent back to DDS. In such situation patient should be immediately switched to the new regimen designed by N/DDR TBC.

Steps for Monthly patient wise box Modification on Nikshay Aushadhi is as under:-

Path: Services→Packaging/Re-Packaging→Box Modification→Box Modification

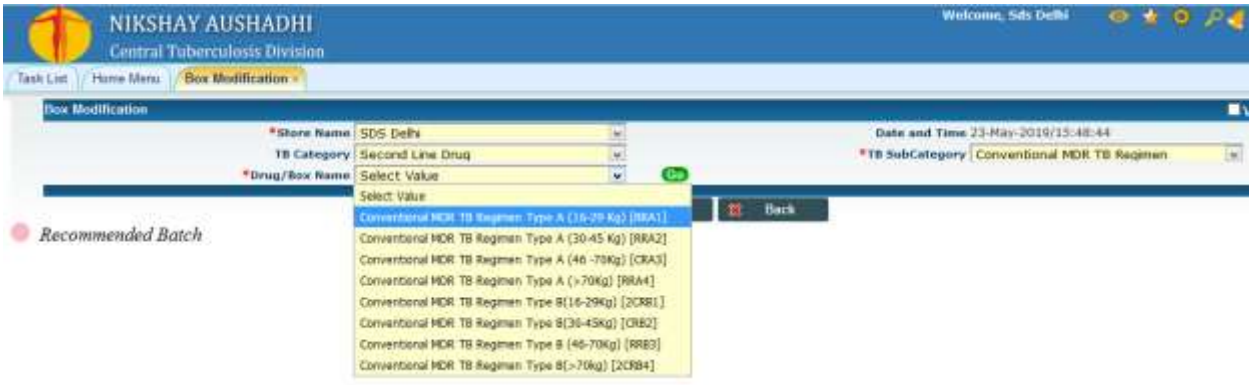


This Process is used to Modify the unpacked Second line Drugs.

1. Select Store Name as any SDS, TB Sub Category

2. Select Drug/ Box Name.

3. Click on Go Button.



4. Fill Box Preparation Quantity. After filling the quantity, "To be used' quantity column will be get updated as:

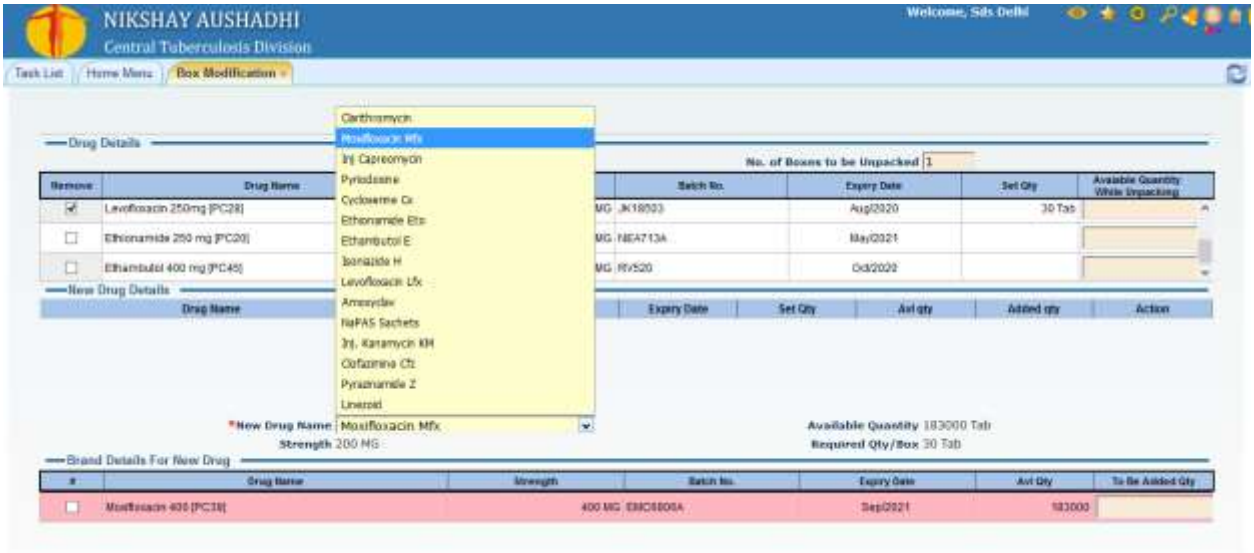
To Be Used Qty= Box Preparation Qty * Required Qty /Box

5. Select a drug by checking the checkbox from Drug Details table. On checking the checkbox, Batch details table will appear. Click on each checkbox to fill the To Be Added Qty(in

multiples of Box Preparation Qty) Certain validations will restrict user to fill the to be added qty which are given as follows:

(a.) To Be Added Qty cannot be greater than the Avl Qty.

(b.) Sum of To Be Added Qty of all the filled textbox cannot be greater than the 'To be Used Qty' given in the drug details table.



6. Added Qty in the drug details gets calculated on the basis of the given formula:

Added Qty =∑ ((Strength of the checked Batch Details* value filled in To Be Added Qty for the checked batch details) / Strength of the checked drug details.)

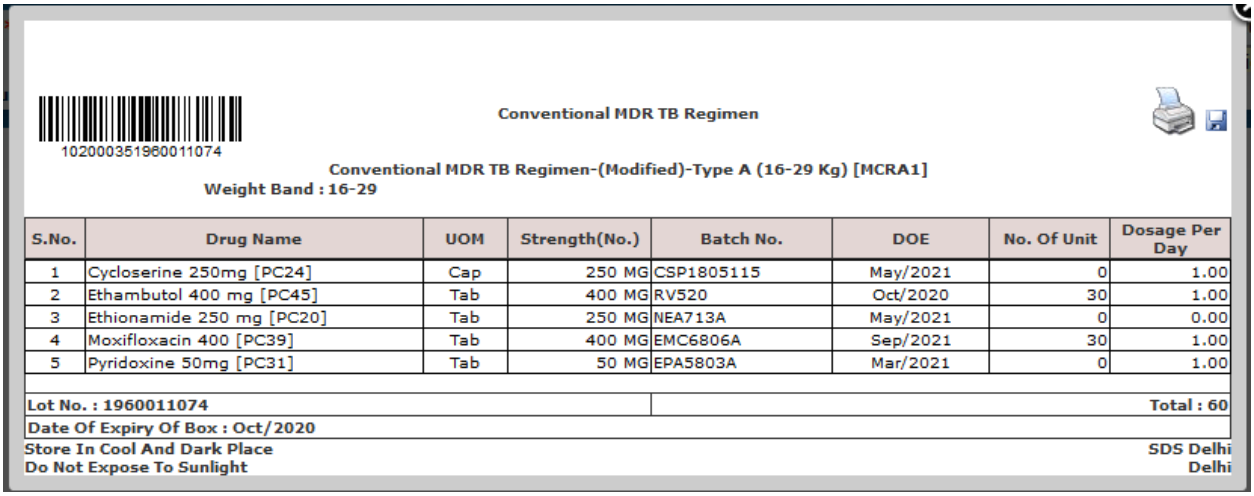
Note: If any strength in the batch details section is greater than the strength in batch details, then for the above calculation, it is considered equal to the strength in the drug details section.

7. The first batch is highlighted with pink color which shows that it is the recommended batch and is to be used first since this is the batch with the nearest expiry among all the batches listed (not mandatory however an alert will be given to tell that the recommended batch has not been selected yet.)

8. Click on Add Button. The selected row in the drug details gets colored in green which means that the given drug has been successfully added.

9. Repeat steps **5-8** after adding one drug in order to fill more drugs in a box.

10. Click on Save. A voucher gets generated as shown below thereby ending the process.



10200035196001107 4

Conventional MDR TB Regimen

Conventional MDR TB Regimen-(Modified)-Type A (16-29 Kg) [MCRA1]

Weight Band : 16-29

S.No.	Drug Name	UOM	Strength(No.)	Batch No.	DOE	No. Of Unit	Dosage Per Day
1	Cycloserine 250mg [PC24]	Cap	250 MG	CSP1805115	May/2021	0	1.00
2	Ethambutol 400 mg [PC45]	Tab	400 MG	RV520	Oct/2020	30	1.00
3	Ethionamide 250 mg [PC20]	Tab	250 MG	NEA713A	May/2021	0	0.00
4	Moxifloxacin 400 [PC39]	Tab	400 MG	EMC6806A	Sep/2021	30	1.00
5	Pyridoxine 50mg [PC31]	Tab	50 MG	EPA5803A	Mar/2021	0	1.00

Lot No. : 1960011074 **Total : 60**

Date Of Expiry Of Box : Oct/2020

Store In Cool And Dark Place **SDS Delhi**

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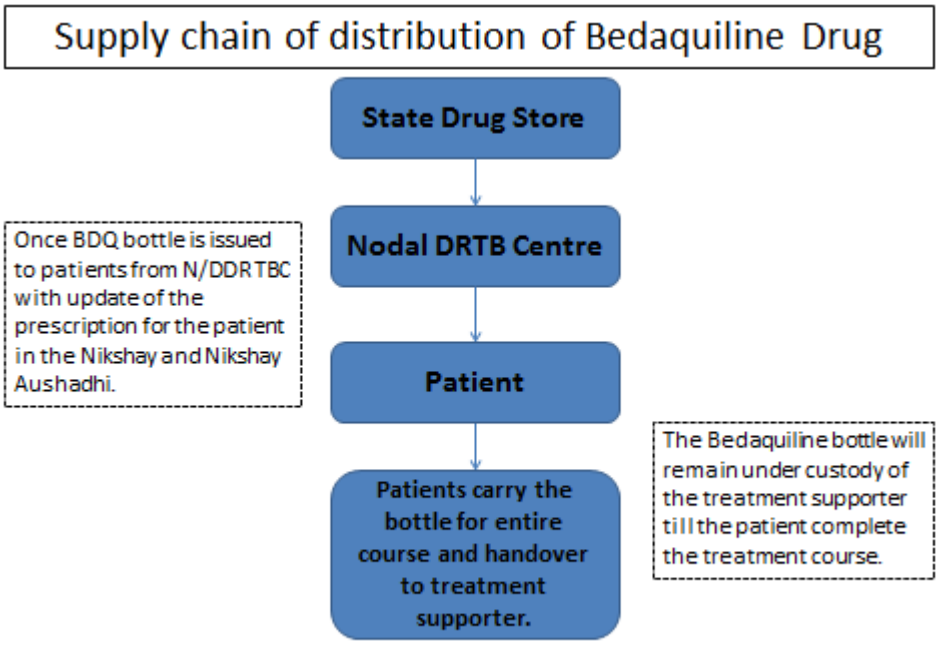
1.6.3 Supply Chain Management of Bedaquiline

For regimen containing Bdq, on discharge, the patient will carry the bottle containing Bdq and hand it over to the treatment supporter under supervision of the senior DR TB/TB-HIV supervisor. The bottle will remain under custody of the treatment supporter till the patient complete the treatment course, while the Type A box containing remaining drugs compositing regimen will be issued on a monthly basis.

For maintaining inventory of Bdq and its accountability, once BDQ bottle is issued to patients from N/DDR TBC with update of the prescription for the patient in the Nikshay and Nikshay

Aushadhi. Information should be communicated to concerned DDS, the stock is entered in the stock register at DDS. The bottle provided to the patient must be handed over to the treatment supporter. Senior DR TB TB-HIV Supervisor of the district shall be the link for passing information to DDS keeper regarding BDQ stock supplies to treatment supporter. DDS keeper shall keep a record of the patients' stock of BDQ in the district drug stock register.

Flow chart of supply chain management of Bedaquiline is illustrated below: -



1.6.4Supply Chain Management of Delamanid

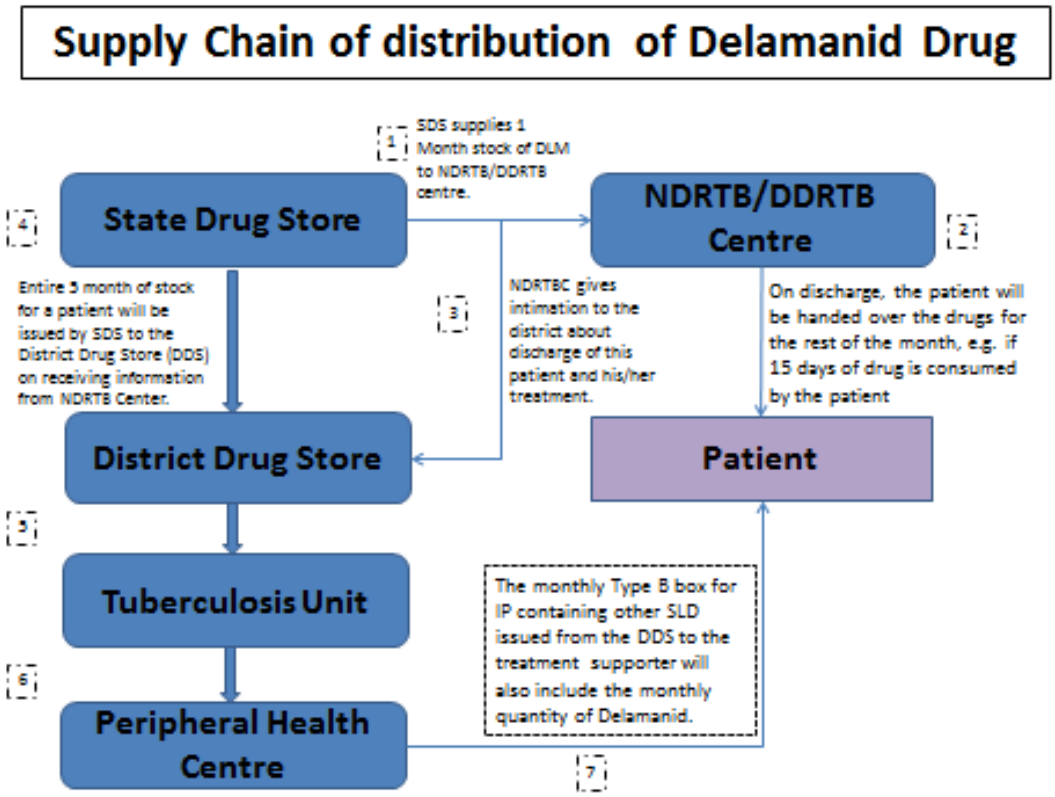
Delamanid will be supplied to the state drug stores (SDS). It has a shelf-life of 5 years and requires to be stored at 25 ºC (15–30 ºC). The drug would be dispensed in the form of strips,

supplied in box of 48 film-coated tablets in aluminium / aluminium packing. Delamanid strips will be issued by the SDS along with the other second-line drugs through the NDR TB centers where the patient is initiated on treatment. From the SDS, on initiation of treatment patient's one-month drugs requirement will be managed. On discharge, the patient will be handed over the drugs for the rest of the month, e.g. if 15 days of drug is consumed by the patient at the NDR TBC then the remaining 15 days (of the one month's course) will be handed over to the patient under information to District TB Officer, Senior Treatment Supervisor, Senior District DR TB & HIV supervisor for management of this patient through the treatment supporter.

Delamanid stock will be issued by SDS to the District Drug Store (DDS) as and when the NDRTBC gives intimation to the district about discharge of this patient and his/her treatment. The

monthly Type B box for the intensive phase containing other second line drugs issued from the DDS to the treatment supporter will also include the monthly quantity of Dlm. The Type B box will be issued on a monthly basis till the end of IP along with the Type A with monthly quantities of Dlm.

Flow chart of supply chain management of Bedaquiline is illustrated below: -



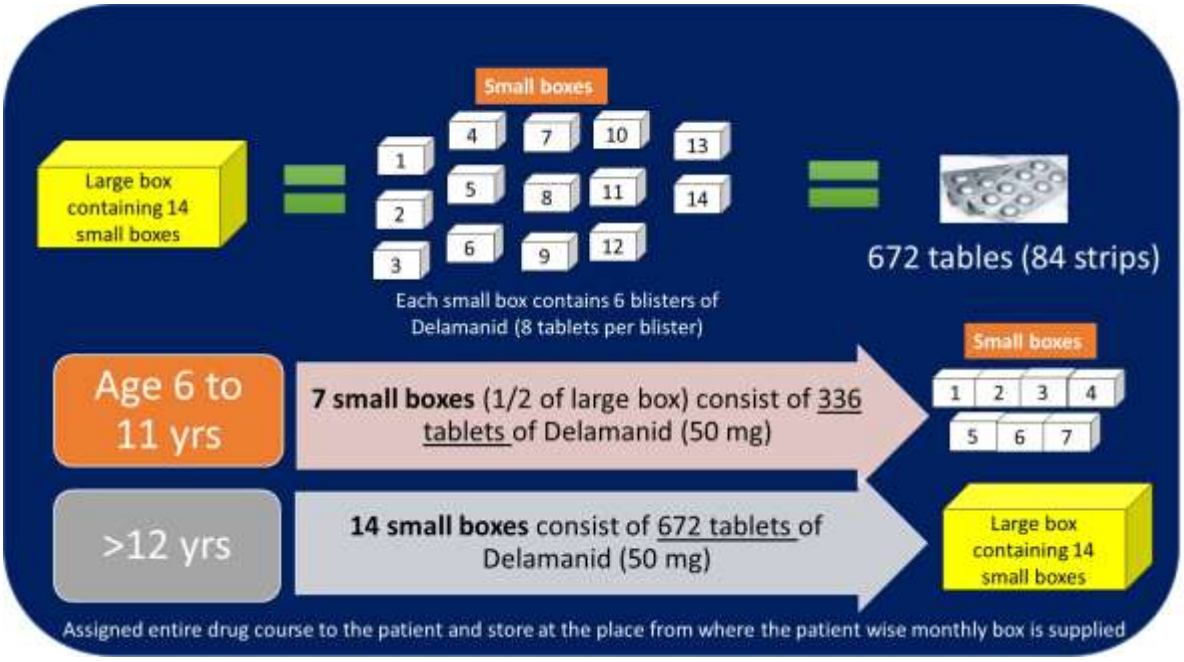
Management of patient drug course

Delamanid will be provided with other second line drugs for a period of 24 weeks, supplied on a monthly basis. Dlm is available as 50mg tablets and the recommended dose is 50 mg twice a day for (6- 11yrs) and 100 mg twice a day for 12 – 17 yrs for 24 weeks

a) 6 years to 11 years of age: 2 tablets a day. 7 boxes to be provided for full duration of treatment. Each box contains 48 tablets i.e. 6 strips of 8 tablets per strip. Patient is provided with 8 strips (64 tablets) every month for 5 months. The four extra tablets issued every month are carried over and in the sixth month only 2 strips are issued, thereby ensuring that the patient consumes only 36 tablets over 18 days.

b) 12 years and above: 4 tablets a day. 14 boxes to be provided for full duration of treatment. Each box contains 48 tablets i.e. 6 strips of 8 tablets per strip. Each box contains 48 tablets i.e. 6 strips of 8 tablets per strip. Patient is provided with 15 strips (120 tablets) every month for 5 months. Only 9 strips are issued in the sixth month thereby ensuring that the patient consumes only 72 tablets over 18 days.

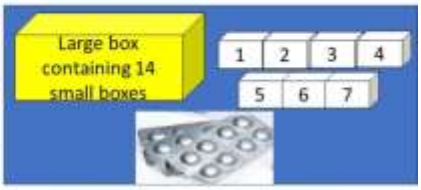
The table below provides the diagrammatic representation of the same:



For Age Group 6-11 Years (Paediatric Patient)

Regimen Box	Month	Monthly Dosage Requirement	Strips to be included in the box
Type P1	1 Month	2 Tabs X 30 Days= **60** Tabs*	8 Strips (containing 64 Tabs)
	2 Month	2 Tabs X 30 Days= **60** Tabs*	8 Strips (containing 64 Tabs)
	3 Month	2 Tabs X 30 Days= **60** Tabs*	8 Strips (containing 64 Tabs)
	4 Month	2 Tabs X 30 Days= **60** Tabs*	8 Strips (containing 64 Tabs)
	5 Month	2 Tabs X 30 Days= **60** Tabs*	8 Strips (containing 64 Tabs)
Type P2	6 Month	2 Tabs X 18 Days= **36** Tabs	2 Strips (containing 16 Tabs)
	Total	**336 Tabs**	**42 Strips**

* Balance tablets (4 in each month) from 1-5 Month will be adjusted in the 6 month to complete the dosage of last month.



For Age Group 12 & above

Regimen Box	Month	Monthly Dosage Requirement	Strips to be included in the box
Type C1	1 Month	4 Tabs X 30 Days= **120** Tabs	15 Strips
	2 Month	4 Tabs X 30 Days= **120** Tabs	15 Strips
	3 Month	4 Tabs X 30 Days= **120** Tabs	15 Strips
	4 Month	4 Tabs X 30 Days= **120** Tabs	15 Strips
	5 Month	4 Tabs X 30 Days= **120** Tabs	15 Strips
Type C2	6 Month	4 Tabs X 18 Days= **72** Tabs	9 Strips
	Total	**672 Tabs**	**84 Strips**

1.7 Repackaging/Reconstitution and use of partially used Second Line Drug Boxes, BDQ and DLM

- In case of default/death/transferred-out/treatment stopped patients, unconsumed boxes shall be brought back from Treatment centre to PHI to TU to DTC within the shortest possible time. The unconsumed box returned to the DTC should be updated in Nikshay Aushadhi. All loose drugs remaining in the boxes received back shall be accounted for in the Stock register and Nikshay Aushadhi at the DDS and same will be issued as per FEFO principles to either N/DDR TBC or for use as loose drugs or for repackaging into monthly boxes;
- Partially used BDQ bottle shall be sent back to SDS where repackaging will also be done. Remaining tablets in the bottle received back shall be accounted for in the Stock register and Nikshay-Aushadhi at SDS. Upon reconstitution, the bottle shall be accounted for in the Stock register (loose tablets to be mentioned in remarks column) to be issued as per FEFO principles. When reconstitution is done, tablets of same expiry can be considered using same container to a maximum of 188 tablets. These reconstituted containers shall be used for treatment of subsequent patients found eligible for Bdq. This reconstitution exercise should be done at the SDS. All such drugs that are taken from the new containers shall be collected as a group of 188 tablets of same expiry and put in a light resistant container as per advice from the manufacturer. The actual expiry of tablets should be mentioned over the container;
- In the event of SDS falling short of 188 tablets from an expiry batch, reconstitution can still be done using number of tablets to complete 188 tablets with another expiry batch. In such a case, tablets of the respective expiry should be retained in their same respective

containers and issued to patients and providers with counselling to consume the tablets with the nearest expiry first; and

- If expiry of remaining tablets is less than six months, the same shall be consumed at NDR TBC for admitted patients. It will be adjusted from the new long expiry bottle on discharge.

The unconsumed box returned to the DTC should be updated in Nikshay Aushadhi. All loose drugs remaining in the boxes received back shall be accounted for in the Stock register and Nikshay Aushadhi at the DDS and same will be issued as per FEFO principles to either DR TBC or for repackaging into monthly Type A or B boxes. On Nikshay Aushadhi Unconsumed/ Partially consumed boxes returned from PHI will be updated in "Unpacking Box" option. Steps for unpacking of Unconsumed/ Partially consumed boxes returned from PHI on Nikshay Aushadhi are as follows:-

Path: Services→Packaging/Re-Packaging→ Packaging/Re-Packaging→Box Modification →Box unpacking

1. Select Store Name as any SDS, TB Sub Category

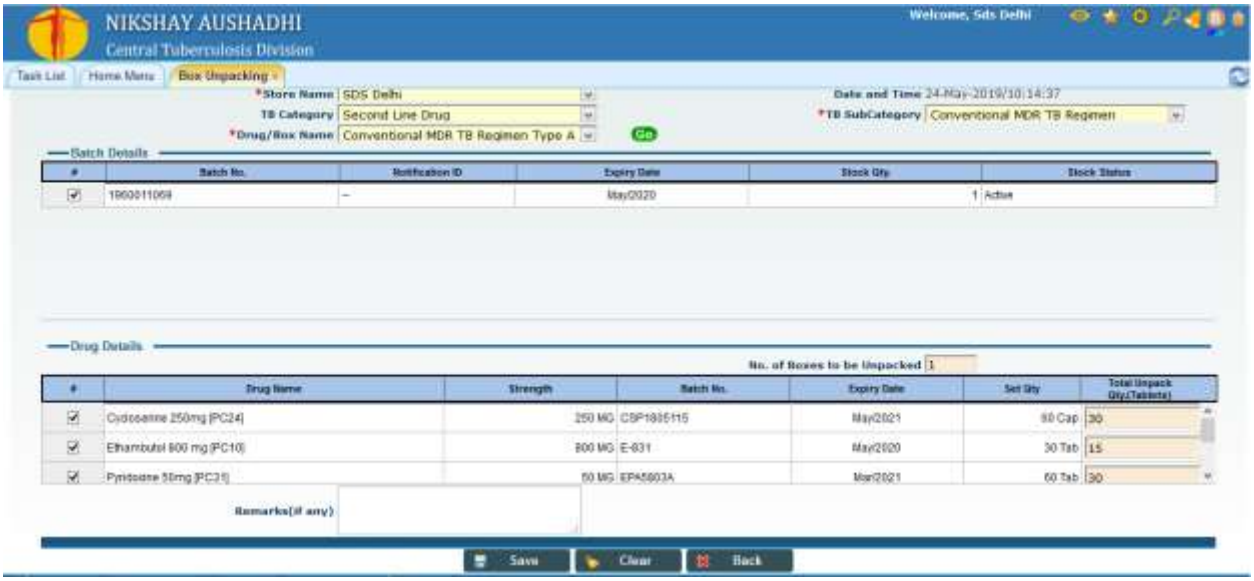
2. Select Drug/ Box Name.

3. Click on Go Button.

4. Select the check box of Box Batch No. you want to unpack.

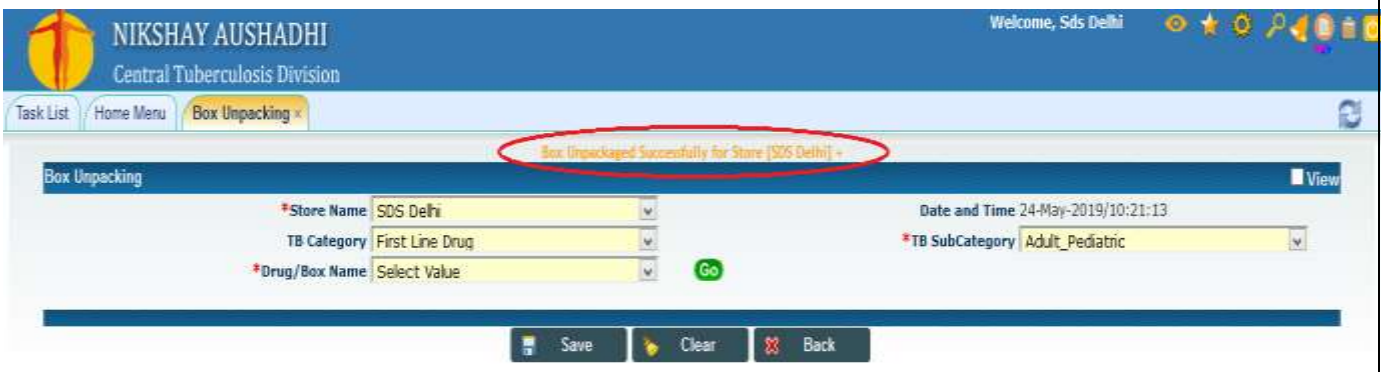
5. On selecting the check box, Drug details of the box will appear.

6. Select the checkbox of drug you want to unpack and write the physical quantity of drug you received for unpacking of box.



7. Repeat the exercise of drug select and write the physical quantity of Drugs.

8. Click on Save button. Next screen will be appeared with the message "Box Unpackaged successfully for Store (SDS).



1.7.2 Reconstitution of Bedaquiline Drug.

Partially used BDQ bottles shall be sent back to SDS where repackaging will also be done. Remaining tablets in the bottle received back shall be accounted for in the reconstitution register and Nikshay Aushadhi at SDS.

Upon reconstitution, the bottle shall be accounted for in the Stock register (loose tablets to be mentioned in remarks column) to be issued as per FEFO principles. When reconstitution is done, tablets of same expiry can be considered using same container to a maximum of 188 tablets. These reconstituted shall be used for treatment of subsequent patients found eligible for Bdq. This reconstitution exercise should be done at the DDS. All such drugs that are taken from the new containers shall be collected as a group of 188 tablets of same expiry and put in a light resistant container as per advice from the manufacturer. The actual expiry of tablets should be mentioned over the container;

- In the event of SDS falling short of 188 tablets from an expiry batch, reconstitution can still be done using number of tablets to complete 188 tablets with another expiry batch. In such a case, tablets of the respective expiry should be retained in their same respective containers and issued to patients and providers with counselling to consume the tablets with the nearest expiry first; and
- If expiry of remaining tablets is less than six months, the same shall be consumed at NDR TBC for admitted patients. It will be adjusted from the new long expiry bottle on discharge.

1.7.3 Reconstitution of Delamanid Drug.

- In the event of loss to follow up or death or discontinuation of Delamanid for any reason, the leftover tablets will also be returned back to the DDS.

- These drugs would be taken back in stock and used under the supervision as per Batch No. & expiry.

- Batch No. & expiry needs to be labelled properly on the box.

- The existing records and reporting formats for second-line drug supply chain management will be used to enter details about Delamanid storage, issue and reconstitution in conjunction with other second-line drugs.

Physical Verification and Reconciliation of Drug Stock

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

Overview

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

1. Regularly at the end of each month

2. Surprise checks during the year

3. At the year-end

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

Monthly Verification and Reconciliation

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

1. Count and determine the number of Cartons / Boxes / Strips physically available at the store, for each of the drugs dealt with by the programme and record details thereof in the Physical Verification Sheet.

2. Also record the number of Cartons/ Boxes/ Strips that should be available at the SDS as per the Stock Register (SR), for all drugs as above.

3. Determine and record discrepancies between stocks as per physical count and the SR, in the PVS.

4. Attempt to eliminate discrepancies between stocks as per physical count and the SR through a process of reconciliation. The following common causes for discrepancies should be checked/ considered during the reconciliation process:

    a. Confirm that all transactions have been properly incorporated in the SR viz.:

        i. Determine all transaction documents for the specified period on the basis of first and last pre-numbered authorized documents. For example, consider all Issue Vouchers pertaining to the SDS for the particular month, etc.

        *(**Note:** The above steps would readily apply only to issues, where Issue Vouchers are consecutively numbered. In the case of receipts- there are multiple source documents e.g. GMSD Issue Voucher, CTD-RO, SIV of transferor stocking unit, etc. and these are not consecutively numbered for the store.*

        For such cases, Store shall have to request each consignor to list all transaction documents raised by them during the period, so that these can be traced into the SR.)

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

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

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

5. The concerned officer-in-charge shall review and sign-off the PVS after thorough verification, comprising the following steps:
    a. Validate that all receipts & issues have been recorded in the SR, based on first and last and/or discrete numbers of related documents confirmed by the suppliers.
    b. Compare transaction entries in the SR with related documents such as the set of documents received along with/ after the receipt of drug consignment, etc.
    c. Verify that details of Batch numbers, Date of Manufacture and Date of Expiry of drugs are consistently recorded in the SR at the time of receipt of each consignment. Also that the SR indicates expiry details in respect of drugs available in inventory.
    d. Confirm evidence of periodic, independent checking of the SR through the recording of observations/ comments and signatures of concerned programme officers.
    e. Compliance with key best practices such as First Expiry First Out (FEFO).
6. Un-reconciled discrepancies determined through the above process should be reported to the STO and CTD.

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

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

Surprise Checks during the Year

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

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

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

Year-end Verification and Reconciliation

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

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

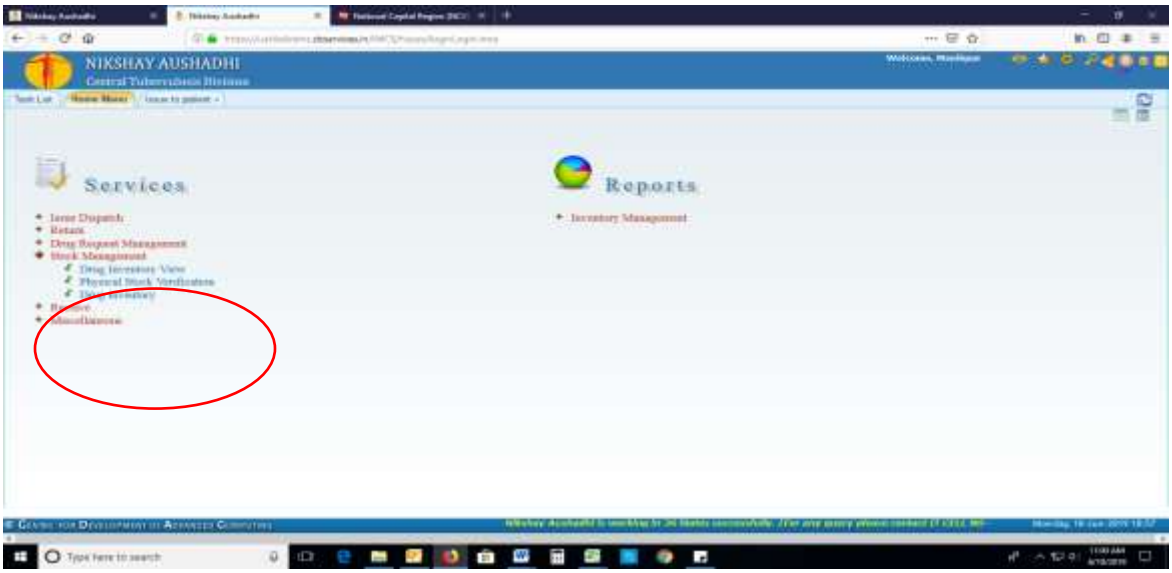
*(**Note:** Cases of shortage or damage to drugs, due to rodents/ pests/ fire/ seepage/ pilferage or expiry of drugs found during physical verification, shall be fully investigated by the STO's Office*

and reasons for the same incorporated in the year-end PVS, prior to forwarding to Central TB Division.

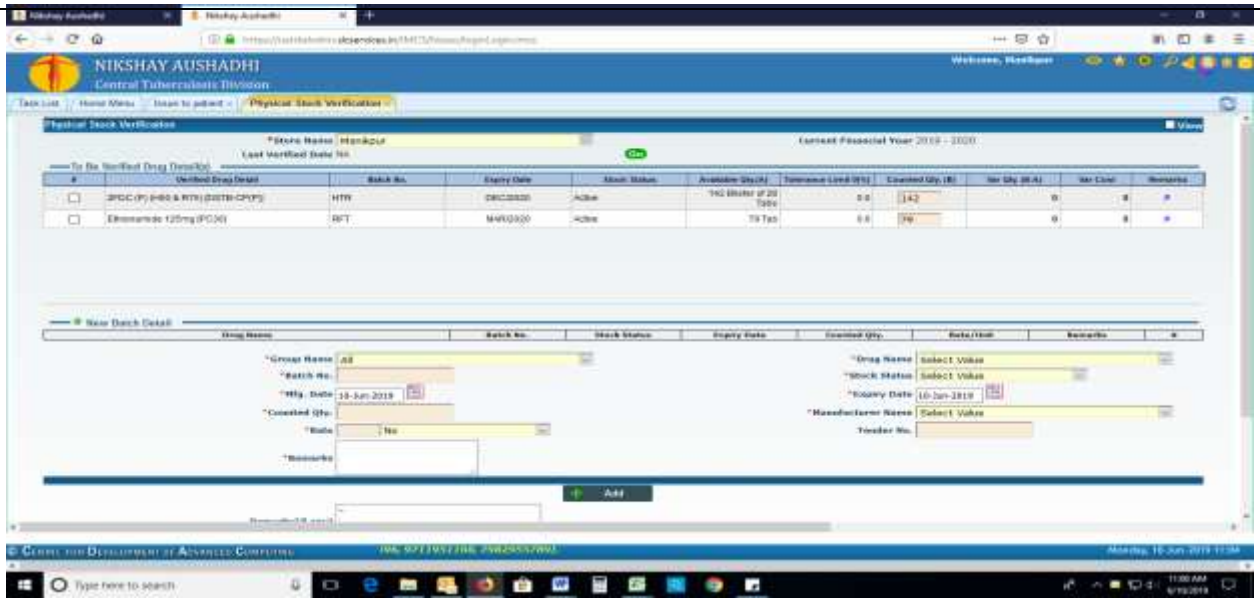
Copy of PVS prepared at the time of monthly/ surprise check/ annual physical verification of drug stocks should be filed securely/ hard bound periodically and available with the SDS at all times).

Recording in Nikshay Aushadhi

Path: Services→Stock Management→ Physical Stock Verification

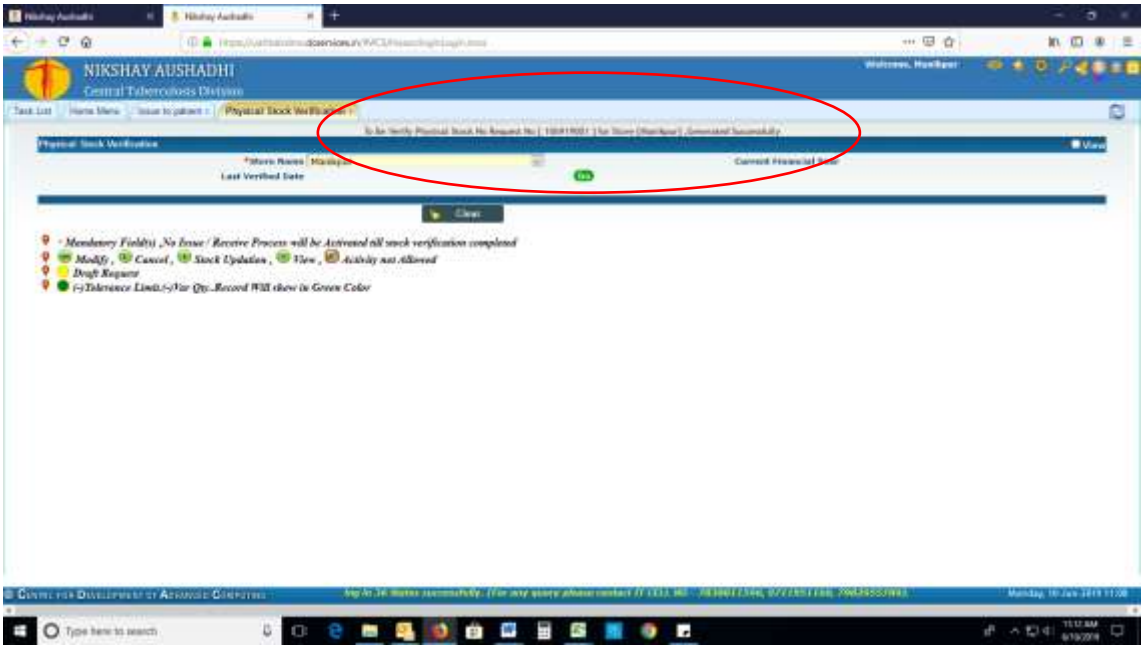


- Window will display, select store name
- Click GO, following screen will appear; enter counted quantity, enter remarks (clicking # key) in case of discrepancy.
-



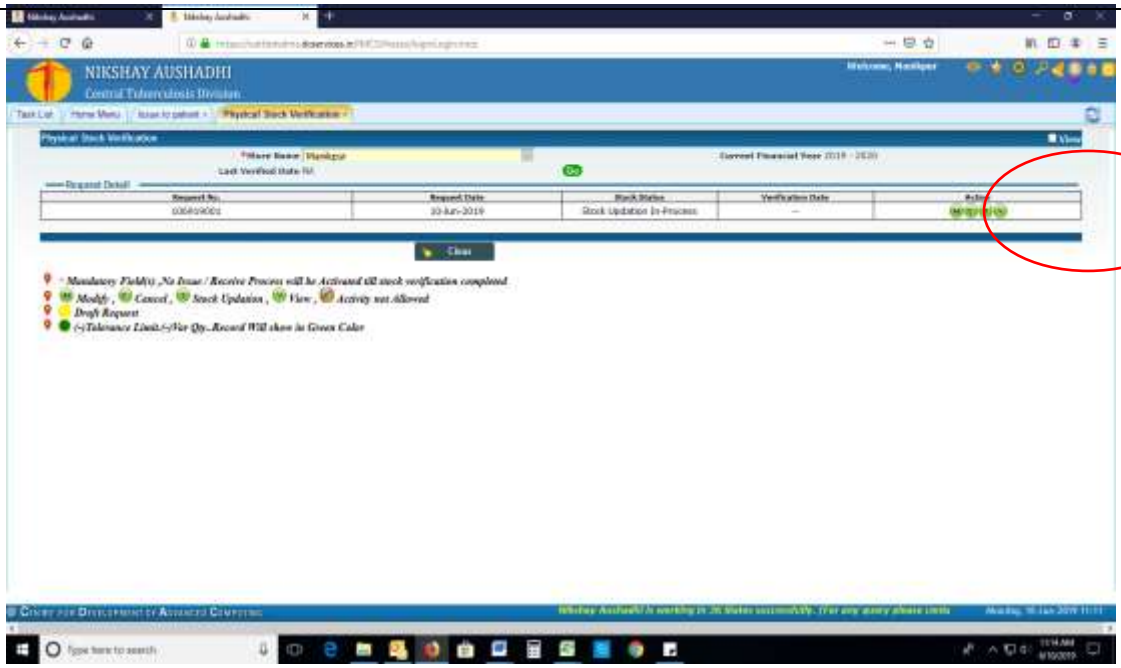
- Add new batch, if any and click on Add button

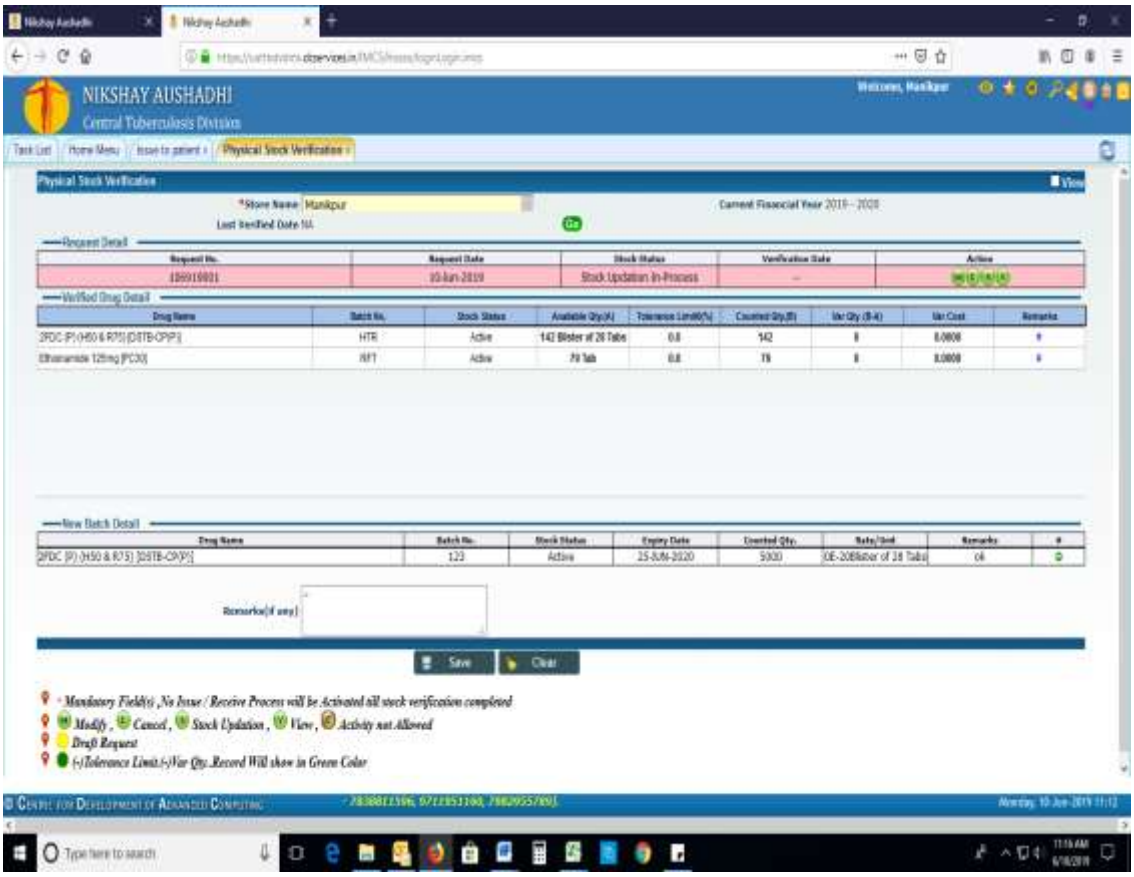
- Click on FINAL SAVE button, phycisal stock verification request will be generated :-



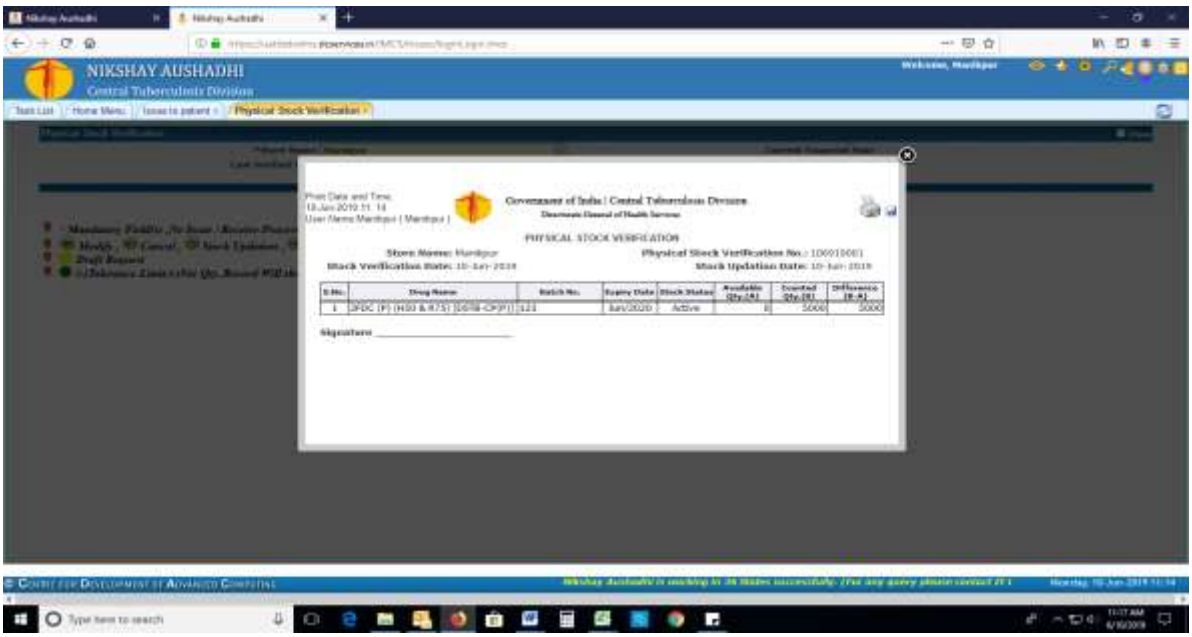
- Refresh the page and select GO

- Following screen will appear, select green button ‘S’

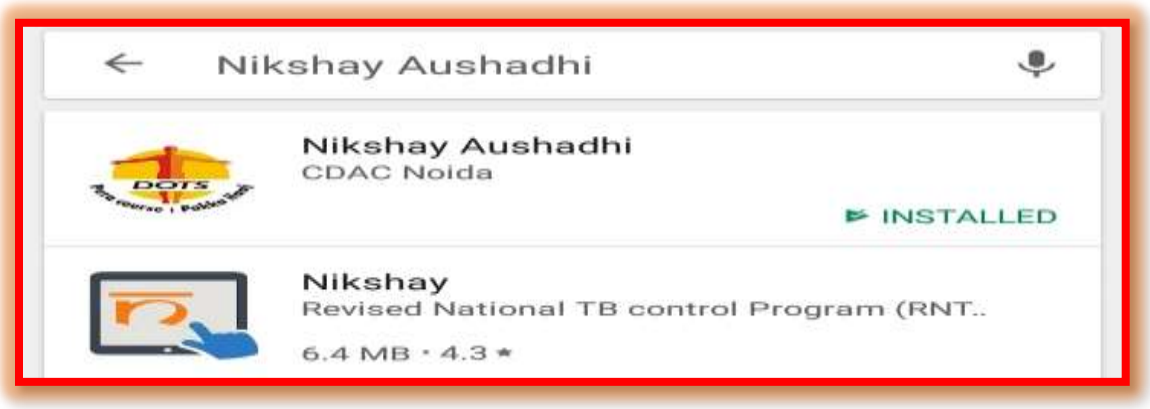




- Check the details and enter remarks
- Click SAVE Button, voucher generated

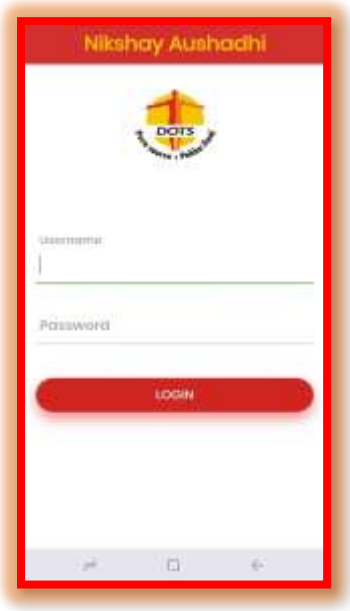

NIKSHAY AUSHADHI
Central Tuberculosis Division
Government of India | Central Tuberculosis Division
PHYSICAL STOCK VERIFICATION

An android based mobile application on Nikshay Aushadhi has been developed which can be easily downloaded from *Google Play Store* with the name 'Nikshay Aushadhi' or through the link available on Nikshay Aushadhi website.



Steps to follow for login through Mobile application

- Each user has been given a login id to manage their own store at State, District and Sub District levels. User can enter into Nikshay Aushadhi application through valid credentials (Username and Password).
- User has to enter valid 'Username' and 'Password' and click on 'Login' to begin.
- The user must be careful while entering the credentials; incorrect entry will result in login failure.

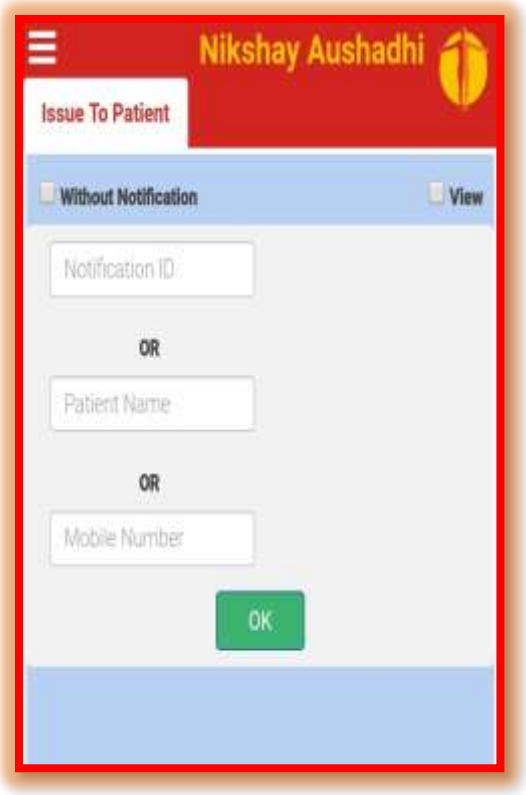


The following features are made available to a user in Nikshay Aushadhi mobile app:

- Status of pending tasks can be seen at one place.
- Drug stock (Inventory) to verify the stock and status of the drugs.
- User can check the stock detail of any drug at its sub-stores by Drug Locator.
- Additional drug request (ADR) can be raised.
- Drugs can be issued against the generated requests.
- Issued drugs can be received through acknowledge.
- Drugs can be issued to Patients from system.
- Barcode scanner is also given to Receive and Issue drugs to Patient.
- Contact detail of every store is provided.

Issue to Patient through mobile app

- A PHI user can issue drugs to patients by two methods: With Notification ID and Without Notification ID.
- If the patient is registered under 'Nikshay' application, then enter either 'Patient Notification ID', 'Patient Name' or 'Mobile Number'.
- Select the drug from 'Drug Finder' and enter the quantity to be issued. Click on 'Save' to issue the drug



Issue to Patient without Notification ID

- In case patient does not have a notification id, 'Without Notification' form will be used, given on the top left corner.
- Enter the details of the patient such as Name, Age, Gender, Reference ID, Mobile Number and address.
- Select the drug from 'Drug Finder' and fill the quantity to be issued. Click on 'Save' to issue the drugs.

Issue of drugs usimg barcode

- User can also use a barcode scanner to directly scan a barcode printed on the drug packing.
- To scan a barcode, click on ‘Scan’ button in drug finder. Scan the barcode and the system will automatically show the details of the drug.
- The scanned drug must be in the inventory of the store.