2.2 Information Technology Audit of Drug Distribution Management System in Tamil Nadu Medical Services Corporation

Executive Summary

Tamil Nadu Medical Services Corporation (TNMSC) Limited is engaged in procurement and supply of drugs, medicines, surgical sutures. TNMSC makes procurements through tenders, stores the stocks in warehouses and supplies to Government medical institutions.

TNMSC had computerised all its major activities through two application software viz., Drug Distribution Management System (DDMS) and Warehouse Information System (WIS).

Audit of DDMS brought out the following significant findings:

- The tender processing module of DDMS was not comprehensive rendering the data held in the system incomplete and unreliable.
- Incorrect mapping of business rules in the system resulted in excess projection of requirement in the pre-order statements due to non-consideration of excess stock available in some warehouses.
- The software failed to prevent placing of orders on blacklisted suppliers due to non-integration of the blacklist module with the purchase order module.
- The system failed to detect/prevent data entry errors in the dates of manufacturing and expiry, making it ineffective in handling outward transfer of drugs and reports on short expiry drugs, pre-order level and stock-out level.
- Despite availability of stock, delay in capturing laboratory test reports resulted in non-supply of drugs in 43,039 instances during 2012-17.
- 590 drugs valuing ` 16.13 crore expired during 2012-17 included 306 drugs valuing ` 5.93 crore which were supplied beyond the stipulated 30 days after manufacturing.
- Due to delay in communication of "stop issue" order and batch number mismatch, in 982 instances, drugs, which failed in quality test were issued to medical institutions after "stop issue" order date.
- The system did not calculate penalty for non-supply or short supply of drugs, leading to non-collection of penalty to the tune of `40.90 crore during 2012-17.
- TNMSC did not implement Disaster Recovery Plan and Business Continuity plan, as envisaged in the e-Security policy of Government of Tamil Nadu.

Introduction

2.2.1 Tamil Nadu Medical Services Corporation Limited (TNMSC) was established (July 1994) with the objective of procurement, storage and timely distribution of quality drugs, medicines, surgical sutures at the most economical cost to cater to the need of all medical institutions⁶³ coming under Directorate of Medical Education, Directorate of Medical & Rural Health Services and Directorate of Public Health and Preventive Medicine.

TNMSC had 29 warehouses throughout the State for storage and distribution of drugs to medical institutions. The total requirements of drugs, medicines and surgical items are finalised by TNMSC by getting the requirements from the Medical Directorates every year. The major activities⁶⁴ of TNMSC were computerised in 1995 as it plays a crucial role in catering to the day-to-day medical needs of the Government medical institutions.

Organisational structure

2.2.2 TNMSC is managed by its Board of Directors with Principal Secretary, Health & Family Welfare as its Chairman. The Managing Director, who is usually an IAS officer, heads the operations. At the district level, the warehouse operations are managed by the Warehouse-in-charge and Assistant Warehouse-in-charge.

Objectives of computerisation

2.2.3 In order to assist the management in planning, procurement and distribution of drugs to the stakeholders, TNMSC had computerised all its major activities through two application softwares *viz.*, Drug Distribution Management System (DDMS) and Warehouse Information System (WIS). DDMS is a centralised database maintained in TNMSC head office. The district warehouses use DDMS and WIS for carrying out their day-to-day functions. In addition, there is Management Information System (MIS) application software to generate reports⁶⁵ for DDMS and WIS.

The above applications are deployed in a mid-range server at the Head Office and desktops at the 29 district warehouses. Initially, these software were developed and maintained by an external agency. From the year 2010 onwards, further development, customisation and maintenance were carried out in-house.

District Head Quarters Hospitals, Taluk Head Quarters Hospitals, Medical College Hospitals, Primary Health Centres.

Identification of Drugs, Forecasting, Tendering, Order Processing & Scheduling, Inventory (stock) management, Passbook utilisation, Quality Control and Bill Processing.

Tender details, EMD/SD Details, Up4o-date stock (warehouses and QC Section), Inwards, Outwards, Consumptions, Unexecuted, Passbook Utilisation, Non-moving, Short-expiries, Nil-stocks, Pending quality results, NOC details, Frozen details, Bill clearance, Sanction order and Cheque details.

Audit objectives

- **2.2.4** The audit objectives were to examine:
- Whether the Information Technology (IT) system was used effectively by TNMSC as per the policy documents on drug procurement and quality control;
- Whether computerisation was in accordance with the IT policy of the Government and as per the norms of an IT enabled system; and
- Whether existing IT-enabled Management Information System was adequate and effectively used for monitoring.

Audit criteria

- **2.2.5** The audit findings were benchmarked against the following criteria:
- Government Orders issued by Health Department on procurement of drugs by TNMSC;
- Circulars/instructions issued by TNMSC and Directorates;
- Tender documents and agreements for procurement of IT assets/drugs;
- Policy documents of TNMSC on drug procurement and quality control;
 and
- System Requirement specifications, user manuals and data dictionary.

Scope and methodology

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2.2.6 The IT audit covered the application software viz., DDMS, WIS and MIS. The period covered by Audit was from April 2012 to March 2017. Audit scrutinised the manual records/files at the Head Office of TNMSC and eight⁶⁶ district warehouses and analysed data available in DDMS and WIS (Oracle data dumps) using SOL queries. The audit team visited the eight sampled warehouses for assessing the working of the above two modules. In addition, the team visited one Government medical institution⁶⁷ in each of the selected eight districts. The audit was conducted from April to September 2017. An Entry Conference was held with Principal Secretary to Government, Health and Family Welfare Department and Managing Director of TNMSC on 24 April 2017. The Draft IT Audit Report was also discussed with the Principal Secretary to Government, Health and Family Welfare Department in the Exit Conference on 16 November 2017. The views expressed by the Government/TNMSC during the Exit Conference as well as the reply received from the Government in November 2017 were considered, wherever found necessary.

Selected through random sampling method - Chennai (KK Nagar Warehouse), Dharmapuri, Dindigul, Erode, Thanjavur, Tiruchirappalli, Tirunelveli and Villupuram.

Government Headquarters Hospitals (Tambaram-Chennai, Villupuram, Srirangam-Tiruchirappalli, Erode, Dindigul and Dharmapuri) and Government Medical College Hospitals (Thanjavur and Tirunelveli)

Tender and Procurement

2.2.7 The tenders are received in two covers, Cover-A (technical bid) and Cover-B (price bid). During scrutiny of Cover-A, it would be ensured that all tender requirements had been met. Subsequently, Cover-B would be opened and the details of the price quoted by the tenderer are fed into the software.

Based on the data entry carried out in the system, the provisional list of tenderers with their rate for each drug is generated and placed before the Tender Committee⁶⁸ of the Board and the lowest (L-1) rates are approved. Thereafter, willingness of other bidders for matching L-1 rate is obtained and 60 *per cent* of the order is placed on L-1 and the balance 40 *per cent* is shared among other bidders, who agreed to match the price of L-1. Performance security is obtained from all bidders and agreement is executed before purchase orders are placed for supply of drugs.

Deficiencies in Tender processing system in DDMS

2.2.8 As per TNMSC manual, the officers nominated to scrutinise tender documents are required to record the conformity or otherwise of the documents in the checklist for updating computer system. Thereafter, the EDP section would be responsible for entering the rates quoted in Cover-B and taking printout of comparative statement.

The information involved in this process is captured in DDMS database. During the scrutiny of the database for the period 2012-13 to 2016-17, following points relating to tender processing were noticed:

(i) The table COVERA_DETAILS of DDMS, which captured details of documents received, did capture the documents/certificates, which were actually received. When the CHECKLIST table, which had the list of documents to be received, was compared with COVERA_DETAILS1 table, it was noticed that in 165 instances (relating to 11 tenders out of 48 tenders), the remarks column indicating the document submitted was not complete.

It was noticed that only the details of non-submission of documents by the tenderers were captured in the system and forwarded to the purchase department for following it up with the tenderers to obtain them before short-listing the tenderers for opening of Cover-B (financial bid). After the production of the documents by the tenderers, the purchase department considered their technical bid as complete. The receipt of pending documents, however, were not updated in the system. As a result, the database was showing bidders short listed were eligible for opening of Cover-B although they had not submitted requisite documents.

(ii) In the table COVERA_DETAILS3, details of Earnest Money Deposit (EMD) and Security Deposit were captured. These details would have a bearing while refunding these deposits to the tenderers. The deficiencies noticed in this table during analysis are as follows:

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Comprising of Chairman, Health Secretary; Managing Director, TNMSC; Director, Finance; Joint Secretary, Finance Department; Director of Medical Education.

- Though EMD was collected in all cases, the system showed non-collection of EMD in 107 instances (relating to 27 tenders and 84 tenderers). This was evidently due to non-capturing of data.
- Similarly, in 521 instances (relating to 38 tenders and 266 tenderers), Security Deposit was shown as not collected from L-1 or bidders matching their rates with L-1 price on whom orders were placed.

Though the application software had been developed with necessary tables to capture the relevant information so as to automate the functionality, the tender processing which is one of the components of DDMS application software for finalising L-1 supplier was partial and the data held in the system was incomplete and unreliable. Since the application software has provisions for processing of the tenders through system, online submission of tenders may be considered to ensure that the bids submitted by the tenderers were received without any omission.

The Government accepted (November 2017) that information were not being properly updated/verified. It was further stated that customisation of payment module in DDMS application to link with EMD/SD details was in progress during 2016-17.

Inconsistencies in Pre-order statements

2.2.9 The drug wise consumption/requirement details of all the warehouses including the manufacturing capacity of the supplier furnished by the suppliers at the tender finalisation stage were used for preparing the pre-order statements. The actual requirement of quantity of drug to be ordered (tender quantity) from the supplier were arrived at by taking into account the past six months' consumption in all the warehouses and reducing the ground stock available in the warehouses and pipeline stock. The pre-order statement generated by the computer system was the input for placing purchase orders (PO) and hence, it was a critical stage in procurement process.

The data relating to pre-order statement pertaining to the year 2016-17, which was generated and stored as a database, was produced to audit. For the years 2014-15 and 2015-16 hard copy of the pre-order statement was produced to audit. On scrutiny, the following observations were made:

(a) Incorrect mapping of business rule in IT system leading to excess procurement

Audit scrutiny indicated that pre-order statements were prepared without taking into account ground stock at warehouses in 232 cases, which resulted in excess procurement of drugs/medicines. This happened due to incorrect mapping of business rules in the computer system.

Excess holding of stock resulted in avoidable investment in drugs not required for consumption in the immediate future and would run the risk of expiry.

The Government stated (November 2017) that a decision was taken to consider the stock position of individual warehouses rather than the stock of State. However, from the year 2017-18, the decision was revised to consider the stock of State for re-order level instead of the individual requirement of the warehouses and also to issue suitable inter-warehouse transfers automatically

for the movement of the drugs from the available warehouses to the required warehouses.

TNMSC should have taken steps for inter-warehouse transfers instead of raising purchase orders to meet the requirement of individual warehouses when the excess stock position was exhibited in the other warehouses as per the pre-order statements generated by the system.

(b) Manual modifications in system-generated pre-order statements

As per clause 13.4 (i) and (ii) of the Tender document, the supplier should supply at least 50 *per cent* of the ordered quantity within 45 days from date of purchase order and balance quantity within next 15 days. There was no condition that preference would be given to the supplier who promised to supply within 10 days.

It was observed from the pre-order statements that quantities to be ordered on finalised suppliers were frequently modified manually by purchase section. We noticed that out of 4,259 drugs, manual modifications were carried out in the pre-order statements of 1,591 (37.36 per cent) drugs.

Instances of manual interventions violating the policy are detailed in **Table 2.2.1**:

Table 2.2.1: Instances of manual intervention in the purchase order

Sl.No.	Pre-order Statement number	Drug code	Instances of manual intervention
1.		2	The purchase department manually modified the pre-order statement and placed entire order on L-1.
		104	The purchase department manually modified the pre-order statement to place the entire order on L-1 supplier on the ground that the firm had agreed to supply in short period of 10 days.
	14.10.2014/01:28:04		The purchase department manually modified the pre-order statement to place the entire order on one supplier, who matched his rates with L-1 on the ground that the previous purchase order was not placed on him and he had agreed to supply the ordered quantity in short period of 10 days. Thus, the L-1 and another supplier who matched his rate with L-1 were not considered.
		232	The purchase department manually modified the pre-order statement to place the order for the entire quantity on L-1 bidder on the ground that the L-1 bidder was ready to supply in 10 days.
2.	16001201703271205	16	The supplier who matched L-1 rate was given order for more than the system-generated quantity without asking L-1 supplier to increase the production capacity resulting in supplier who matched L-1 rate getting 63 per cent of the

Sl.No.	Pre-order Statement number	Drug code	Instances of manual intervention
			quantity as against the norm of 40 per cent of the total quantity.
		17	Both L-1 and suppliers who matched L-1 rates were given order for more than the system generated quantity stating that the suppliers had increased their production capacity.

(Source: Database of DDMS)

The above cases indicated that the permission granted to the purchase department to manually over-ride the purchase order was against TNMSC's policy and defeated the objective of IT enabled tender finalisation system.

(c) Excess stock and drug out status in warehouses

The table DRUGINW of DDMS, captured supplies received from suppliers and by inter-warehouse inward transfers. The DRUGOUT table captured supplies made to medical institutions and inter-warehouse outward transfers and the table WHSTOCK captures the closing balance. Ideally, ground stock was to be 35 per cent of annual consumption and if the stock position was less than 10 per cent, then it might lead to unavailability of drug stock for issue to medical institutions.

- An analysis of closing balance during 2012-13 to 2016-17, disclosed that the closing balance was more than the prescribed 35 per cent of annual consumption in respect of 9,174 cases. In 73 cases, the stock was in excess of 35 per cent continuously⁶⁹ for the last five years (2012-13 to for last 2016-17), in 114 cases four years (2013-14 to 2016-17) and in 228 cases for last three years (2014-15 to 2016-17).
- Out of 9,174 cases, the closing balance of drugs at each warehouse was less than 10 per cent in eight cases continuously for last five years (2012-13 to 2016-17), in 19 cases for last four years (2013-14 to 2016-17) and in 95 cases for last three years (2014-15 to 2016-17).
- There were no ground/pipeline stock as it showed 'NIL' stock in the warehouses in the pre-order statements generated during 2016-17 in respect of 406 drugs in 2,014 cases. Audit noticed that against 6,106 indents received from the medical institutions during this period, no supply was made in 1,122 indents due to non-availability of stock.
- In 87,072 records (relating to 16,525 indents and 1,482 drugs) for the period 2012-13 to 2016-17, the required drugs could not be supplied to the indenting institutions due to non-availability of ground stock.

The excess/short stock position discussed above indicated that there were inadequacies in planning, procurement and monitoring by TNMSC in spite of DDMS and MIS being in operation for more than 22 years. Further, deficiency in the system also contributed to this situation as it considered the previous

⁶⁹ 2014-15 to 2016-17 - ranging between 35.23 per cent and 99.43 per cent; 2013-14 to 2016-17 - ranging between 35.23 per cent and 99.07 per cent; 2012-13 to 2016-17 – ranging between 35.39 per cent to 98.33 per cent.

year's consumption (static) for preparation of pre-order statement to decide the requirement of drugs instead of immediate 12 months' consumption (dynamic) as contemplated in the purchase policy of TNMSC. This resulted in preparation of pre-order statement not in line with the real requirement.

The Government replied (November 2017) that eventhough the stock was 'Nil' at the warehouse level, the hospitals would be left with a month's stock to meet their requirement. It further stated that instructions were given to the medical institutions to place their indents 15 days in advance to mobilise the drugs from suppliers/warehouses. The reply was not acceptable since as per clause 18.2 of Purchase Policy of TNMSC, four months' stock was to be maintained in its warehouses and two months stocks in pipeline for all the drugs.

Placement of purchase orders on blacklisted suppliers

2.2.10 As per tender conditions, the supplier would be blacklisted for two years if he failed to execute at least 70 *per cent* of the ordered quantity for any three purchase orders of the same drug.

Further, if the stock supplied was declared to be 'Not of Standard Quality' or spurious or adulterated or misbranded, such batch/batches would be deemed to be rejected goods and the supplier would be blacklisted.

Analysis of tables 'ORDERPROCESS', 'BLACKLISTED', 'DRUGINW', 'DRUGOUT' and 'BILLPASS' revealed that:

- During the period from July 2013 to March 2017, 1,115 purchase orders were placed on firms blacklisted by purchase department. Out of 1,115 purchase orders, 10 purchase orders were subsequently cancelled, whereas in 925 cases supplies were received. However, no supply was received in respect of balance 180 cases.
- In four instances as detailed in **Table 2.2.2**, though the supplier had been blacklisted for supplying 'Not of Standard Quality' drugs, the system had generated purchase orders and the entire supply had been delivered.

SI. Supplier name Purchase Date of Drug **Quantity** Amount Blacklisted order purchase (In (In `) period Code No. numbers) number order 1 Safe Surgical OA0029 26-May-12 R142 1,14,000 1,16,96,400 20-Jun-08 to Industries 19-Jun-13 OA0059 26-Jul-12 R142 1,66,000 1,70,31,600 20-Jun-08 to Safe Surgical Industries 19-Jun-13 20-Jun-08 to 3 OA0119 26-Oct-12 R142 69,800 71,61,480 Safe Surgical 19-Jun-13 Industries Safe Surgical QA0152 06-Dec-12 R142 96,700 99,21,420 20-Jun-08 to Industries 19-Jun-13 4,58,10,900 Total

Table 2.2.2: Orders placed on blacklisted suppliers

(Source: Database of DDMS)

The software failed to prevent placement of purchase orders on blacklisted suppliers due to non-integration of the blacklist module with the purchase order module. Further, due to lack of monitoring at different level users despite

having a Management Information System, these purchase orders had been processed and items were delivered.

In respect of blacklisting of the surgical item (Drug code: R142- Absorbent cotton wool IP), the Government stated (November 2017) that details of blacklisting was not available in the Drugs Purchase Section, Quality Control Section and in the Electronic Data Processing section of TNMSC at the time of finalising the tender during 2012-13. Therefore, tender had been finalised and product received from the firm.

The reply is not acceptable since the procurement of surgical item was from the supplier who had been blacklisted since 2008. This error happened as the detail had been updated on 2 June 2010 with flag Active 'Y' in database. Due to non-availability of inbuilt alerts and input controls at purchase order issue stage and receipt at supply stage, the system failed to integrate inter-related tables and filter the ineligible suppliers and items failed in quality test.

Supply of drugs

Supply of drugs with lesser shelf-life

2.2.11 As per tender conditions, the supplier should supply the products within 30 days from the date of manufacturing. In case, the product is received after 30 days of manufacture and the product is not consumed before its expiry, the supplier should replace the expired quantity with fresh stock of longer shelf-life. In case of non-replacement, the cost of expired quantity would be recovered.

It was observed from the table 'DRUGINW' that 1,245 drugs were supplied after 30 days from the date of manufacturing. The analysis of 'DRUGOUT' tables revealed that:

- 590 drugs valuing `16.13 crore expired during 2012-17.
- Out of these, 306 drugs valuing `5.93 crore were supplied after 30 days of manufacturing for which the recovery was pending as of September 2017.

This indicated that neither internal controls were integrated into the system nor TNMSC ensured replacement of drugs, which had shorter shelf-life.

As the system installed at Head Office of TNMSC capture due or extended date of delivery for a particular supply of drugs, it was possible to monitor the supply of drug with short expiry.

Non-blacklisting of suppliers

- **2.2.12** The tender conditions envisaged blacklisting of suppliers if they failed to adhere to the prescribed time for supply. The tables 'ORDERPROCESS', 'BLACKLISTED' and 'DRUGINW' were analysed and the following observations are made:
- (i) In 43 out of 655 instances, the firms supplied less than the prescribed 70 *per cent* of purchase order quantity of same drug under same tender for more than two times. However, 41 out of 43 instances, the firms were not blacklisted.

(ii) Though 115 purchase orders were cancelled due to failure of the suppliers to adhere to tender conditions warranting blacklisting, the system did not blacklist the suppliers automatically.

The Government stated (November 2017) that the majority of suppliers failed to acknowledge the receipt of purchase orders issued to them. Though the system had been designed to prevent acceptance of supply beyond the stipulated date of delivery at the warehouse, the system failed to cancel such purchase orders.

(iii) Whenever the supplier defaults in supply of drugs, TNMSC resorted to placement of Emergency Purchase Orders (EPOs) on another supplier at the risk and cost of the defaulted supplier. It had been observed that during 2012-17, 145 EPOs were placed, which included 138 EPOs with higher cost amounting to `3.37 crore. As the system was not designed to capture recovery of the amount from the defaulted suppliers, audit could not ascertain the recovery of differential cost by TNMSC from the defaulted suppliers.

Thus, the system failed to detect the habitual defaulters and lack of monitoring at different levels, which resulted in issue of purchase orders to defaulted suppliers and resultant EPOs at higher cost.

The Government stated (November 2017) that they had implemented a module in DDMS in October 2017 to generate blacklist report on performance, as per the tender conditions. Further, necessary modifications had been made in DDMS to indicate the details of blacklisted suppliers in the pre-order statement and also to restrict purchase order entry on such supplier and such errors would not occur in future.

Discrepancies in data capture

2.2.13 On receipt of goods, the warehouse-in-charge entered the details of receipt in Inwards Goods Register and handed over the same to Data Entry Operator for capturing the inward drug details in the system. As the data was stored in the database without any verification and authorisation by the warehouse-in-charge, there were errors in capture of manufacturing/expiry date of drugs for same Purchase Order Numbers, Drug Codes and Batch Numbers as detailed in **Table 2.2.3**.

SI. Type of error Number of Error impact on shelf-life of the instances No. Errors in capture of expiry date across (-) 3,653 days to (+) 6,200 days 3.082 all warehouses Errors in capture of expiry date within a (-) 365 days to (+) 365 days 10 warehouse 3 Errors in capture of manufacturing date 1,889 (-) 1,248 days to (+) 9,131 days across all warehouses 4 Errors in capture of manufacturing date (-) 214 days to (+) 731 days 16 within a warehouse

Table 2.2.3: Discrepancy in data capture

(Source: Database of DDMS)

As errors in expiry date would affect the chain report for transfer of drugs, short expiry drugs etc., the failure of the system to detect/prevent these errors at input

stage revealed lack of input controls including at the level of warehouse-in-charge.

The Government accepted (November 2017) the audit observation and stated that necessary validation modules had been incorporated at the input stage to prevent discrepancies in future. Remedial action taken in respect of cases observed by audit had not been furnished.

Quality control

2.2.14 Under the Quality Control (QC) process, samples were selected and assigned secret code numbers by the system and sent to empanelled private Analytical Laboratories. The testing reports were received as soft copies by email and as hard copies. The drugs could be supplied from the warehouse only when the drugs cleared the quality test. In case of failure of the samples in two successive tests, stop issue order is issued to warehouses and drugs are returned to suppliers. Timelines have been fixed for different stages of quality control process.

Non-drawal of samples as per the prescribed procedure

2.2.15 According to the "Quality control policy and procedure" of TNMSC, soon after receipt of drugs in the warehouse, the warehouse-in-charge had to number the boxes. The total number of boxes received had to be fed into computer system batch-wise and item-wise. The computer system had been programmed to randomly select box numbers from which the samples had to be drawn by the warehouse-in-charge for laboratory test.

During field visit to eight warehouses, it was ascertained that the above activity was being carried out only manually. This led to drawal of samples by the warehouse-in-charges at their own discretion, which did not serve the intended purpose.

Delays in quality testing process

2.2.16 Audit noticed delays at all stages of QC process as discussed below:

(a) Delay in receipt of samples in TNMSC headquarters from warehouses

An analysis of 1,11,023 records of inward and outward transactions relating to quality control testing samples during 2012-17 revealed that in 54,646 records, the drug samples were received in the HO from the warehouses, after a delay of more than three days as against the stipulated norms of sending samples within two days. An analysis is given in **Table 2.2.4**.

Table 2.2.4: Delay in receipt of sample

(In numbers)

Year	Delay in excess of three days with number of instances						
	01 to 04 days	05 to 11 days	12 to 27 days	More than 27 days			
2012-13	4	1					
2013-14	55	5					
2014-15	168	13	4	6			
2015-16	19,306	7,653	841	106			

Year	Delay in excess of three days with number of instances						
	01 to 04 days	05 to 11 days	12 to 27 days	More than 27 days			
2016-17	24,184 1,803		365	132			
Total	43,717	9,475	1,210	244			

(Source: Database of DDMS)

The warehouse-in-charges stated (July 2017) that delays were due to transportation problems, batch number mis-match, *etc*. The delays stated by the warehouse-in-charges could have been avoided had the MIS relating to receipt of samples in TNMSC HO been effectively used. The mis-match in batch numbers was avoidable by using barcode readers.

The Government accepted (November 2017) the audit observation and stated that necessary monitoring mechanism had been incorporated in the DDMS Head office module to list out details of warehouses which did not send QC samples to Head Office. Though it was stated that provision has been incorporated to list out details of warehouses which did not send QC samples to Head Office, there is no provision of 'Edit Module' to update the mis-match of batch entries and no trail of the resample sent in case of damage or short supply of drug sent for quality testing.

(b) Delay in receipt of empanelled laboratory reports

As per tender conditions for testing of drugs, the Analytical Laboratory had to furnish the test reports within eight days of receipt of the samples for Category-A⁷⁰drugs and within 21 days for Category-B⁷¹ drugs. For any delay, one *per cent* of the testing charges per week and the part thereof would be deducted as penalty. If the delay occurred consecutively for four times or more than eight times in a year, then the penalty would be two *per cent* of testing charges per week or part thereof.

An analysis of data containing information on laboratory reports (1,25,876 records) disclosed that in 17,778 records, the QC testing results of Category-A drugs were reported by the laboratories after 12 days (eight days + transit days) and in 4,564 instances, the QC testing results of Category-B drugs were reported by the laboratories, after 25 days (21 days + transit days) as given in **Table 2.2.5**.

Table 2.2.5: Delay in receipt of laboratory reports

(In numbers)

Drug	De	Total			
category	01 to 07 days	08 to 14 days	15 to 60 days	More than 60 days	
Category-A	13,915	2,557	1,251	55	17,778
Category-B	3,351	758	433	22	4,564
Total					22,342

(Source: Database of DDMS)

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Category-A - tablets, capsules, pessaries, ointments, powder, liquid oral preparations and other items.

Category-B - intravenous fluid injections, disinfectants, surgical and sutures.

It was observed that out of 22,342 records, though there were delays in reporting the test results in 11,880 records, Liquidated Damages (LD) were not levied to the extent of `0.81 lakh.

The Government stated (November 2017) that QC section was taking utmost care to minimise the delay and sending reminders to the empanelled laboratories for the pending analytical reports. Though the Government stated that QC was regularly deducting the penalty for the sample reports received after the due period and the deduction of penalty was programmed in the system, the details of recovery of LD as per tender conditions in the cases pointed out by audit had not been furnished.

(c) Delay in receipt of Government laboratory reports

Drug samples, which failed in the first analysis are sent to Government Analyst (GA). Audit analysis of 1,869 records in respect of samples sent to GA revealed that QC test results were not received within the time limit stipulated for empanelled laboratories for first/second time analysis in 1.728 records (92 per cent) of Category-A/Category-B drugs as detailed in Table 2.2.6.

Table 2.2.6: Delay in receipt of Government laboratory reports

(In numbers)

SI.N	o. Drug category	Analysis	Delayed results	'Pass' samples	'Fail' samples
1	A	First	504	313	191
2	В	First	500	365	135
3	A	Second	454	281	173
4	В	B Second		164	106
Tota	l	1,728	1,123	605	

(Source: Database of DDMS)

Since results from GA are considered as final, any delay would affect the timely supply of quality drugs to end users.

The Government stated (November 2017) that laboratories owned by it were not bound by TNMSC's tender conditions and TNMSC's QC section was regularly requesting them to provide the analytical report at the earliest.

However, in the Exit Conference (November 2017), TNMSC informed that the Drug Controller General of India had directed the State Government laboratories to submit their reports within 60 days.

As the Government Analytical Laboratory was functioning under the Health and Family Welfare Department, TNMSC may take up the matter with Government to fix time for furnishing QC report so that timely supply of quality drugs, prevention of expiry of frozen drugs, prevention of delay in return of frozen drugs to suppliers would be ensured.

(d) Delay in entry of laboratory test results in the system

As per the system in vogue, the Manager (QC) in TNMSC headquarters would receive test reports from laboratories and arrange to enter the data in the system. Based on test results, 'Issue Letter' or 'Stop issue Letter' would be issued by Manager (QC) to the warehouse-in-charge. Thus, timely receipt and entry of test reports are important activities to start/stop dispensing drugs by warehouses.

An analysis of information on laboratory reports (1,25,876 records) disclosed that 74,787 'pass' reports and 871 'fail' reports were captured in the system after two days as detailed in **Table 2.2.7** below:

Table 2.2.7: Delay in entry of laboratory test reports results in the system

(In numbers)

Result	Delay	Total			
	01 to 05 days				
Pass	39,995	23,643	9,396	1,753	74,787
Fail	398	235	143	41	817

(Source: Database of DDMS)

The delay at various stages brought out in the preceding paragraphs affected the distribution of drugs as only the drugs passed in quality control testing were distributed to medical institutions. Further, data analysis of 38,02,088 records revealed that in respect of 43,039 records (relating to 13,900 indents and 480 drugs) for the period 2012-13 to 2016-17, no drug supply was made and in 72,005 records (relating to 16,233 indents and 968 drugs) the indenting institutions were supplied drugs partially due to non-availability or insufficient quantity of drugs, which had passed quality control tests, respectively.

The Government stated (November 2017) that the date mentioned in the analytical reports could be the date of completion of tests. Later the analytical reports were verified, authorised by the technical person from the concerned laboratories and then sent to TNMSC by e-mail. Hence, the date mentioned in the report was not the date of TNMSC report receiving date.

The reply is not acceptable, since there was no provision in the database table to capture separately the report date and report receipt date. Further, the report date is the data, which was to be used for calculating the date of receipt of laboratory reports and levy of LD for delayed reports. Moreover, as per the procedure laid down under clause 6.2 of Quality Control Policy, the reports were to be uploaded by the laboratories on the website of TNMSC and simultaneously e-mailed to TNMSC Head office apart from sending it by fax/e-mail.

Testing by non-empanelled laboratories

2.2.17 The analytical laboratories are empanelled through a tender process after considering various factors such as their quality process, adherence to 'Good Laboratory Practice', past three years turnover, *etc*.

An analysis of data files, containing information on drug-wise list of samples sent to laboratories, disclosed that in 2,656 out of 1,25,876 instances, samples were sent to non-empanelled analytical laboratories.

As empanelled laboratories were meant for ensuring quality drug testing, sending drugs to laboratories which were not empanelled for the particular

financial year/particular drug was on account of deficiencies in the computer system.

The Government replied (November 2017) that due to urgency, such samples were sent to other laboratories after obtaining willingness from them. The reply was not acceptable as it was a deviation from the prescribed procedure for empanelment of analytical testing laboratories. Further, the reply was silent about the approval of the Board for entrusting the samples for quality tests to non-empanelled laboratories.

Non-inclusion of drug batches for sample selection

2.2.18 As per the system being followed, drug-wise and batch-wise samples are selected by the system from the samples received from the warehouses and sent to analytical laboratories for QC test.

An analysis of data disclosed that during 2014-17, a total of 384 batches of drugs were missed out in the sample selection process for quality test, rendering the selection process deficient.

In response to specific instances pointed out by audit, TNMSC stated that the sample drugs were omitted in the random sampling as they were not listed in MIS report. Audit observed that the MIS report, which was being relied upon, was deficient as it was restricted to the current financial year and hence the year-end transactions of the previous year were not displayed.

The Government accepted (November 2017) the audit observation and stated that application software had been modified in such a way that sample selection module automatically search entries both from current year and previous year tables to avoid delay and manual intervention.

Non-analysis of stocks held for more than six months

2.2.19 With a view to ensure the quality of the drugs during the storage period, samples were to be drawn from the lots which were lying in the warehouse for more than six months. An analysis of data on inward and outward transaction of drugs revealed that during 2012-17, supplies made in 6,949 instances, which were lying in the warehouses for more than six months were not sent for second time QC testing.

There was no provision in the software application to generate the list of drugs, which were lying without being quality tested for the second time after six months.

During field visit to eight district warehouses, it was noticed that 81 drugs were reported (2014-17) to be 'Not of Standard Quality' by Government Drug Inspectors. Since, the prescribed procedures for re-testing of quality after six months were not followed, these quality issues were not detected in-house before distribution to hospitals.

The Government accepted (November 2017) the audit observation and stated that necessary modules had been implemented in DDMS to list out pending samples to QC section to ensure quality of drugs throughout the shelf life of the drug as prescribed. However, no reply had been furnished on deputing officers for inspection at warehouses to draw random samples for quality check.

Not blacklisting the suppliers of failed drugs

2.2.20 An analysis of data on laboratory reports (1,25,876 records) and blacklisting of the suppliers (113 records) disclosed that in 61 instances, a drug supplied by 46 suppliers, failed in Government laboratories more than once within tender period. But the suppliers of the drugs were not blacklisted as per QC policy and terms and conditions of tender.

The above deficiencies revealed that in spite of requisite data available in the system, no provision had been made to identify the suppliers, whose drugs had failed repeatedly to enable the management to take necessary action against defaulters.

Not blacklisting the laboratories despite discrepancies in their results

2.2.21 As per tender conditions, if there were repeated variations⁷² in the analytical reports furnished by the empanelled laboratories, they would be blacklisted for a period of two years.

An analysis of data of laboratory reports (1,25,876 records) disclosed that only 1,176 entries were made for the fields,⁷³ which related to the analytical test details. This omission had resulted in non-review of laboratory reports through the system. It was also observed that QC test results of same drug of same batch within a short period differed between two empanelled laboratories and between an empanelled laboratory and Government analyst in respect of 2,184 samples during 2012-17.

Periodical reviews were not conducted by TNMSC in respect of above mentioned 2,184 samples involving 41 laboratories, where the results differed. The system did not generate any report on laboratories producing conflicting reports. This resulted in failure to blacklist the laboratories concerned so as to ensure supply of quality drugs.

The Government, while accepting the audit observation, replied (November 2017) that due to increase in the number of samples year after year, compared to the available laboratories, blacklisting clause of the tender condition could not be enforced. The Government stated that several other parameters were also to be considered. However, these information were not captured due to lack of provision in the system, which had resulted in non-review of laboratory reports through system.

Sending more than one sample drugs to Analytical Laboratories

2.2.22 As per the QC policy, the samples received from the warehouses were to be segregated drug-wise and batch number-wise and then the common batches of the drugs were eliminated and samples randomly selected by the system.

An analysis of data relating to laboratory reports (1,25,876 records) disclosed that in 2,017 records, samples from same batch number for the same drug were

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If there is any variation in the analytical reports furnished by the empanelled laboratories (either pass or fail) with the Government Laboratory for 3 times in assay and 4 times for parameters other than assay for any drug in a year, the empanelled laboratory would be blacklisted for a period of 2 years besides forfeiture of the security deposit after following the due process.

^{&#}x27;MILLIGRAM1', 'MILLIGRAM2', 'PERCENT1' and 'PERCENT2'

selected and sent for analysis, resulting in duplicate testing of these samples and incurring excess expenditure of `9.92 lakh.

The Government replied (November 2017) that as per instructions, random sample was being selected in DDMS application software based on purchase order number, drug code and batch number. The reply was not acceptable as it was a deviation from clause 4.2 of the Quality control policy for sample analysis which contemplated that the sample receipts from warehouses were segregated drug-wise and batch number-wise.

Distribution of drugs

2.2.23 The medical institutions draw their requirement of drugs from their jurisdictional warehouse using indents. The value of drugs and other supplies issued were debited in the Medicine Pass Book issued to the institution indicating the annual budget.

Distribution of drugs after "stop issue" order

2.2.24 If a drug failed in the quality test of the analytical laboratory or in the Government analytical laboratory, TNMSC headquarters issued the "stop issue" order to all warehouses and also issued instructions to retrieve any quantity already issued to the medical institutions.

An analysis of the data held in 'lab result' and 'drug out' tables revealed that in 982 out of 25,680 instances, during 2014-17, drugs were issued to various medical institutions by the warehouses, after the date of "stop issue" order by TNMSC headquarters. This was due to the non-updating of the latest test results, in an automated manner.

The district warehouse-in-charges in the eight test-checked warehouses replied (July 2017) that due to delay in receipt of "stop issue" orders at the warehouses and batch number mismatch, drugs were continued to be issued to medical institutions after the "stop issue" order date.

As the warehouse database is accessible to TNMSC Electronic Data Processing, controls should have been included in the application software to ensure that distribution of drugs was not done after issue of "stop issue" order. This deficiency in the software had resulted in continued distribution of sub-standard drugs even after "stop issue" order.

The Government, while accepting the audit observation, replied (November 2017) that necessary changes had been incorporated in the application software from July 2017 to prevent issue of drugs which failed the quality test.

Deficiencies in transfer of stock between warehouses

2.2.25 TNMSC has a policy to conduct a fortnightly review of short expiry drugs lying in the warehouses so as to transfer the same to the needy warehouses for issue before expiry. These transfers were effected by TNMSC Head office based on the request from the needy warehouse or on its own initiative.

An analysis of WHTRASFER table, which contain the information on transfer between warehouses, indicated non-adherence to transfer proposals as indicated in **Table 2.2.8**.

Table 2.2.8: Inter-warehouse transfer of drugs

Year	Tr	ansfer Propos	Drug-	Percentage	
	Total number of transfer orders	Total number of drugs	Total quantity (In numbers)	wise transfers not done (In numbers)	of drug- wise transfer not done
2012-13	11,123	594	44,85,05,015	1,873	16.84
2013-14	11,729	691	33,62,12,443	10,492	89.45
2014-15	13,115	608	41,34,04,203	2,950	22.49
2015-16	7,186	552	28,20,50,451	643	8.95
2016-17	11,658	804	29,64,25,231	1,009	8.66
Total	54,811	3,249	177,65,97,343	16,967	30.96

(Source: Database of DDMS)

It could be seen that out of total drug-wise 54,811 transfers, 16,967 transfers were not effected.

We observed that poor planning with regard to scheduling of deliveries, inadequate assessment of requirement and monitoring of supplies led to number of inter-warehouse transfers. We also observed that necessary controls in the application software could have minimised these inter-warehouse transfers.

Difference in value of drugs between 'indent master' and 'indent details'

2.2.26 The major details of indents received *viz.*, indent number, passbook number of the medical institution, date of indent and total value of the drugs indented are stored in the 'Indent Master' table of the database at the warehouse. The details of drugs issued and value of each drug (indent number is the linking or key field between the master and detail table) are stored in the 'Indent Detail' table. In other words, the total value of the drugs issued under an indent is sum of the value of each drug in the indent detail table and under no circumstances the total value of drugs and sum of break-up value of each drug can differ. However, in 173 cases involving 24 warehouses, it was noticed that there was a difference in value between the two tables discussed above indicating lack of referential integrity.

The Government replied (November 2017) that the validation mechanism is being incorporated at the back end in the new module to avoid the variations pointed out by audit.

Payments to suppliers

Non-levy of penalty for short supply

2.2.27 As per the tender conditions, if the supplier failed to execute the supply within the stipulated time, TNMSC was at liberty to make alternative purchase and impose a penalty of upto 30 *per cent* on the value of unexecuted order.

(a) Non-supply

Audit noticed that supply was not received in respect of 2,603 purchase orders. Out of these, TNMSC levied penalty of `7.30 crore for non-supply in respect

of 915 purchase orders. But, the system did not generate the penalty amount for the unexecuted quantity, which worked out to `34.77 crore.74

The Government stated (November 2017) that supply had been made in respect of 788 cases and in remaining cases, penalty had been calculated and recovered fully/partially. As of October 2017, ` 13.13 crore had been recovered and ` 7.63 crore was pending recovery.

The fact, however, remained that no recovery has been initiated in respect of the balance amount of `14.01 crore pointed out by audit.

(b) Partial supply

An analysis of data containing information on placement of purchase orders, supply at warehouses and payments disclosed that in 8,033 purchase orders, supplies were partially made. In 4,595 purchase orders, penalty of 30 *per cent* was not generated by the system for the unexecuted value of the purchase orders, which worked out to `6.13 crore.

The audit trail revealed that lack of documentation (Data Flow Diagrams, Data Dictionary, *etc.*,) had rendered the data available in the system incomplete, inconsistent and unreliable for calculation of penalty for unexecuted value of supply order.

The Government replied (November 2017) that the data required for audit trail was available in the system.

The reply was not acceptable as the details of unexecuted quantity, date of supply, penalty for unexecuted quantity, *etc.*, were not available in the database provided by TNMSC.

Refund of penalty despite non-supply

2.2.28 An analysis of data containing information on placement of purchase orders, supply at warehouses and payments, revealed that out of 1,385 cases of refund of penalty on unexecuted orders, in 791 cases the penalty amounts were refunded in full though the unexecuted portion of the order were not supplied. In the remaining 594 cases, the penalty was refunded either fully or partially though there were unexecuted portions of supply.

Audit observed that there was no rule provision in TNMSC to refund the penalty. It was also observed that system had failed to correlate the supplies and the refund of penalty, resulting in return of the penalty even in the cases of non/partial supply.

The Government stated (November 2017) that in respect of 594 cases, it had levied penalty of `4.08 crore. It further stated that the penalty was refunded in respect of the balance 791 cases based on the tender condition for refund in case of damaged supplies. The reply is not acceptable since the tender condition provided for refund of a maximum of five *per cent* on each order quantity for Ampoules, Vials and Glass Bottles and two *per cent* for remaining drugs in

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⁷⁴ 2012-13 - ` 5.26 crore (264 cases); 2013-14 - ` 4.06 crore (108 cases); 2014-15 - ` 1.23 crore (57 cases); 2015-16 - ` 0.09 crore (nine cases) and 2016-17 - ` 24.13 crore (1,250 cases).

damaged supplies. Thus, the amount refunded in violation of the above condition, resulted in loss of `62.39 lakh.

Levy of penalty on empanelled laboratories

2.2.29 As per tender conditions, Analytical Laboratories had to furnish the test reports within eight days for Category-A and 21 days for Category-B drugs. For any delay, one *per cent* of the testing charges per week and the part thereof would be deducted as penalty. For repeated delays⁷⁵ the penalty would be two *per cent* of testing charges per week and part thereof.

An analysis of data of laboratory reports (1,25,876 records) revealed that in 81 instances involving 14,332 records, the test results from empanelled laboratories were received with delay occurrences of more than eight times in a year or delay of more than ten days. Contrary to the tender conditions to levy penalty at two *per cent*, the system levied penalty at one *per cent*.

In 5,179 out of 23,595 records, penalty was levied though the testing results were received within the stipulated time.

Thus, the systems failed to correlate the data relating to date of sending samples to laboratories for quality testing and the date of receipt of laboratory results based on which the penalty is calculated. This resulted in incorrect calculation of penalty by the system and unwarranted correspondence with the laboratories.

The Government stated (November 2017) that audit had calculated the delay from the difference in days between 'date sent' and 'report date' whereas TNMSC calculated the difference in days between 'date sent' and 'result entry date' and accordingly penalty was deducted from their payment.

The reply of the Government is not acceptable due to the fact that as per clause 23 (h) of the tender condition, the report was to be sent by e-mail/fax to TNMSC head office as soon as the test is completed. Audit observed that the test report should be sent to TNMSC as soon as the test was completed and that date (report date) should be reckoned for arriving difference in days to levy penalty, in case the stipulated days exceeded 8 and 21 days for Category-A and Category-B, respectively. Even if the analysis to work out the delay in submitting the report was calculated as per the reply of TNMSC, there were 414 out of 23,595 records, where penalty had been levied though the testing results had been received within the stipulated time.

Demurrage charges not computed

2.2.30 As per tender conditions, drugs found to be 'Not of Standard Quality' was to be taken back by the supplier within 30 days of communication of test results. In case of failure by the supplier, TNMSC would collect demurrage charges, at the rate of two *per cent* per week, on the value of the drugs rejected. Such unlifted/rejected stocks would be liable to be destroyed after 90 days.

We computed that `6.38 lakh and `2.36 lakh was leviable as demurrage during 2015-16 and 2016-17, respectively. TNMSC, however, did not collect any demurrage charges.

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If the delay occurred consecutively for four times or more than eight times in a year or a delay of more than 10 days occurs over the time period stipulated.

Audit observed that though the required data for such calculation was available in the database, no provision was available in the application software to automatically work out the demurrage charges, which resulted in financial loss to TNMSC.

Government accepted (November 2017) the audit observation and stated that the application software was being customised to collect demurrage from respective suppliers.

General

Change management control and documentation

2.2.31 The e-Security Policy of 2010 of Government of Tamil Nadu, contemplated that maintenance of software developed by the department has to be logged to ensure changes are authorised, tested and accepted to maintain software accuracy and integrity.

The present system was evolved by incorporating the changes required from time-to-time. The change management⁷⁶ from FoxPro application was carried out after re-engineering and documented. However, while upgrading to web-based architecture, the re-engineering process was neither done nor supported by change management control process and documentation.

To cite an instance, in the warehouses, both DDMS and WIS application software were used. It was seen that DDMS was modified 18 times in warehouses during the year 2016-17.

We observed that whenever there was a change of architecture (from client-server to web-based) or changes are made in the existing application software to cater to the needs of the user departments, there should be change management process and documentation for efficient and effective management of the IT System with transparency.

Deficiencies brought out by audit in this report were also due to absence of the change management controls and documentation.

The Government replied (November 2017) that the basic system flow was not changed from the earlier version of documentation and only the business logic and data dictionary changed from time-to-time, needed to be documented. It also stated that on completion of migration process, the existing document would be updated.

Lack of third-party IT Security Assessments

2.2.32 According to the e-security policy, 2010 of GoTN, Government or third party IT security assessments of all IT devices, applications and assets was to be carried out annually. The 'e-Security Policy' envisaged comprehensive vulnerability assessment covering all devices and applications that formed the network.

any related incidents upon service.

Change management arising from various factors including hardware or software change, change in a process, change in technology, change in configurationetc., is one of the key disciplines of IT service management, which ensures a systematic and efficient approach to managing change in order to minimise the number and impact of

We noticed that such assessments for ensuring the security of the IT Systems were never carried out till date (September 2017). As a result, TNMSC had no inkling of the security issues and other vulnerabilities of the system relied upon for its functions.

While accepting the audit observation, the Government stated that (November 2017) necessary steps had been taken to conduct IT Security audit of their web portals and IT infrastructure. However, no timeline has been indicated in the reply.

Non-adherence to business continuity planning and disaster recovery Site

2.2.33 The e-Security Policy, 2010 of GoTN envisaged contingency planning which included (a) definition of critical information, threats, controls, system environment and roles and responsibilities, (b) establishment of critical information back-up services and (c) determination of recovery strategies (preventive/maintenance/corrective). However, except taking periodical back-up of the data held in TNMSC headquarters and warehouses and storing them in server systems/external storage devices, no plan and setup was in place in TNMSC. Considering the criticality of the IT Systems through which the day-to-day functions of TNMSC were carried out, Audit observed that a business continuity and disaster recovery plan, as envisaged in the e-Security policy is required.

The Government accepted (November 2017) the audit observation and stated that on completion of the planned migration of application software into webbased, the application would be hosted at Tamil Nadu State Data Centre with support from existing disaster and recovery infrastructure. However, no timeline has been indicated in the reply, for the planned conversion.

Conclusion

The computerised activities of TNMSC while catering to the day-to-day medical needs of the Government medical institutions had deficiencies which were attributable to ineffective implementation and dilution of the system controls by manual interventions.

- Inadequate mapping of business rules, lack of change management control processes and documentation were noticed.
- Tender processing data held in the system was incomplete and unreliable and purchase order quantities worked out by the system were manually modified.
- Inadequate planning and non-adherence to procurement policy resulted in excess/short stock position noticed in warehouses.
- TNMSC accepted supply of drugs with lesser-shelf life and also did not obtain replacement of drugs received after expiry valued at `5.93 crore.
- The prescribed procedure for drawal of samples was not followed. TNMSC could have avoided delay at various stages in quality control through alerts in the system.

- Non implementation of validation controls in the application software resulted in issue of drugs even after generation of "stop issue" order in the system.
- The system was deficient in blacklisting the defaulting supplier/laboratories.
- The system had deficiencies in calculating the penalty on unexecuted orders, refunds, liquidated damages and demurrage charges.
- There was no business continuity and disaster recovery plan. No third party e-security assessment was carried out so far.

Recommendations

TNMSC may ensure

- Overall effective utilisation of the system in tender processing by limiting human intervention to the minimum.
- Complete automation and eliminating human intervention in bid submission and processing, deciding bidder-wise order quantity with audit trail and blacklisting of suppliers/laboratories to enhance transparency.
- Incorporation of controls into the system to ensure replacement of drugs which had shorter shelf life at the time of supply and to prevent distribution of sub-standard drugs after 'stop issue' order.
- Streamlining of inter-warehouse transfers with added features in the system.
- Proper mapping of business rules on charging of penalty on unexecuted purchase orders, refunds, liquidated damages and demurrage charges.
- Efficient use of MIS reports to avoid delays in quality control process at various stages and to monitor stock position at warehouses.
- Documentation of system upgrades and business continuity & disaster recovery plans.