CHAPTER VI : MINISTRY OF HEALTH AND FAMILY WELFARE

National AIDS Control Organization (NACO)

6.1 Non achievement of project objectives

National AIDS Control Organisation is a division of the Ministry of Health and Family Welfare that provides leadership to HIV/AIDS control programme in India through various HIV/AIDS Prevention and Control Societies. National Aids Control Organisation (NACO), proposed (March 2005) to create quality access to condoms in high risk areas through Condom Vending Machines (CVMs) under Social Marketing Scheme. The Scheme envisaged promotion of safer sexual health practices by increasing access to and availability of quality condoms at all times in high risk areas of the country. The strategy adopted to achieve this objective was through installation of CVMs at public places viz., railway station, restaurants, bus terminals, cinema houses, red light areas, banks, post offices etc.

The scheme was operationalised in phased manner as detailed below:

Project phase	No. of districts covered	No. of CVMs[1] planned to be installed	Implementing agency	Financial arrangement	
Phase-I	67	11025 LTDOs-8000 MTDOs-3000 HTDOs-25	HLL Lifecare Ltd (formerly Hindustan Latex Limited) a PSU	₹ 10 crore released in March 2005	₹ 8.33 crore for procuring the machines and balance for meeting the operational and promotional expenditure
Phase-II	68	10025 LTDOs-10000 HTDOs-25	Hindustan Latex Family Planning Promotion Trust (HLFPPT), a Trust under HLL	₹ 10 crore released in January 2007. ₹ 1.50 crore released in 2010-11 to 2012-13, along with a recurring expenditure of ₹ 50,000 per month for maintenance cost of CVMs in West Bengal.	₹ 8.85 crore for procuring the machines and the balance for meeting the promotional, operational costs Extended the implementation of the programme till December 2012.

Audit noted the following irregularities in the implementation of the scheme.

[1] Low, Medium and High Traffic Dispensing Outlets

6.1.1 Physical performance of the project

6.1.1.1 Poor Planning

The Ministry initiated the scheme (Phase-I) on the basis of the proposal submitted by Hindustan Latex Limited for undertaking social marketing of condoms through vending machines. Audit noted that the Ministry did not undertake any comprehensive feasibility study before going ahead with the scheme.

In October 2006, a meeting was held in the Ministry to consider the proposal of installation of 11025 condom vending machines by the HLFPPT under the scheme (Phase-II). With the proposal a progress report submitted by the HLFPPT, in which, it claimed a sale of 13.33 million condoms through the vending machines during January to August 2006. Audit noted that this roughly worked out to 4.98 condoms per machine per day. This was less than the minimum targeted sale of 6 condoms per day. Audit further, noted that prior to releasing the grant for II phase in January 2007, the sale further dipped to 1.57 and 1.55 condoms per machine per day in October and November 2006 respectively. However, the Standing Finance Committee (SFC) proposal for the Phase-II of the project was given a go-ahead purportedly on the basis of the evaluation report given by the implementing firm itself.

Thus, neither the Ministry undertook any comprehensive feasibility study before going ahead with the scheme nor it evaluated the effectiveness of the scheme delivery under the Phase-I before releasing further funds for the Phase-II of the scheme.

6.1.1.2 Delay in installation of machines

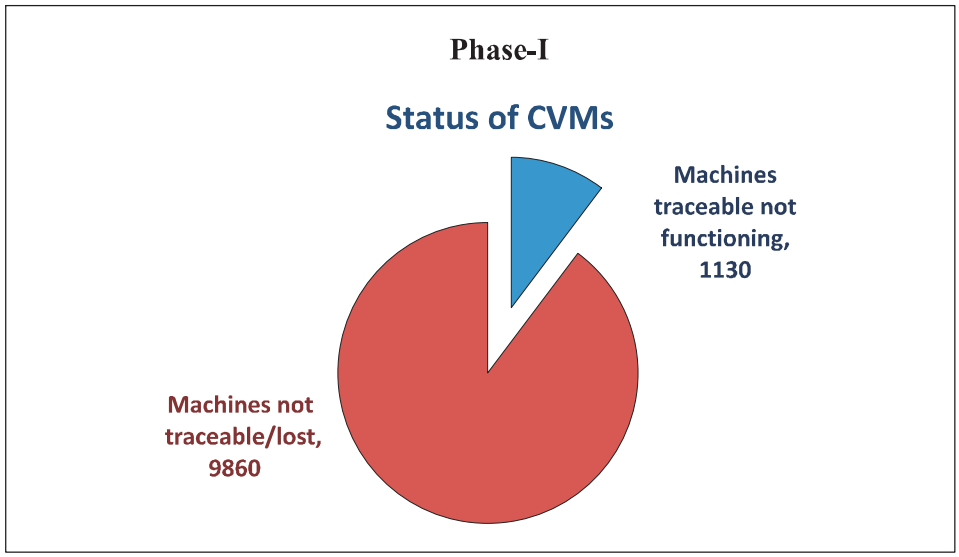
As per the minutes of the meeting of the SFC held in March 2005, M/s HLL was to procure and install CVMs within a period of six months. The notification award issued by HLL to the supplier stipulated that the machines were to be delivered, installed and commissioned on or before 30 September 2005 in Phase–I. In Phase-II, the machines were to be installed between April and July 2008.

Audit, however, found that in Phase-I, machines were actually installed during October 2005 to January 2006. The installation process for Phase–II commenced from August 2008 i.e., after the stipulated date of commissioning of the CVMs. The reasons for delay in installation of the machines were attributed to delay in selection of sites, worker's strike, torrential rains etc. The delay impacted the outcomes of the scheme vis-à-vis the targets envisaged.

6.1.2 Poor maintenance of CVMs due to absence of agreement with HLL/HLFPPT

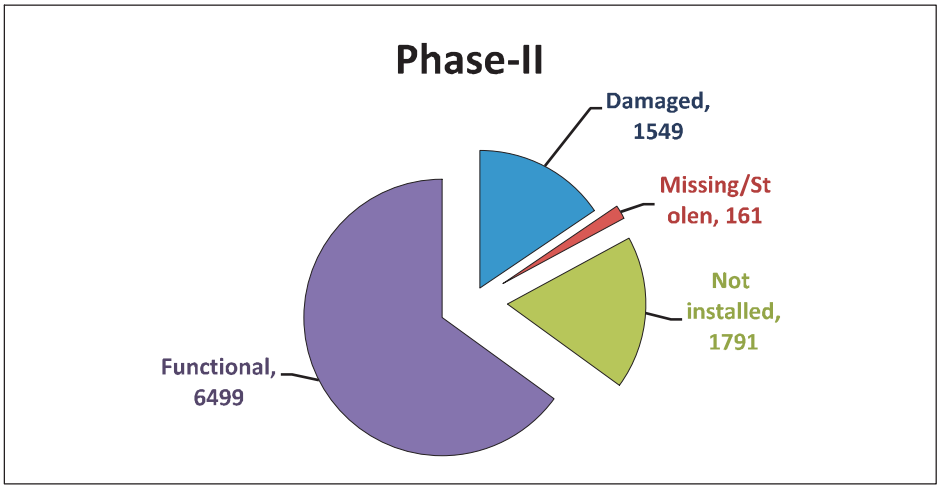
The Ministry/NACO did not enter into an agreement/Memorandum of Understanding with HLL/HLFPPT for management of the project and for assigning responsibility for safety, security and maintenance of the CVMs. Consequently the scope of the work relating to maintenance of the CVMs was not clearly defined.

Audit noted that the normal lifespan of a CVM was three years, extendable up to seven years with timely maintenance. During the first phase, the warranty on the machines expired in January 2009. These machines were serviced by the suppliers till March 2009. However, subsequently, due to absence of Annual Maintenance contract with the suppliers, the machines could not be serviced. HLL Lifecare Ltd. submitted (April 2009) a proposal for further operation and maintenance of the machines. The status of the functioning the CVMs as provided by HLL and HLFPPT to the NACO was as under:



As can be seen from the above only 1130 machines under Phase-I were available/traceable on sites. As the CVMs installed under Phase-I were not insured against theft and damage, thus, no recovery/claim could be made in respect of stolen machines.

HLL had requested (August 2011) to NACO to take suitable action as some of these machines could be made functional with some repairs. However, no action was evident in the records of the NACO as of March 2013.



The machines installed under Phase-II were maintained till June 2010 within the cost of ₹ 10 crore. The project was extended till March 2011 for operation and maintenance of CVMs at an extra cost of ₹ 90 lakh. A contract to this effect was entered (January 2011) into with M/s HLFPPT. The payments were released in two instalments during February and November 2011. The project was further extended till September 2011 with an additional cost of ₹ 60 lakh. The status of machines under Phase-II was better. However, given the fact that these machines had completed their useful life of seven years, NACO's decision to support their continued maintenance by incurring substantial expenditure needs to be reviewed in the light of their utility and impact.

The NACO stated that contract was not signed with the implementing entities because HLL was Central PSU and HLFPPT, a trust promoted by the PSU. The reply is not in consonance with the extant provision of GFR rule 204 (iv-d), which stipulates that contract should invariably be executed in cases of turnkey works or agreements for maintenance of equipment and provision of services. The reply was also contrary to its decision to enter into a contract with the M/S HLFPPT in January 2011 for extension and implementation of Phase-II of the SMP.

6.1.3 Poor sale of condoms through CVMs

NACO had estimated an average sale of 6, 12 and 35 pieces of condom per day from each Low Traffic Dispensing Outlets (LTDO), Medium Traffic Dispensing Outlets and High Traffic Dispensing Outlets respectively in the first year. It was, however, observed that 16 million pieces of condoms at an average of 1.34 pieces per machines/day were dispensed through 11025 CVMs of Phase-I during 36 months till January 2009. In the case of Phase-II, as per the data submitted by Technical Support Group, the average off take of condoms during 2008-11 was as low as 0.42 condom per machine per day. As

the programme had been merged with Social Marketing Organisations (SMOs), therefore, the average off take of condoms from CVMs during the period 2011-12 to 2012-13 could not be ascertained separately by the NACO.

Even by using the minimum sales estimation of six condoms per machine per day, it is evident that the actual sale of condoms through the CVMs was much lower. The reason for the lower sale may be attributed partially to the poor maintenance of the machines. The Ministry failed to assess reasons for poor sale of condoms for taking remedial action.

6.1.4 Lack of clarity regarding revenue to be generated through sale of Condoms

As per the Memorandum for the SFC submitted by the Ministry in March 2005, the project was to be sustained from the income generated from the sale of condoms. From the second year onwards the sales realization from the operation was to be utilized to meet the network maintenance costs, branding costs etc. Audit, however, noted that this proposal remained only on paper as the quantum of revenue realized or its utilization thereof did not find a mention subsequently in the records of the Ministry or NACO. NACO did not provide the information despite specific requests. Consequently, the arrangements in place for safe custody of money received through sale of condoms and its utilization could not be ascertained by Audit.

Audit also noted that under both Phases I and II, NACO was proposed to create a replenishment fund out of the contribution from the sale of condoms at the rate of Re. 0.05 and 0.10 per condom respectively. However, the proposed fund was not created. The reasons were also not found on record and were not provided despite specific request from audit.

6.1.5 Discontinuation of the Project

As per the decision taken subsequently in August 2011, the project was being discontinued by NACO due to operational and maintenance difficulties and it was proposed to merge the project with Condom Social Marketing Programme (CSMP). A total of 6499 machines which were functional as of September 2011 were to be handed over to SMOs implementing CSMP in six States and some machines were also be relocated by HLFPPT. The handing over and relocation of the machines was completed by HLFPPT in all concerned States except in the State of West Bengal where the existing SMO had refused to take over the machines. Therefore, HLFPPT was asked to continue the maintenance and operation of the 794 CVMs located in West Bengal at the

cost of ₹ 50,000 per month till December 2012. The payment @ ₹ 50,000 per month from October 2011 to June 2012 has been made to HLFPPT.

6.1.6 Conclusion

The CVM scheme by the NACO was characterized by poor planning and implementation. The Ministry did not undertake a comprehensive feasibility study. In the absence of a valid documented agreement, the issues relating to security and maintenance of the CVMs remained unaddressed. Consequently, the project was discontinued by NACO.

The sale of condoms through CVMs was very low in comparison to the projections of the NACO. The intended objective of improving the accessibility of condoms in high risk areas through CVMs was not achieved despite investment of ₹ 21.54 crore under the scheme. The hasty manner of release of funds by the Ministry under Phase-II without ascertaining the status of CVMs installed earlier was inappropriate.

The matter was referred to the Ministry in May 2013; their reply was awaited as of June 2013.

6.2 Pradhan Mantri Swasthya Suraksha Yojana

6.2.1 Introduction

Pradhan Mantri Swasthya Suraksha Yojana (PMSSY) was announced (August 2003) by the Government with the aim of correcting regional imbalances in the availability of affordable/reliable tertiary healthcare services and also to augment facilities for quality medical education in the country. It was proposed to establish in the next three years, six new hospitals in backward States with modern facilities like those available at All India Institute of Medical Sciences (AIIMS) in Delhi.

The Cabinet Committee of Economic Affairs (CCEA) approved (March 2006/June 2006) the first phase of PMSSY with two components i.e. (i) creation of six AIIMS like (AL) institutions[2] and (ii) upgradation of 13 medical colleges. The Phase-II of PMSSY proposed (February 2009) to establish AL institutions in two more states[3] and to upgrade six more medical colleges. The tentative cost of Phase-I of PMSSY was ₹ 9307 crore in February 2010. The Budget and Expenditure under the scheme is given below:

[2] Bihar (Patna), Chhattishgarh (Raipur), Madhya Pradesh (Bhopal), Orissa (Bhubaneshwar), Rajasthan (Jodhpur) and Uttarakhand (Rishikesh).
[3] Uttar Pradesh and West Bengal

(₹ in crore)

Year	Revenue		Saving	Saving in %	Capital		Saving	Saving in %
	Budget allocation	Actual expenditure			Budget allocation	Actual expenditure		
2004-05	60	6.16	53.84	89.73	-	-	-	-
2005-06	250	2.52	247.48	98.99	-	-	-	-
2006-07	75	6.27	68.73	91.64	-	-	-	-
2007-08	150	87.49	62.51	41.67	-	-	-	-
2008-09	50	33.46	16.54	33.08	440	450.54	-	-
2009-10	148	12.67	135.33	91.44	1300	461.81	838.19	64.48
2010-11	50	21.54	28.46	56.92	700	632.30	67.70	9.67
2011-12	55.94	42.29	13.65	24.40	1560.63	834.81	725.82	46.51

6.2.2 Status

Financial and Physical progress of six AL institutions indicating status of PMSSY-phase I as on 30 June 2012 are tabulated below:

(₹ in crore)

AIIMS project at	Total tendered costs for construction of residential complex and other four packages	Physical progress in %				
		Construction of Residential complex	Package I Construction of Medical College	Package II Construction of Hospital complex & HVAC	Package III Electrical services	Package IV Estate service
Bhopal	521.26	92.30	74.30	46.10	7.88	5.35
Bhubaneswar	531.00	21.00	72.52	55.19	2.15	Nil
Jodhpur	389.50	100.00	76.00	68.00	20.00	Nil
Patna	583.83	99.20	83.50	43.90	48.17	5.73
Raipur	512.54	100.00	49.21	43.92	34.30	2.13
Rishikesh	490.41	93.10	63.17	69.03	30.00	Nil
	3028.54	68.39	70.86	53.73	22.13	4.32

6.2.3 Audit findings

An audit of the process of selection and payments made to consultants and contractors for different stages of construction of the six AL institutions covered under Phase-I of the scheme was conducted during June-August 2012. The findings are discussed in the succeeding paragraphs.

6.2.3.1 Irregularity in selection of Project Consultant

The Ministry through its in-house[4] consultant HLL, invited (August 2007) 'Expression of Interest (EOI)' for appointment of Project Consultants for

[4] As an inhouse consultant HLL has been (March 2007) rendering various activities services viz., coordinate, liaise, monitor implementation activities, undertake bid process management, make payments to consultants, coordinate with State Governments etc. on behalf of the Ministry of Health and Family Welfare.

construction of Hospital and Medical college complex under PMSSY. The EOI contained qualifying criteria for issue of Request for Proposal (RFP) to the prospective bidders. Para 16 of the EOI provided that applications received after the stipulated time frame would not be considered under any circumstances.

In response, 14 Firms submitted EOI. Audit noted that out of these, four Firms did not have sufficient project experience while three Firms (including M/s SMEC) submitted the applications after the stipulated timeline. As such, only seven Firms were eligible for issue of RFP. However, after the evaluation of EOI, HLL, in December 2007, issued (December 2007), RFP to the 13 shortlisted Firms (including four technically disqualified Firms and two Firms which had submitted their application late). Subsequently, after evaluation of RFP bids, four successful Firms were selected (April 2008) as Project Consultants for six AL institutions (April 2008). M/s SMEC was selected as Project Consultant for AIIMS, Rishikesh at a cost of ₹ 5.18 crore. Payment of ₹ 2.17 crore was made to the firm as consultancy charges till April 2012.

Audit noted that M/s SMEC was not eligible for issue of RFP in terms of the EOI. Thus the selection of the firm as project consultant was not in compliance with the EOI and consequentially led to irregular payment of ₹ 2.17 crore to the firm.

The Ministry stated (July 2013) that HLL may have entertained the late submission of EOI for having wider participation and to have better competition.

The reply is inconsistent with the terms of the para 16 of the EOI document which stipulated that application received after the prescribed timeframe would not be considered under any circumstances. Further, after the receipt of bids, even the Ministry through its letter of September 2007 had drawn the attention of M/s HLL to this stipulation of EOI.

6.2.3.2 Irregular expenditure on escalation charges for civil work of hospital complex

The Ministry decided (August 2009) to carry out the civil work for medical college and hospital complex in two separate packages. It was also decided to

split the electrical works into two packages viz (i) sub-station, UPS, DG sets etc; and (ii) HVAC and BMS[5] etc.

During the course of technical evaluation in respect of civil package-II i.e. hospital complex, the Ministry decided that HVAC work and BMS would be included as part of the package-II. Accordingly revised financial bids were invited by the Ministry with additional scope of work. However, during financial evaluation for package-II it was observed that the rates quoted by the bidders were unreasonably high with respect to estimated cost of each of the project. Accordingly, with the approval of Health & Family Welfare Minister (HFM) it was decided (May 2010) to cancel the tenders for package-II and invite fresh bids. Subsequently, HFM approved the proposal of the Ministry that "*escalation clause for material and labour except HVAC & BMS work may be included in the tender as per CPWD norms to cater for realistic payments to the contractors as per actual price escalation*".

Audit noted that the subsequent RFP issued on 30 May 2010 clearly mentioned that escalation clause would not be applicable for HVAC & BMS work[6]. However, after the pre-bid conference held in June 2010 the Ministry decided that "escalation shall be payable for HVAC works also as per clause 10 CC of CPWD GCC". It was noted in Audit that this issue was not raised by the prospective bidders in pre-bid conference. Thus, the amendment to this effect in the tender document after pre-bid conference without seeking the approval of HFM was irregular. Finally, contracts for package-II were awarded in July 2010 and an expenditure of ₹ 1.56 crore as detailed in **Annex -2** was incurred on account of escalation clause for HVAC and BMS work against the specific orders of the HFM.

The Ministry stated (July 2013) that based on pre-bid conference held on 21 June 2010 the amendments were made to HVAC work by the Technical Evaluation Committee.

The reply however does not address the issue of non compliance with specific orders of HFM. Moreover, this issue was not a part of pre-bid queries raised by the prospective bidders.

6.2.3.3 Incorrect release of mobilization advance

As per section 32.5 of CPWD works manual and clause 10B (ii) of the General Conditions of Contract (GCC) entered into by the Ministry with

[5] Heating, ventilation and air-conditioning (HVAC), building management system (BMS)
[6] clause 10CC of RFP/GCC relating to payment due to increase/decrease in prices/wages

various contractors, mobilization advance (MA) not exceeding 10 *per cent* of the tendered value may be allowed. However, the request was to be made by the contractor within one month of the order to commence the work. Further, as per clause 10B V of General Conditions of contract, entered into with contractors '*if circumstances are considered reasonable by the Engineer in charge, the period of one month be extended at the discretion of Engineer-in-charge*'. Further, Para 32.5 (ii) of CPWD works manual provides that the advance should be released in not less than two instalments.

Audit noticed incorrect release of mobilization advance of ₹ 8.32 crore in the following three cases as depicted in the Table given below:

Sl. No.	Name of the work	Name of the contractor	Amount of MA released (₹ in crore)	Remarks
1.	Residential complex at AIIMS Bhubaneswar	M/s RDB reality and Infrastructure Ltd.	4.89	The Ministry released MA @ 10 *per cent* of tender value of ₹ 48.86 crore in one instalment in violation of provision of CPWD manual.
2.	Residential complex at AIIMS Bhopal	M/s Kumar Colonizers and Const. Pvt. Ltd.	1.18	The Project consultant (HLL) extended the period for grant of MA in violation of the General Conditions of the Contract. Further, justification submitted by HLL that MA was required to commence the work was incorrect as the work was already in progress.
3.	Residential complex at AIIMS Patna	M/s RDB Industries Ltd.	2.25	MA was released by M/s HLL after the lapse of stipulated period. However the fact was not brought to the notice of the Ministry.

The Ministry stated that in the case of Residential complex at AIIMS Bhubaneswar, M/s Hospital Service Consultancy Corporation (HSCC) had not released MA to the agency and in the case of Residential complex at AIIMS Bhopal and Patna, the MA has since been fully recovered.

The reply however does not address the issue of irregular grant of MA by the Ministry in contravention of the laid down provisions.

6.2.3.4 Excess payment of ₹ 25.20 lakh to in house consultant

The Ministry entered (August 2008) into agreement with HLL retrospectively from March 2007. As per para 4.5 of the agreement, advertisement charges,

legal expenses and actual of insurance premia paid for the maintenance of insurance cover, charges levied by local authorities, payment for security arrangements, expenses on logistics for running Project Cell at sites were to be reimbursed by the Ministry on actual basis.

Audit noted that the Ministry reimbursed expenditure of ₹ 25.20 lakh to M/s HLL on account of fees for sub-consultancy, for preparation of zoning plans and towards document and other miscellaneous expenses even before the agreement was signed. Further the payments made to HLL were not covered in the agreement. Thus to excess payment of ₹ 25.20 lakh was made to HLL.

The Ministry stated (July 2013) that the payment was made to M/s HLL prior to the signing of the consultancy agreement which was for their services rendered for completion of pre-project formalities.

The fact remains that these payments were not covered under the provisions of the agreement which was given effect retrospectively.

6.2.4 Other irregularities

- As per Rule 56 (3) of General Financial Rules, rush of disbursement, particularly in the closing months of the financial year, is to be regarded as a breach of financial propriety and should be avoided. Audit noted that the Ministry in violation of instructions of GFR released substantial funds aggregating to ₹ 81.62 crore to consultants/contractors during the months of March as advance during 2009-10, 2010-11 and 2011-12.

- The Ministry awarded (October 2007) consultancy work for construction of residential complex for AL institutions to M/s Hindustan Latex Limited (HLL) for Rishikesh and Patna sites and M/s HSCC for Bhubaneswar and Raipur sites. The contract agreements between Ministry and HLL/HSCC provided for payments for execution of work carried out by the contractors through Project Consultants based on actual progress of the project.

Audit noted that the Ministry had been releasing funds to HLL/HSCC on the basis of their estimated fund requirements on quarterly basis instead of actual progress of work. The consultants, in turn, were releasing the funds to the respective contractors on the basis of actual progress of respective works. This led to blocking of funds with consultants.

Further, as per clause 10.6 of these agreements '*any interest earned on the deposit received/advance drawn from the Government of India by the*

Consultant shall be added to the deposit received/advance drawn from Government of India'. However the Ministry did not carry out any assessment of the interest earned by the consultants on the funds retained in excess by them. Audit noted that during November 2008 to March 2010, funds of ₹ 0.57 crore to ₹ 16.66 crore remained blocked with the consultants (HLL and HSCC) for periods ranging between 1 and 166 days. This had an interest impact of ₹ 2.72 crore[7] **(Annex-3).**

The Ministry stated (July 2013) that interest earned on funds released to consultants was being accounted for and would be adjusted at the time of final payments.

The reply does not explain the need for placing the excess funds at the disposal of the consultants.

- As per Clause 3.6 of the agreement, the consultant M/s HLL shall submit a performance guarantee equivalent to 5 *per cent* of the consultancy charges of ₹ 12 crore within one month of the signing of the agreement. Audit noted that M/s HLL had initially submitted a performance guarantee of ₹ 60 lakh covering the period from 27 September 2008 to 03 October 2011 and no fresh guarantee for ₹ 87.05 lakh (5 *per cent* of the total amount paid to M/s HLL - ₹ 17.41 crore) was obtained from the firm.

The deficiencies in selection of project consultants and payment processes to consultants and contractors as brought out above indicates that the Ministry did not exercise adequate due diligence in implementing the project. The issues raised by Audit require immediate attention and corrective action by the Ministry.

6.3 Procurement of Allopathic drugs in CGHS

6.3.1 Introduction

The Ministry of Health and Family Welfare (Ministry) provides comprehensive health care facilities through "Central Government Health Scheme" (CGHS) to Central Government employees and pensioners and their dependents residing in 23 cities covered under CGHS apart from Delhi NCR. The medical facilities are provided through 250 CGHS wellness centres (earlier called as dispensaries) across the country.

[7] Based on average cost of borrowing of the Central Government during 2011-12 (7.9 *per cent*)

Medical Stores Organisation (MSO) is entrusted with the task of procurement of drugs and medicines required for CGHS hospitals and wellness centres outside Delhi. The MSO operates through seven Medical Stores Depots (MSD)[8]. Government Medical Store Depot (GMSD), Delhi is the nodal centre for procurement, storage and distribution of drugs for all CGHS wellness centres in Delhi.

6.3.1.1 Organisational set up

CGHS is headed by Director CGHS. Additional Director (Headquarters) is the administrative head of MSD Delhi and four zonal Offices of CGHS. The zonal offices exercise administrative control over CGHS wellness centres in their zone, and are responsible for processing and making payments of bills relating to local purchase made by the CGHS wellness centres. In cities outside Delhi, the CGHS is headed by Joint/Additional Director who exercises overall administrative control over the CGHS units and authorises payments to the suppliers of medicines against their bills.

6.3.1.2 Scope of Audit

The audit covered scrutiny of procurement of allopathic drugs in CGHS by Medical Store Depots and CGHS wellness Centres in Delhi, Ahmedabad, Jaipur, Chandigarh, Bhopal, Jabalpur, Kolkata, Chennai, Thiruvananthapuram, Hyderabad, Bangalore, Allahabad, Bhubaneswar and Mumbai during 2009-10 to 2011-12.

In Delhi, related records were examined in offices of Medical Store Organisation (MSO), MSD and the Ministry. In cities outside Delhi related records were examined at the offices of concerned Joint/Addl. Director CGHS, Central Medical Stores/Medical Store Depots and at the CGHS wellness centres.

6.3.2 Expenditure on Procurement of Drugs in CGHS

The total expenditure incurred by the Ministry on procurement of drugs for CGHS for the period 2009 to 2012 is given in table below:

[8] Mumbai, Kolkata, Chennai, Hyderabad, Guwahati, Karnal and New Delhi.

Total expenditure on procurement of drugs in CGHS Delhi and outside Delhi

(₹in crore)

	2009-10	2010-11	2011-12	Total
CGHS DELHI	328.15	387.28	326.93	**1043.35**
CGHS OUTSIDE DELHI*	200.40	232.83	270.00	**703.23**

6.3.3 Drugs Procurement system in CGHS

The Ministry maintains a list of drugs called drug formulary, separately for Branded and Generic drugs, for Government hospitals, Medical Store Organisation and CGHS. As of 31 March 2012 the Generic formulary consisted of 1128 drugs and the Branded formulary of 622 drugs.

Generic and Branded drugs

A Generic drug is defined as a term referring to any drug marketed under its chemical name without advertising; therefore Generic drugs are listed as the name of the constituent drug unlike Branded drugs.

A Branded drug is a drug/medication sold by a pharmaceutical company under a trademark-protected name.

The drug formulary is prepared by a committee[9] comprising, inter-alia, senior doctors from government hospitals. The Ministry finalizes the rates of the drugs listed in the formulary. These drugs are subject to mandatory testing in laboratories before supply to CGHS. In Delhi, the responsibility for procurement of formulary drugs/ medicines for CGHS wellness centres has been outsourced to M/s Hospital Services Consultancy Corporation Ltd. (HSCC). Every year, MSD constitutes a provisioning committee comprising zonal heads of four zones of MSD, which finalises the annual requirement of quantity of Branded and Generic drug for CGHS. The requirement finalized by the provisioning committee is sent to HSCC for supply of medicines to MSD.

For local purchase of drugs not listed in formulary, MSD Delhi empanels the local chemists and fixes the rates of discount on Maximum Retail Price (MRP) of drugs after negotiation with the chemists. Similarly, in cities outside Delhi, concerned head of CGHS units empanels the local chemists.

CGHS purchases drugs outside formulary on daily basis, on prescription of doctors, without any lab testing or any other verification.

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* Expenditure incurred in 23 cities covered in CGHS outside Delhi.

[9] Joint Secretary (Chairman) , Medical Superintendents, and HOD Medicine of AIIMS and RML hospitals, Director AIIMS, nominees from PGIMER Chandigarh, and JIPMER Pondicherry, Addl. DG Stores (MSO) and Addl. Director (HQ) CGHS.

6.3.4 Previous Audit Findings and Reports of the Parliamentary Committee

A performance audit of the procurement of medicines and medical equipment under the Ministry of Health and Family Welfare was conducted during 2006-07. The related findings were brought out in Report No. 20 of 2007 presented to the Parliament in November 2007.

The Report *inter-alia* touched upon the high incidence of local purchase of drugs and irregularities in such procurements.

The Public Accounts Committee took up the subject for detailed examination. In its Report on the subject (Twenty Fourth Report of the Fifteenth Lok Sabha) the Committee expressed concerns over the prescription pattern of the Doctors leading to high incidence of local purchase of drugs. The Committee advised the Ministry to take measures to avoid unnecessary local purchase of medicines.

The Ministry in its Action Taken Report stated that efforts would be made to reduce the incidence of local purchase.

Further, the Parliamentary Committee[10] in its 45th Report submitted to the Parliament in August 2010 observed that the current prices of many brands of drugs were highly inflated with no relation to their costs as detailed below:

Name of brand	Name of manufacturer	Drug composition	Price for 10 tablets
ORTHOBID	Abbot Health Care Pvt. Ltd.	NIMESULIDE 100mg	29.19
NIMULID	Panacea Biotech	NIMESULIDE 100mg	38.72
NICIP	Cipla Limited	NIMESULIDE 100mg	21.00
NISE	Dr. Reddy Laboratories	NIMESULIDE 100mg	48.00

The Parliamentary Committee noted that the cost of producing a strip of 10 tablets of Nimesulide was no more than ₹ 1.40. It was evident that huge margins are being made by both the drug companies and traders. There would be many examples of such price effects.

The Parliamentary Committee also noted that despite there being a code of ethics in the Indian Medical Council Rules introduced in December 2009

[10] 45th Report of Parliamentary Standing Committee on 'Issues relating to availability of Generic, Generic Branded and Branded Medicine, paragraph 30 and 31

forbidding doctors from accepting any gift, hospitality, trips to foreign and domestic destinations etc. from healthcare industry, there is no let-up in this evil practice and the pharma companies continue to sponsor foreign trips of many doctors and shower the obliging prescribers who prescribe costlier drugs with high value gifts like air conditioners, cars, music systems, gold chains etc. as quid pro quo.

The present audit seeks to examine the system of procurement of allopathic drugs in CGHS.

6.3.5 Audit findings

The objective of a drug formulary is to identify drugs commonly required for treatment of patients in hospitals/wellness centres. The formulary helps the doctors to restrict the treatment regimen within these drugs and reduce the incidence of local purchase of other drugs. The audit findings are discussed in the succeeding paragraphs.

6.3.6 Preparation/revision of drug formulary for Branded drugs

The Ministry constituted (September 2008) a Committee[11] for preparation/revision of the existing drug formulary for Branded drugs. The Committee decided to include new items in the formulary by identifying those drugs which were commonly procured in the CGHS, Delhi during 2008 through local purchase. The inclusion of various drugs was further subject to valid drug licence, registration of the manufacturing firm with MSO. Consequently, the Committee recommended (December 2009) inclusion of 382 more drugs over the existing 350 drugs. Subsequently, a total of 622 drugs were notified in the revised formulary in September 2010.

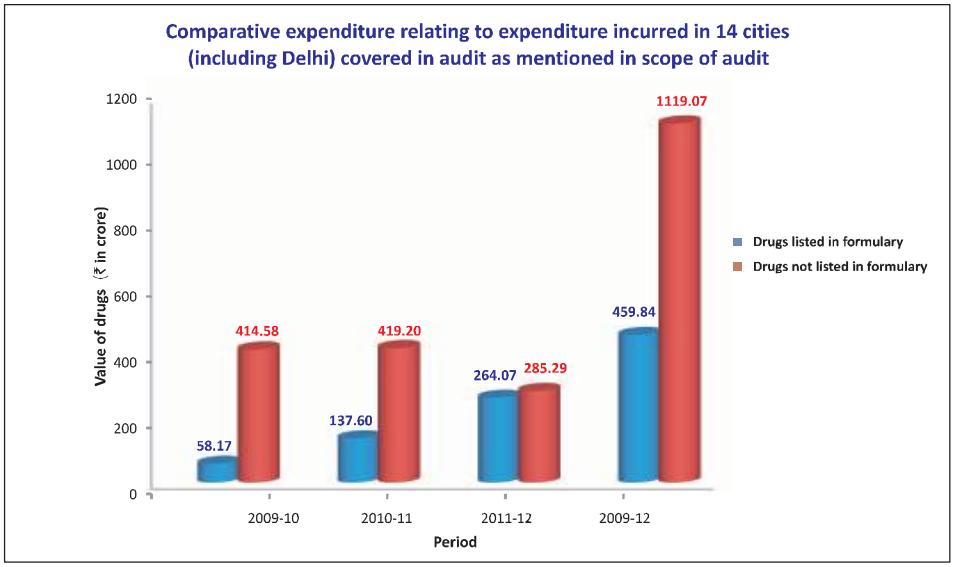
Audit noted that the Committee, while identifying the drugs for inclusion in the formulary, opted for commonly prescribed brands of drugs instead of identifying commonly prescribed drug composition. Thus, the methodology adopted by the Committee was predominantly based on the prescription of specific brands by doctors. The selection of items by adopting the drug composition approach would have provided many options that would be cost effective, as there were many brands of same drug composition available in the market at different rates.

[11] Under chairmanship of Joint Secretary the committee comprised of Medical Superintendents, and HOD Medicine of AIIMS and RML hospitals, Director AIIMS, nominees from PGIMER Chandigarh, and JIPMER Pondichery, Addl. DG Stores (MSO) and Addl. Director (HQ) CGHS

Test check of 21 cases in the Branded drug formulary revealed availability of several low cost brands in the same category of drugs. Audit also noted that even the discounted price of the selected brand was much higher than the MRP of other low cost brands available in the market. Audit compared the prices of these 21 test checked brands with other brands of identical drugs and found that CGHS Delhi incurred avoidable expenditure of ₹ 9.25 crore during 2011-12 by opting for higher priced brands **(Annex-4)**.

6.3.7 Procurement of drugs not listed in the formulary

The expenditure incurred by the Ministry on procurement of formulary and non-formulary drugs during the years 2009-12 is given in the chart below:



Analysis of the procurement pattern indicates that during 2009-10 to 2011-12, 71 *per cent* of the total expenditure was incurred on procurement of drugs not listed in the formulary. Further, CGHS Delhi procured only 19 *per cent* of items from within the formulary while 81 *per cent* items were outside the formulary as detailed in **Annex-5**. In cities outside Delhi covered in Audit, CGHS incurred about 50 *per cent* of the total expenditure on procurement of drugs outside the formulary during 2009-12.

Audit analysed the approved rates of drugs listed in the formulary and found that during 2011-12 the Ministry was able to obtain discounts in the range 12 to 50 *per cent* on the maximum retail price of these drugs. In comparison, CGHS was able to obtain discounts in the range of 10 *per cent* to 30 *per cent* for drugs outside the formulary. Thus the drugs listed in the formulary are substantially cheaper. However, Audit is unable to quantify the exact financial implication on this account as rates of non-formulary drugs are not maintained and therefore are not available for comparison.

Audit noted that the following factors played a significant role which led to drugs being procured outside the formulary.

(a) Non-finalisation of procurement rates of drugs listed in the formulary

One of the most important factors for timely supply of drugs of good quality is the speedy finalisation of the procurement rates of the drugs listed in the formulary by the Ministry. Audit noted that the rates of large number of drugs, particularly during 2009-10 and 2010-11, were not finalised by the Ministry. The details are given below:

Formulary	Year	Total nos. of drug listed in formulary	Drug for which rates finalised	Drug for which rates not finalised	Percentage of drugs of which rate had not been finalised
Branded drugs	2009-10	504	350	154	30.56 %
	2010-11	504	339	165	32.74 %
	2011-12	622	592	30	4.82 %

The reasons for non-finalisation of rates of various drugs were attributed to items being de-registered by the Drug Controller, rates of drugs not being negotiable, firms having changed drug composition to bypass NPPA[12], the firm not being the manufacturer of the quoted item, etc. Thus non availability of rates of drugs within the formulary is likely to lead to procurement of drugs outside the formulary which in turn would lead to extra expenditure as already mentioned at para 6.3.7 above.

(b) Inadequate and incomplete drug formulary

Audit noted that the doctors continued to prescribe drugs outside the formulary despite the adverse recommendations of the Parliamentary Committee. As a result, drugs valuing ₹ 1119 crore were purchased from outside the formulary during 2009-12 as detailed in paragraph 6.3.7 above. The fact that 71 *per cent* of the expenditure during 2009-12 was spent on drugs outside the formulary points to drug formulary not being comprehensive enough to cover drugs for wide-ranging ailments/diseases.

6.3.8 Procurement of Generic drugs

Audit further noted that many drugs are available in both Generic and Branded version. Generic drugs are substantially cheaper than the Branded version.

The following example would illustrate the point:

[12] National Pharmaceuticals Pricing Authority (NPPA) is an independent body of experts and is responsible for implementing the drug price control order (DPCO). DPCO is an order issued by the Government for fixing the prices of some essential bulk drugs and their formulations.

Generic drugs					Branded Drugs		
Generic name	Strength	Type	Pack	Price	Brand	Manufacturer	Price
Nimesulide	100mg	Tab	10	2.70	Nimulid	Panacea Biotech	29.00
					Nise	Dr. Reddy Lab	32.00
Amikacin	100mg/2ml	vial	2ml vial	6.25	Zycin	Zydus Cadila	19.50
					Amexel	Nicholas Piramal	15.10
Source :www. janaushidhi.gov.in							

The Minister of Health and Family Welfare while approving (September 2010) the revised formulary of Branded drugs, expressed serious concern on prescribing of Branded drugs by doctors instead of Generic versions and directed for a complete shift towards Generic drugs, within one year, both in prescriptions and supplies. In order to promote Generic drugs the Ministry, in May 2011, revised its Generic drug formulary from 818 to 1128 drugs.

Audit further noted that the Ministry did not finalise procurement rates of most of the drugs listed in the Generic formulary as detailed below:

Formulary	Year	Total nos. of drug listed in formulary	Drug for which rates finalised	Drug for which rates not finalised	Percentage of drugs of which rate had not been finalised
Generic drugs	2009-10	818	264	554	67.73 %
	2010-11	818	127	691	84.47 %
	2011-12	1128	279	849	75.26 %

The reason for non-finalisation of the rates of Generic drugs was mainly attributed to poor response from the drug manufacturers.

As a result, CGHS procured only 2 to 55 *per cent* of the Generic drugs listed in the formulary as detailed in the Table below:

Name of city covered in audit	Year	Percentage of drugs procured from Generic list
Delhi	2009-10	2.08
	2010-11	2.20
	2011-12	5.14
Ahmedabad	2009-10	54.5
	2010-11	8.17
	2011-12	4.43
Kolkata	2009-10	27.63
	2010-11	9.90
	2011-12	8.33
Chennai	2009-10	14.18

	2010-11	3.45
	2011-12	4.26
Mumbai	2009-10	40.61
	2010-11	16.78
	2011-12	24.59
Bhubaneswar	2009-10	6.80
	2010-11	6.80
	2011-12	5.07

Further, the expenditure on procurement of Generic drugs in CGHS, Delhi during 2009-12 constituted a mere 0.19 *per cent*.

Test check also revealed that 59 drugs selected for Branded drug formulary were already listed in the Generic formulary **(Annex-6)**. Further, a comparison of rates of 30 Branded drugs with rates of Generic drugs in Janaushidhi scheme[13] revealed that an amount of ₹ 11.81 crore could have been saved by CGHS Delhi during 2011-12, had Generic drugs been procured instead of Branded drugs as detailed in **Annex-7**.

6.3.9 Delays in procurement of drugs listed in formulary

Hospital Service Consultancy Corporation (HSCC) places the supply orders on vendors at rates already finalized by the Ministry. HSCC provides 60 days to the suppliers for making drugs ready for inspection and testing.

Audit noted that drugs were received in MSD after a delay of two to six months after communication of the requirement to HSCC. Further, issue of drugs from MSD to CGHS wellness centres took another three to five months **(Annex-8)**. In effect the drugs were received in CGHS wellness centres with significant delays.

Similarly in CGHS Chennai, Jaipur, Kolkata, Chandigarh, Thiruvananthapuram, Hyderabad and Bhubaneswar, drugs were received from respective MSDs after a delay of two to ten months from placing the orders.

In CGHS Hyderabad, Thiruvananthapuram, Chandigarh, Mumbai and Bhubaneswar there was a short supply/non-supply up to 85 *per cent* of drugs indented to the GMSD during 2009-10 to 2011-12.

The delays in procurement and non-availability of formulary drugs at CGHS wellness centres led to procurement of these drugs by CGHS centres from local chemists at higher rates leading to an extra expenditure of ₹ 3.05 crore as detailed below:

[13]Under Janaushidhi scheme Generic drugs which are available at lower prices but are equivalent in potency to the Branded expensive drugs are made available to public through Janaushidhi stores.

Extra expenditure on purchasing formulary drug from local chemists at higher rates

(₹ in lakh)

Name of CGHS covered city	Amount of extra expenditure incurred
Delhi	231.83*
Kolkata	0.18
Hyderabad	12.77
Jaipur	14.44
Chennai	45.58
Total	**304.80**

* Details in **Annex-9**

6.3.10 Avoidable expenditure of ₹ 13.52 crore in procurement of formulary drugs in Delhi through HSCC

In terms of Rule 165 of General Financial Rules and Para 1.2.1 of Manual of Policies and Procedure of Employment of Consultants issued by Ministry of Finance; the consultants may be employed in the condition of absence of required expertise in–house and when it is felt absolutely essential.

MSD Delhi is the nodal office which procures drugs for all CGHS wellness centres in Delhi. Procurement rates and concerned suppliers of the drug, listed in the approved drug formulary, are finalized by the Ministry. However, MSD procures these drugs through HSCC instead of procuring them directly from notified suppliers. MSD paid consultancy charges of 4.5 *per cent* to HSCC for this procurement till October 2008 and 2.5 *per cent* thereafter.

Audit noted that HSCC did not add any value to the procurement process and simply acted as a conduit between the Ministry and the supplier. This is so because the rates and suppliers had already been finalised for drugs procured through HSCC. Thus, MSD Delhi incurred avoidable extra expenditure of ₹ 13.52 crore on consultancy charges paid to the HSCC during 2002-03 to 2010-11.

6.3.11 Pilot Project to streamlining procurement of drugs

CGHS proposed (January 2007) to implement a Pilot Project to streamline procurement of drugs in CGHS. The project envisaged assessment of monthly consumption of drugs at CGHS centres. Requirements, thus assessed, were to be intimated to the supplier at the end of month. The drugs were to be delivered at the beginning of each month directly to the CGHS wellness centre by the supplier. This project was supposed to eliminate delays in supply of

drugs present in the prevailing central procurement system through HSCC in Delhi and through GMSDs in cities outside Delhi.

The Ministry approved (March 2007) the Pilot Project for 10 CGHS centres in Delhi initially. The project was implemented from July 2008.

Audit, however, noted that contrary to the proposal, which envisaged procurement of both formulary and non-formulary drugs, the approved list under pilot project contained only non-formulary drugs. It included 235 drugs that were stated to be commonly prescribed drugs purchased locally in CGHS. The project was extended to all the CGHS centres by September 2009. Later the list of drugs in the pilot project was revised to 272 drugs and were included in the Branded formulary of the Ministry (September 2010).

Audit also noted that MSD submitted (September 2010) that all the 622 drugs in the new drug formulary as approved by the Ministry may be included in the Pilot Project. This was meant to cut down delays in procurement through HSCC as well as to effect savings of commission of 2.5 *per cent* commission being paid to HSCC. The proposal was, however, not approved by the Ministry, the reasons for which were not on record.

Audit also noted that in CGHS Chennai, Kolkata, Jaipur and Hyderabad, even the drugs included in the Pilot Project were procured through local purchase at higher rates leading to an extra expenditure of ₹ 85.22 lakh.

6.3.12 Procurement of life saving drugs

CGHS maintains a list of 382 drugs under the category of life saving drugs. This is distinct from the approved drug formulary of the Ministry. These drugs include drugs for cancer, kidney diseases, osteoporosis, dialysis, haemophilia etc.

MSD finalizes procurement rates of these drugs on the basis of quotations received from the manufacturers. MSD procures the drugs based on the prescription made by the CGHS doctors, on approved rates.

As noted in the case of other Branded drugs, there were more than one brands of the same drug composition. Audit noted that there were 206 such brands of 72 drug compositions in the list of life saving drugs as on December 2011. Further, prices of the different brands having same drug composition varied substantially.

Test check of records related to procurement of life saving drugs in CGHS Delhi, Thiruvananthapuram, Allahabad and Kolkata revealed that CGHS incurred avoidable extra expenditure of ₹ 6.26 crore on procuring higher

priced drug brands despite availability of low cost brands within the list itself **(Annex-10).** CGHS did not accord reasons for including several brands of the drug of the same composition in the list of life saving drugs. This led to procurement of drugs in an arbitrary manner.

In CGHS Hyderabad, it was observed that life saving drugs were purchased at rates higher than the authorised list resulting in avoidable extra expenditure of ₹ 20.22 lakh.

Audit further noted that the MSD Delhi initiated (June 2009) an open tendering process for procurement of Generic drugs. However, the tender documents could not be finalised due to issues relating to modification of clauses in the tender documents. Thus the MSD failed to implement the proposal of procuring life saving drugs through open tender as of July 2012.

6.3.13 Quality Assurance

The drugs procured by MSD are subject to mandatory testing in laboratories before supply to CGHS.

In CGHS Kolkata drugs were issued to the patients before receipt of test reports, which were later reported as sub-standard by GMSD. In CGHS Mumbai medicines worth ₹ 28.45 lakh received from GMSD during 2009-2012 were declared sub-standard. Out of these, medicines worth ₹ 15.66 lakh were already issued to patients. Such instances highlight the absence of a robust mechanism for quality assurance, which exposes the patients to the hazards of sub-standard medicines and drugs.

In CGHS Hyderabad drugs worth ₹ 21.39 lakh procured from GMSD did not have prescribed shelf life and the shortfalls in shelf life were in the range of one to three months.

In Chandigarh drugs valuing ₹ 13.53 lakh expired between April 2009 and November 2011 implying that the requirement of drugs was not assessed properly.

6.3.14 Conclusion

It is recognised that the prices of drugs in the formulary are lower than non-formulary drugs. However, Audit noted that 71 *per cent* of the drugs procured consisted of drugs outside the formulary.

Further, procedures relating to procurement of drugs were not directed to effecting maximum economy. As a result, higher priced, Branded drugs were procured despite availability of low cost brands.

Branded drugs continue to be preferred over Generic drugs despite adverse remarks of the Parliamentary Committee. This caused significant financial burden on the exchequer. The money value included in this report relates to only test checked cases which constitute only a small percentage of actual procurement. Therefore, the monetary impact of such irregular practice would be much higher if the entire procurement were to be reckoned.

The Ministry may review the arrangement currently in place for procurement of drugs in light of the audit findings.

The matter was referred to Ministry in May 2013; their reply was awaited as of June 2013.

Directorate General of Health Services

6.4 Loss due to expiry of anti-TB drugs

Improper planning in procurement of anti-TB drugs by the Central Tuberculosis Division of the Ministry resulted in losses due to the expiry of drugs valuing ₹ 5.06 crore.

Tuberculosis (TB) is a major public health problem in India. To address the problems related to shortages and irregular supply of drugs for TB the Revised National Tuberculosis Programme (RNTCP) was launched in 1997. RNTCP is an application of World Health Organization recommended Directly Observed Treatment Short Course strategy.

Under the RNTCP the principle of continuous uninterrupted supply of drugs are followed whereas for the non-DOTS[14] regimen loose anti-TB drugs are procured. The Central Tuberculosis Division (CTD) of the Ministry of Health and Family Welfare, based on the assessment of the quantity required, procures anti-TB drugs through procurement agents for both DOTS and non-DOTS regimen.

The drugs are received by six GMSDs[15] through procurement agents. Further, the CTD issues release orders to GMSDs for distribution of the drugs to the respective State Drug Stores and District TB Control Societies.

In the Comptroller and Auditor General's Audit Report no. 2 of 2005, an audit finding, was made regarding the expiry of the shelf life of anti-TB drugs valuing ₹ 28.67 lakh in the GMSD, Kolkata, during February and November

[14] DOTS strategy means Directly Observed Treatment Short Course strategy under which a patient wise box is earmarked for a patient and it ensures that the TB patient receives drugs for the entire duration of the treatment. Whereas, under the non-DOTS regimen loose tablets are distributed to the patients.

[15] GMSD at Mumbai, Kolkata, Karnal, Hyderabad, Guwahati and Chennai

2002. In their Action Taken Note (March 2007), the Ministry of Health and Family Welfare attributed the expiry of drugs mainly to change in the strategy of TB programme. It also assured to improve upon the drug management system by ensuring that the drugs were procured in different tranches to have maximum shelf life and through optimal utilisation of stocks.

Subsequent examination of the records of the CTD revealed that during 2004-05 to 2005-06, the six GMSDs had received 25.09 crore loose anti-TB drugs tablets for non-DOTS regimen costing ₹ 16.64 crore. The loose anti-TB drugs were procured on the basis of the assessment that at least 10 *per cent* of the patients would require to be put on non-DOTS regimen i.e., in the form of loose drugs. The assessment of 10 *per cent* was made after assuming that some patients would find it difficult to take treatment under DOTS or who do not accept DOTS for other reasons.

Audit, however, noted from the relevant documents in the Ministry that detailed analysis or records of deliberation to arrive at the figure of 10 *per cent* were absent. Thus, the assumption of 10 *per cent* non-DOTS requirement did not have a reasonable basis. This analysis was critical as the drugs under the two regimen were not interchangeable.

Audit noted that the shelf life of five years of 11.09 crore tablets valuing ₹ 5.06 crore had expired in the GMSDs by October 2011. This worked out to 46 *per cent* of the total quantity available.

Thus, the Ministry sustained losses of ₹ 5.06 crore due to expiry of the shelf life of the anti-TB drugs. Of these, drugs valuing ₹ 2.75 crore[16] had been written off during 2007-11. The process for regularization of the remaining expired drugs was being initiated by the Central TB Division of the Ministry. Audit noted that the Ministry of Finance while concurring to the proposal for writing off the loss on account of expiry of the drugs had noted that the Ministry of Health and Family Welfare should ensure non-recurrence of such lapses.

Audit further noted that the Ministry while stating the reasons for expiry of loose anti-TB drugs to the Ministry of Finance, mentioned that the drugs expired due to a change in strategy requiring the programme to follow WHO recommended DOTS strategy instead of non-DOTS regimen used for patients earlier. The reason attributed by the Ministry was not convincing, as the WHO recommended DOTS strategy, popularly named as RNTCP, was in operation since 1997. Moreover, the fact that same reason had been advanced

[16] ₹ 2.59 crore written off by Ministry of Finance in December 2011 and ₹ 15.68 lakh written off by Ministry of Health and Family Welfare in November 2007.

by the Ministry, in their ATN, to an earlier Audit Para, indicates that appropriate remedial measures have not been taken by the Ministry to address this critical issue.

The Ministry in its reply to an audit observation stated (January 2013) that it had estimated that 10 *per cent* of the TB patients would continue to be put on non-DOTS regimen while actually less than one *per cent* of the patients were put on it. The Ministry further stated that it had taken steps to avoid such recurrences.

Subsequently, the Ministry reiterated (July 2013) that adoption of DOTS programme was a major shift in the strategy. The loss was not significant when compared to the total programme outlay and coverage. Further, it stated that the expiry and incomplete utilisation of the loose drugs was linked to accelerated coverage of DOTS and also delayed supplies of Non-DOTS regimen.

The replies of the Ministry establish that the procurement planning was improper. The assessment of patients for non-DOTS regimen was arbitrary leading to substantial losses. As a result, the assurance rendered to the Public Accounts Committee has not been complied with. It is recommended that responsibility for this lapse must be ascertained.