

## **Chapter IV**

# **Availability of Drugs, Medicines, Equipment and other Consumables**



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### Availability of Drugs, Medicines, Equipment and other Consumables

Drug Policy of NCT of Delhi (April 1994) provides for Central Drug Procurement, Storage and Distribution Centre with modern techniques of drug storage and inventory control. However, even after a lapse of 29 years this objective could not be achieved. CPA, which was entrusted with the duties of procurement of drugs and equipment, failed to deliver as the percentage of essential drugs to be procured by hospitals ranged between 33.74 and 47.29 *per cent* of the total EDL during 2016-17 to 2021-22. Similarly, during 2016-17 to 2022-23 (till September 2022), out of 86 contracts floated for procurement of equipment by CPA, only 24 (28 *per cent*) were finally awarded. CPA also failed to meet the demand of hospitals, forcing the latter to procure the drugs and equipment themselves thereby denying the benefits of economy of scale. Many of the essential drugs were not found available in the test checked hospitals. Even, there was short supply/shortage of injections for rare/fatal diseases like Haemophilia and Rabies. Hospitals failed to monitor and evaluate timely and regularly the need of repair, maintenance, replacement and condemnation of equipment.

CPA failed to update and prepare EDL on annual basis as envisaged in the Drug Policy of NCT of Delhi, to ensure availability of best drugs in health facilities and keeping pace with the ever changing field of drug industry. Formulary of Medicines was not prepared which would have facilitated doctors in prescribing drugs on rational basis, except in 1994 when the Drug Policy was formulated. On the quality control front, CPA did not engage laboratories to test biological quality control to rule out any chances of contamination. It also failed to ensure accreditation of empanelled laboratories and efficacy of test reports of empanelled labs. Procurement of medicines from blacklisted and debarred firms was observed along with administration of expired drugs due to mismanagement of stocks.

#### 4.1 Introduction

The Drug Policy of NCT of Delhi, envisaged (April 1994) pooled procurement of drugs for all hospitals in Delhi along with establishment of a central drug procurement, storage and distribution centre. In Delhi, the Central Procurement Agency (CPA), under the administrative charge of the Directorate General of Health Services, is entrusted with the responsibility of procurement of all medicines required in health facilities under GNCTD. It is also entrusted with the responsibility of procuring equipment for various Delhi Government health institutions as per their demand. Besides, the Finance Department, GNCTD vide OM dated 7 August 2019 delegated full financial powers to the Head of Departments, Administrative Departments and Secretaries for purchase of

medical stores and equipment. As per the Government policy, health care institutions should ensure availability of all essential drugs at all times. As CPA did not ensure timely procurement and distribution of medicines and equipment to healthcare facilities, hospitals had to make their own agreements with local chemists to purchase medicines and float tenders to purchase various equipment.

## **4.2 Procurement and Availability of Drugs, Medicines and Consumables**

### **4.2.1 Irregularities in preparation of Essential Drugs List (EDL)**

(i) The Drug Policy of Delhi aimed at preparation of EDL<sup>1</sup>, every year by a Special Committee consisting of eminent experts, to be used throughout the State at different levels of health care system. This Essential Drugs List was to be prepared annually by a Committee of Specialists, after consultations with concerned doctors. Suggestions were to be obtained from all health facilities, both hospitals and dispensaries, for inclusion and deletion of medicines. This list is then circulated amongst all the members of the Committee for Selection of essential medicines and finally after approval, to various Delhi Government health facilities. The procurement of medicines in EDL is done by CPA as well as by the hospitals concerned.

Audit noted that EDL was not prepared annually and was prepared only thrice<sup>2</sup> during the last ten years.

Essential Medicines List 2013 had two categories viz. Core-medicines<sup>3</sup> and Complementary-medicines<sup>4</sup>. The EDL was further segregated on the basis of the level of health care facility, i.e Primary, Secondary and Tertiary Health care facilities. EDL of 2016 and 2018, however, was not prepared on the basis of levels of health care facility/service.

(ii) The Essential Drug List 2018 was approved by Director General of Health Services (DGHS) in March 2018, on the basis of inputs received from a committee comprising of representatives from major hospitals. Audit noted that the Department received a letter (11 June 2018) from Minister of Health wherein, the issue of irregular inclusion of combination formulations and branded medicines in EDL 2018 was flagged. The Department was directed to

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<sup>1</sup> Essential medicines are those that satisfy the priority health care needs of the population and are intended to be available at all times in adequate amounts, in appropriate dosage forms with assured quality and adequate information and at a price the individual and community can afford.

<sup>2</sup> 2013, 2016 and 2018.

<sup>3</sup> Core which are defined as efficacious, safe, and cost effective medicines for priority conditions.

<sup>4</sup> Complementary defined as medicines for priority diseases which are efficacious, safe and cost effective but not necessarily affordable or for which specialized health care facilities or services may be needed.

stop floating of tender of about 150 medicines with instructions to constitute a committee of experts from hospitals to examine the essentiality of combination, branded and proprietary drugs for inclusion in the EDL of Delhi Government hospitals.

Accordingly, a committee was constituted by DGHS (26 June 2018) to examine the issue, which submitted its report on 9 July 2018. Perusal of the report revealed that the Committee examined 182 drugs out of which 43 drugs were not approved for inclusion in the EDL.

Thus, exclusion of about 24 *per cent* of items from the list indicates that initially due diligence was not exercised while considering drugs to be included in EDL 2018.

It is clear from the above facts that the mechanism evolved by CPA to include medicines in the Essential Drug List as per actual requirement, was not functioning properly.

***Recommendation 4.1: The Government should prepare EDL on annual basis as envisaged in the Drug Policy.***

#### **4.2.2 Delay in preparation of Formulary**

The Drug Policy, 1994 of GNCTD provides for setting up a Formulary Committee every year for preparation of Delhi State Formulary<sup>5</sup> which would be made available to doctors and pharmacists free of cost. Audit noted that Formulary was last prepared in 1994.

Department replied (February 2022) that proposal would be started afresh for preparation/updating formulary.

***Recommendation 4.2: The Government should take measures to prepare a Delhi State Formulary for facilitating the doctors in prescribing and dispensing drugs.***

#### **4.2.3 Centralized procurement of drugs**

As per decision taken in the meeting held on 16 August 2017 chaired by Chief Minister of Delhi, CPA was to ensure 100 *per cent* availability of medicines. It was directed to issue tenders in time, much before any medicine got exhausted. Thus, it was imperative on the part of CPA to invite tenders, process and finalize the rate contracts with the suppliers of drugs. Audit observed that despite establishment of a Centralized Procurement Unit, many drugs were left to be procured by the hospitals as shown in the **Table 4.1**.

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<sup>5</sup> Formulary is a manual containing clinically oriented summaries of pharmacological information about selected drugs. The manual may also include administrative and regulatory information pertaining to the prescribing and dispensing of drugs.

**Table 4.1: Status of drugs procured under EDL during 2016-17 to 2021-22**

Period	Total number of drugs in EDL	Total number of drugs to be procured by Hospitals	Percentage of drugs to be procured by Hospitals
2016-17	1390	469	33.74
2017-18	1390	469	33.74
2018-19	1180	558	47.29
2019-20	1180	480	40.68
2020-21	1180	480	40.68
2021-22	1180	480	40.68

Source: Information furnished by CPA

It can be seen from the above table that the percentage of essential drugs to be procured by hospitals ranged between 33.74 and 47.29 *per cent* of the total EDL during 2016-17 to 2021-22.

CPA replied (January 2022) that it had no information as to how various medical institutions met the requirement of medicines in EDL. In the absence of finalization of contracts/non-procurement by it, the burden of purchasing essential drugs is passed on to the patients by public health care facilities.

The Government accepted (February 2023) the facts and stated that as of December 2022, rate contracts were available for more than 55 *per cent* of medicines and would reach between 80-90 *per cent* by March 2023 (including Anti Rabies vaccines).

The EDL medicines demanded by four test checked hospitals<sup>6</sup> and supplied by CPA for the period 2016-17 to 2021-22 is shown in **Table 4.2**.

**Table 4.2: Demand and Supply of drugs in selected hospitals**

Period	Total number of items demanded by hospital	Total number of items for which supply order not issued by CPA	Total number of items not received against the Supply order	Gross total of items not received against demand	Shortfall (in <i>per cent</i> )
<b>Lok Nayak Hospital</b>					
2016-17	1295	135	255	390	30.12
2017-18	1246	315	303	618	49.60
2018-19	1968	502	453	955	48.53
2019-20	1307	415	266	681	52.10
2020-21	1120	443	86	529	47.23
2021-22	1540	676	42	718	46.62
<b>Chacha Nehru Bal Chikitalaya</b>					
2016-17	1021	324	76	400	39.18
2017-18	621	62	0	62	9.98
2018-19	832	144	0	144	17.31
2019-20	889	326	0	326	36.67

<sup>6</sup> Nirantar Portal Database

Period	Total number of items demanded by hospital	Total number of items for which supply order not issued by CPA	Total number of items not received against the Supply order	Gross total of items not received against demand	Shortfall (in per cent)
2020-21	977	349	0	349	35.72
2021-22	661	191	52	243	36.76
<b>Janakpuri Super Speciality Hospital</b>					
2016-17	944	203	84	287	30.40
2017-18	748	158	47	205	27.41
2018-19	1026	321	35	356	34.70
2019-20	644	156	0	156	24.22
2020-21	475	176	0	176	37.05
2021-22	692	236	30	266	38.44
<b>Rajiv Gandhi Super Specialty Hospital</b>					
2018-19	182	63	0	63	34.62
2019-20	471	120	0	120	25.48
2020-21	374	91	0	91	24.33
2021-22	806	295	0	295	36.60

Source: CPA portal

It can be seen from above that against the items demanded by the hospital, the total number of items not received by hospital ranged between 30 and 52 *per cent* in LNH, 9 and 39 *per cent* in CNBC, 24 and 38 *per cent* in JSSH and 24 and 36 *per cent* in RGSSH.

Thus, CPA was not able to fulfil the supply of items requested by the hospitals which shows lack of seriousness of the Department in implementing the Drug Policy. It also indicates poor inventory control of drugs, as in the absence of central procurement, CPA was unable to undertake need based re-allocation of drugs in the health care facilities. Audit analysis revealed that tenders were floated with delays ranging between seven months and two years.

The reasons attributed by CPA for not finalising the rate contracts were deficit in logistics and trained manpower.

***Recommendation 4.3: The Government should take necessary action to revamp CPA so as to enable it to carry out its duties in an efficient and effective manner.***

#### **4.2.4 Risk purchase/penalty clause for non-supply of orders**

As per tender document, in order to ensure 100 *per cent* availability of medicines, in case of alternate purchase effected by CPA due to late execution/not executing of orders by the suppliers, the differential cost/risk purchase amount incurred was to be recovered from the suppliers along with 20 *per cent* of value of such supply orders. If such default occurs for three or more supply orders placed during the tender period, penal action like blacklisting from participating in present and future tenders may be enforced.

Department did not respond about the total amount recoverable from the suppliers on account of failure to supply and risk purchase made during 2016-17 to 2021-22, along with letters issued to the suppliers concerned. However, analysis of CPA data revealed that against 67 supply orders issued to 329 suppliers during the period 2016-17 to 2022-23 (as on 30 September 2022), risk purchase and failure to supply penalty amounting to ₹ 27.98 crore was recovered from the suppliers. Test check also revealed that CPA had issued repeated supply orders<sup>7</sup> in September 2019 to three suppliers who defaulted on previous occasions as shown in **Table 4.3**.

**Table 4.3: List of repeat defaulting suppliers**

(Amount in ₹)

Sl. No.	Name of the firm (M/s)	Risk purchase amount recoverable in tenders 16_08 and 17_03	Amount recoverable in tenders 18_01 and 18_04
1.	Biogenetic Drugs Pvt. Ltd.	42,590	2,84,738
2.	Daffodills Pharmaceuticals Ltd.	324,111	6,87,947
3.	Eurolife Healthcare Pvt. Ltd.	3,29,594	22,35,644

Government stated (February 2023) that last order for risk purchase by CPA was placed on 4 February 2020 and that no risk purchase/penalty was imposed for not supplying because of Order issued (May 2020) by GoI which stipulated that penalty clause will not be invoked if the default was on account of disruption of supply chains due to spread of Corona Virus. Reply is not tenable as the GoI order was not applicable since the cases mentioned in Table 4.3 pertained to September 2019, i.e., prior to Covid period.

#### **4.2.5 Local purchase of drugs/surgical/consumable items in test checked hospitals**

(a) **LNH:** For the purpose of selection of empanelment of agency for supplying medicines/surgical/consumable items/general items, LNH had estimated (August 2016) a total annual requirement of drugs and other items costing ₹ 2.37 crore. One of the conditions stipulated that address of the firm should be within five kilometre radius of the hospital. Two agencies<sup>8</sup> were selected for two years from December 2016 on the basis of maximum discount offered on MRP. Further the contract was extended from time to time for 28 months up to April 2021.

As per contract, the agency was to supply emergency/casualty items immediately or within three hours after receipt of order. Delivery of the other supplies was to be made immediately/next working day by 9 AM or at the earliest opening hours of the units/store of the hospital.

<sup>7</sup> Supply orders dated 14.9.2019, 16.9.2019, 17.9.2019 and 21.9.2019

<sup>8</sup> M/s Super Medicos and M/s Popular Generics



Audit however, noted that:

- Selection of agencies was based on annual requirement of ₹ 2.37 crore whereas the actual procurement<sup>9</sup> was much higher and ranged between 225 per cent and 1,364 per cent of the annual requirement. Besides, fresh contract could not be initiated and finalized timely, as a result, the contract period was extended regularly up to 28 months till April 2021.
- Procurement from local chemist was to meet emergency requirement only. However, Audit noted that ₹ 94.09 crore was incurred on local purchases, which included procurement of medicines and other consumable items in bulk from these agencies to meet the day to day requirements.
- The distance criteria adopted by the hospital limited the competition as two out of nine agencies applied for the tender were rejected on this ground.

For new contract period starting from April 2021, only a single firm finally qualified for supplying medicines, injection, IV fluids, surgical consumables and Implant and devices. Audit noted that the above contract also was restrictive as it allowed bidding by firms within seven kilometre radius of the hospital only.

LNH replied (May 2022) that CPA failed to supply medicines as per the demand raised by the hospital and suggested either CPA should function properly or it should be dissolved. In order to ensure availability of all medicines as per the Government policy, hospital had to procure locally. Government further stated (November 2022) that the selection of local chemist in LNH in April 2021 was not based on single tender as there were 10 bids and the firm was selected as it offered more discount than the previous contract. The fact remains that the only eligible firm was awarded the contract.

**(b) CNBC:** The hospital was also procuring medicines/surgical consumable items/general items which were not available in the store from local chemists on the basis of approved discount rate on MRP. As per terms and conditions of the rate contract, vendor was to supply the drugs within 24 hours of the placement of order. Test check of records relating to local procurement of items which were not available in store revealed that in some cases, it took more than two days for supply of drugs.

CNBC stated (August 2022) that it takes time as supply orders were placed after approval of competent authority and enquiry of rate from firms approved for local purchase.

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<sup>9</sup> ₹ 5.34 crore, ₹ 10.36 crore, ₹ 15.03 crore, ₹ 31.03 crore and ₹ 32.33 crore during year 2016-17, 2017-18, 2018-19, 2019-20 and 2020-21 respectively

#### **4.2.6 Quality Control**

Quality of public procurement and logistics is a major challenge to ensure access to free drugs and diagnostics through public facilities.

##### **4.2.6.1 Warehouse facilities for drugs storage not developed**

The Drug Policy of NCT of Delhi (April 1994), envisaged establishment of Central Drug Procurement, Storage and Distribution Centre to ensure modern techniques of drug storage and inventory control. The aim was to ensure that drugs did not pass their expiry dates and that any imbalances, such as shortage of a particular drug at one hospital and unused stocks at another, are identified and corrective measures taken well in time. A meeting was also convened in the chamber of Minister of Health (May 2015) to discuss issues related to drug procurement. After due deliberations, it was decided that CPA shall procure all medicines, consumables, non-consumables lab items, major equipment and their maintenance and other miscellaneous items required in health facilities/hospitals under GNCTD. It was also decided to establish initially four drug warehouses in different geographical locations of Delhi for issuing of medicines and other items to health facilities/hospitals on monthly basis.

For this purpose, Director Health Services was to prepare a proposal for site selection, infrastructure and staff requirement, etc. In this regard, DGHS was requested to furnish the Action Taken Report. However, no report was furnished.

Audit also noted that DGHS failed to provide adequate space to CPA for warehouse. It was further observed that though temporary arrangements were made for warehouse facilities at three locations, nevertheless, the programme was not successful due to absence of adequate space for receiving goods. Thus, the Department missed an opportunity to reap the benefits of modern techniques of drug storage and inventory control as envisaged in the Drug Policy, due to failure of DGHS to arrange for adequate space for warehouse.

Government stated (February 2023) that all consignees of CPA have their own drugs store which has adequate storage space for the items procured by CPA so there is no requirement of separate warehouse at present. Reply of the Government shows laxity in implementing its own Drug Policy to ensure modern techniques of drug storage and inventory control which could have avoided expiry of drugs as pointed out by Audit.

##### **4.2.6.2 Distribution of drugs to patients before testing of samples**

Drug Policy of NCT of Delhi envisages making available safe, effective and good quality drugs at health facilities but does not elaborate on specific steps to be taken to ensure quality of drugs.

Audit noted that medicines procured by CPA are supplied directly to Hospitals by the suppliers. After the stipulated supply period, samples<sup>10</sup> are picked up from hospitals by CPA for quality testing in the empanelled laboratories. In case any sample shows undesired results (not of standard quality), the testing report is conveyed to all user departments for taking necessary action as per the tender conditions.

During test check of records of LNH and CNBC, Audit noted that there was a time gap of two to three months between the receipt of drugs from the CPA and receipt of Government Analyst's report regarding quality of the drugs supplied. Audit noted that a few drugs supplied by the CPA were later reported as inferior quality (**Annexure III**). Audit observed that some of these inferior quality drugs were consumed in the hospital before the receipt of quality testing reports.

LNH reiterated (May 2022) the procedure for testing of medicines supplied by CPA, however, it did not comment on the use of inferior drugs in the hospital.

Further, the Department was requested to elaborate on the mechanism put in place by it to ensure that all the firms attach certificates from lab that the drugs are of standard quality. Similarly, end-user wise stock position of drugs showing quantity consumed, unused quantity of drugs available and total unused quantity disposed off as per tender conditions in respect of samples which were declared as 'Not of Standard Quality' were also sought. The Department, however, failed to furnish the requisite information. In view of the time lag between consumption of drugs, their analysis and eventual intimation to the stakeholders concerned, efficacy and safety of drugs distributed to patients could not be vouched for.

Government stated (February 2023) that CPA mandates requirement of valid drugs licence and in-house quality analysis report of the supplied batch of medicines and the same is approved by the state Drugs Controller Authority. CPA considers these reports to be sufficient for quality assurance. The reply furnished by the Government is not tenable as procedure in place was inadequate to ensure that only quality drugs are provided to patients.

***Recommendation 4.4: The drug samples for testing should be picked up in such a way that there should not be any time lag between the delivery of drugs and test reports to avoid the use of inferior quality medicines in hospitals.***

#### **4.2.6.3 Delay in empanelment of drug testing laboratories**

The Drug Policy of NCT of Delhi, emphasizes on good quality control and assurance system for providing safe and effective drugs. Records relating to empanelment of laboratories for testing of drug samples revealed delay in empanelment of drug testing laboratories. It was observed that agreement for

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<sup>10</sup> The particular batches of medicines for testing are picked up by the CPA through its procurement software, NIRANTAR based on where the maximum quantity is received.

fresh empanelment of laboratories was signed by DGHS in May 2018 though extension of empanelment was only upto April 2017. It was further noted that the renewal of empanelment again became due in May 2021, however, the same was approved in July 2021 and that only six out of 11 labs gave consent for renewal of empanelment.

The Department was requested to furnish (a) specific reasons for delay in empanelment of labs, (b) capacity of each of the empanelled laboratory in terms of the number of samples that could be tested and stored per day, and (c) details of drug samples that were sent for testing to the labs during the period when validity of empanelment of labs ceased to exist. The Department, however, did not respond to the audit query which indicates lackadaisical approach of the department to ensure a sound system for quality control of drugs being made available at public health care facilities.

Government attributed (February 2023) delay in empanelment of drug testing labs to cancellation of tenders due to problems in BOQ and glitches in the tender. It was further submitted that new tender has been uploaded on e-tendering site.

***Recommendation 4.5: The Government should emphasize on good quality control and assurance system for providing safe and effective drugs at public health care facilities.***

#### **4.2.6.4 Empanelment of Labs without ensuring NABL Accreditation and license from Drug Control Department**

Drug Policy of NCT of Delhi, envisages making available safe, effective and good quality drugs at all times at all health facilities. This requires strengthening of quality control mechanism. The empanelled lab should have a valid Accreditation from NABL<sup>11</sup> and license<sup>12</sup> from any State Drug Control Department/Central Drug Standard Control Organisation. This was one of the tender conditions pre-requisite for empanelment of labs for testing samples of drugs.

Audit noted the following issues in the empanelment of laboratories:

- NABL Certifications were available for part periods for 11 labs empanelled in May 2018 and for six labs empanelled from July 2021 as per records produced to audit. Government stated (February 2023) that

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<sup>11</sup> National Board for Testing and Calibration Laboratories (NABL) has been established with the objective of providing Government, Industry Associations and Industry in general with a scheme of Conformity Assessment Body's accreditation which involves third-party assessment of the technical competence of testing including medical and calibration laboratories.

<sup>12</sup> The Drugs and Cosmetics Rules 1945 provides that approval for carrying out such tests of identity, purity, quality and strength of drugs or cosmetics, on behalf of licensee for manufacture of drugs or cosmetics shall be granted in Form 37 and its renewal in Form 38 by the Licensing Authority appointed by the State Government.

the Tender Evaluation Committee had checked on e-tendering portal and mentioned in file that the NABL Accreditation Certificates in respect of all empanelled labs were available on the portal at that time. Moreover, letters have been written to all empanelled labs to provide their NABL Accreditation Certificates.

- Names of two labs<sup>13</sup> also featured in the list of labs suspended by NABL, effective date of suspension being 16 August 2019 and 11 October 2019 respectively which shows that there was no mechanism in the Department to ensure NABL Accreditation status of labs.
- In five out of 11 NABL accredited labs, approval (Form 37)/renewal of approval (Form 38) for carrying out tests of identity, purity, quality and strength of drugs or cosmetics from the Licensing Authority was not available on record, whereas, in case of two labs, the approval was available for only part periods pertaining to the years 2016-17 to 2021-22. Likewise, in six labs, empanelled from July 2021, requisite approval was available for part periods in only two cases. The Department, however, failed to provide copies of approvals/renewals in respect of remaining laboratories/period, in the absence of which testing of drug samples by unauthorized laboratories could not be ruled out.

Department did not reply on the details of samples sent to different labs during the period of audit.

***Recommendation 4.6: CPA should ensure that laboratories who have tendered for testing of sample drugs fulfil the eligibility criteria of valid NABL Accreditation and License from Drugs Control Department.***

#### **4.2.6.5 Verification of efficacy of empanelled laboratories not done**

To assess the correctness of test results being given by the empanelled laboratories and to ward off collusion with the suppliers, CPA was required to send random samples to the government analyst or another empanelled laboratory for testing. In case of gross variation in the analytical reports, empanelled laboratory may be blacklisted for a period of two years.

Audit noted that CPA had no mechanism for sending samples to either government lab or to any another lab, on random basis. The two labs empanelled by the DGHS on 24 May 2018 were blacklisted in other States, for a period of five<sup>14</sup> years, due to variation in test reports. Audit also noted that samples were sent for testing to a lab which was not in the approved list of empanelled labs.

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<sup>13</sup> M/s Standard Analytical Laboratory (ND) Pvt. Ltd. and M/s Shree Sai Test House Pvt. Ltd.

<sup>14</sup> M/s Ozone Pharmaceuticals Ltd. (Analytical Lab), Bahadurgarh, Haryana and M/s Devansh Testing and Research Laboratory Pvt. Ltd. black listed for five years each w.e.f. 7.4.2017 and 1.8.2018 by Odisha and Haryana respectively.

Government stated (February 2023) that CPA empanels only NABL accredited laboratories licenced by the State Drugs Controller Authority and also asks for Form 37 and 38 from the laboratories to ensure their efficacy. Moreover, the government analyst is involved only in case of dispute. Reply of the Government reaffirms Audit apprehension that verification of lab reports of the empanelled lab to ensure correctness of reports was not being done.

***Recommendation 4.7: The Government may develop a mechanism to test check the efficacy of test reports of empanelled laboratories from government or another laboratory.***

#### **4.2.6.6 Analysis of biological products not conducted**

Biological products include vaccines, blood and blood components, etc. which tend to be heat sensitive and susceptible to microbial contamination. Audit noted that biological products were ordinarily not tested post-delivery to stores.

Department stated (April 2022) that biological products were not sent for testing as they required specialized facilities for testing. Thus, the Department compromised with biological quality control testing to rule out any chances of contamination.

Government stated (February 2023) that biological analysis facility is available only in government laboratories and CPA accepts supply only after submission of biological analysis report by government laboratories. Reply given by the Government contradicts the reply furnished by the Department in April 2022. Moreover, Government failed to show any documentary evidence in support of its reply.

#### **4.2.6.7 Procurement of medicines from blacklisted and debarred firms**

As per one of the eligibility conditions for supplying medicines to CPA, the bidder should not be currently blacklisted, debarred or de-registered for forgery, mis-representation or supplying “Not of Standard Quality” (NSQ) product(s) by any government/autonomous body/ institution, hospital in India. It was, however, observed that the Department procured medicines from firms without ensuring that they were not blacklisted/debarred by other institutions in India. Some cases are illustrated in **Table 4.4**.

**Table 4.4: List of blacklisted and debarred firms**

Sl. No.	Name of the firm (M/s)	Institution by whom blacklisted/debarred	Period of debarment	Period of default in GNCTD
1.	Jackson Laboratories Pvt. Ltd.	Blacklisted by Tamil Nadu Medical Services Corporation Limited	5.12.2017 to 4.12.2022	The firm also defaulted in supplying medicines in tender 16_08 & 17_03, as well as in paying risk purchase/penalty amount.
2.	Aculife Healthcare Pvt. Ltd.	Blacklisted by Odisha State Medical Corporation Ltd.	10.8.2018 to 9.8.2021	The firm defaulted in supplying medicines in tender 18_01 to 18_04, as well as in paying risk purchase/penalty amount. The firm was also declared non-eligible for bidding (Order dated 15.3.2018) by O/o Deputy Director Health Services, West Bengal, being a loss making company.
3.	Centurion Laboratories Pvt. Ltd.	Blacklisted by Gujarat Medical Services Corporation Ltd. and Haryana Medical Services Corporation Ltd.	GMSCCL: 02.09.2016 to 01.09.2019; & HMSCL: 28.12.2016 to 27.12.2019	The firm also defaulted in supplying medicines in tender 16_08 & 17_03, as well as in paying risk purchase/penalty amount.
4.	Maan Pharmaceuticals Ltd.	Debarred by Gujarat Medical Services Corporation Ltd.	9.12.2021 to 8.12.2024 (for supplying NSQ items during 2019).	The firm also defaulted in supplying medicines in tender 18_01 to 18_04, as well as in paying risk purchase/penalty amount.

Source: Departmental records

The Department could not provide the list of blacklisted/debarred firms during 2016-17 to 2020-21, by drug controllers/institutions of other states. The above facts show that the Department had not evolved a mechanism to ensure eligibility of firms in this regard.

Government stated (February 2023) that adequate care is taken during technical evaluation of the participating firms with respect to their debarring and black listing in other states to ensure no such firms qualify in the tendering stage. The reply is not tenable as it does not clarify on the blacklisted firms from whom procurement of drugs was made.

***Recommendation 4.8: The Government should evolve a mechanism to check that the firms supplying essential drugs are not debarred by other States for quality issues. The Government should also fix responsibility for the lapse of procurement of medicine from blacklisted firms.***

#### **4.2.6.8 Drug Therapeutic Committees and Prescription audit**

As per the Standard Operating Procedure for pharmacists issued by the DGHS, GNCT of Delhi, in 2016, all hospitals need to establish Drug Therapeutic Committees as a first step to improve quality of management of drugs in all stages of use. Further, it has to conduct the prescription audit. It stipulates that doctors should write prescriptions in clear, legible hand writing and affix their name and stamp with date. They should recommend only generic medicines which are in the EDL.

An audit record of prescribing habits of all doctors should be maintained and in case of any default, remedial action may be taken against the clinician. For this

purpose audit record of at least two *per cent* of the prescriptions should be scanned and kept.

Audit noted that:

- Drug Therapeutic Committee was formed in July 2021 (RGSSH) and December 2021 (LNH) only. Drug Therapeutic Committees were in existence in CNBC and JSSH during the period of audit.
- Prescription audit in LNH was conducted in March 2022. Report revealed that in 43 *per cent* cases, dosage of drugs/right strength was not mentioned, known allergy was not documented in all the test-checked prescriptions, medicines were not mentioned in capital letters in 97 *per cent* cases. Branded medicines were prescribed in 57 *per cent* cases and irrational use/over prescription noticed in 26 *per cent* cases.
- JSSH had conducted only one prescription audit in September 2020 covering June to August 2020. Report revealed that known allergy was not documented in 72 *per cent*, abbreviations were used in 70 *per cent*, vital charting not mentioned in 36 *per cent* and drug frequency in hours was not mentioned in 25 *per cent* of test checked cases.
- CNBC had conducted six prescription audits. Major issues pointed out in the reports were lack of documentation of known allergy, use of un-approved abbreviations and medicines not mentioned in capital letters.

CNBC stated (August 2022) that cases of non-compliance mentioned above were due to high workload and shortage of doctors as compared to daily OPD patient load. It further stated that the hospital was making continuous efforts to improve prescription compliance through induction training programmes and special lectures.

Thus, essential function of Drug Therapeutic Committee through prescription audit for ensuring accuracy and completeness in prescriptions was not ensured in the test checked hospitals.

***Recommendation 4.9: Hospitals should ensure proper functioning of Drug Therapeutic Committee and conduct regular prescription audit to ensure management of drugs in all stages of use.***

#### **4.2.6.9 Delay in receipt of Line Probe Assay (LPA) Test Reports**

Programmatic Management of Drug Resistant Tuberculosis (PMDT) Guidelines 2017 prescribe two tests for detection of specific/multiple drug resistance TB cases viz. (i) Cartridge Based-Nucleic Acid Amplification Test (CBNAAT) and (ii) Line Probe Assay (LPA). The regimen of the medicines would be changed on the basis of the reports, if the patients are diagnosed as Drug Resistant (DR-TB) or Multi Drug Resistant (MDR)-TB as per PMDT guidelines. The Guidelines prescribe that the District Drug Resistance -TB Centre should be in close proximity of the CBNAAT site/ LPA lab in the district.



Audit noted that the facility for Line Probe Assay (LPA) Test was not available in Chest Clinic, Nehru Nagar and patients were referred to AIIMS, New Delhi. As this arrangement led to considerable delay of more than one month against the prescribed time of 72 hours in receiving the reports, patients were given first line anti-TB medicines even though such patients were found diagnosed with Drug Resistant (DR-TB) or Multi Drug Resistant (MDR) TB on receipt of report. Thus, due to lack of availability of LPA test facilities, MDR patients were deprived from prompt and targeted treatment.

***Recommendation 4.10: The Government may develop testing facilities for prompt and targeted treatment as per Programmatic Management of Drug Resistant Tuberculosis (PMDT) Guidelines 2017.***

### **4.3 Effective System for Inventory Control**

#### **4.3.1 Annual Physical verification**

Rule 213 (2) of General Financial Rules 2017 stipulates that physical verification of all consumable goods and materials should be undertaken at least once in a year and discrepancies, if any, should be recorded in the stock register for appropriate action by the competent authority.

The Central Store under DGHS issues surgical items to Delhi Government Dispensaries. The records were maintained manually and no computerised system of inventory management was being used. Audit noted that the Store (as nodal store) issued various items viz. Sanitizer, Gloves, N-95 mask, surgical mask and PPE kits to all Delhi Government Hospitals during the pandemic. Audit was unable to verify the veracity of the physical verification of Central Store as complete information was not available as detailed below:

- In three (2016-18 and 2020-21) out of five years' audit period, no date was mentioned on the Physical Verification Certificate to ascertain actual date of verification of stores.
- 3,520 items expired during 2017-18, however, the facts were mentioned only after five years in the Physical Verification Report of 2021-22. Moreover, these expired items were neither found to be stored separately, to avoid inadvertent distribution for human consumption, nor disposed off as of May 2022.
- In two years (2018-20), a common date, i.e. 23 September 2020 was mentioned on the certificates, implying that verification for two years was irregularly done at the same time rendering the whole exercise futile.

Government stated (December 2022) that inadvertently dates were not mentioned in the report but were mentioned on the noting side of the file. Regarding expiry of 3,520 items, it was stated that only 35 items expired during 2017-18 and that these items were stored in a separate room for which process

of disposal was in progress. On conducting physical verification for two years on same date, it was attributed to unavoidable reasons and assured to conduct next physical verification on time.

Reply is not acceptable as the Government failed to furnish Physical Verification Reports on the basis of which certificates were issued. In the absence of supporting reports, discrepancies, if any, detected during verification and action taken by competent authority on them could not be verified in audit. As far as expiry of items is concerned, the reply is not tenable as the Physical Verification Certificate for the year concerned contradicts the contention of the Government.

#### **4.3.2 Physical verification of stocks in selected hospitals**

Audit noted in LNH and RGSSH, physical verification of drugs, equipment, linen, general stores, and wards of selected departments<sup>15</sup> was not conducted except for the year 2018-19 in the case of LNH. Further, Cardiology Department of RGSSH has not maintained stock registers of drugs. Other two hospitals (CNBC and JSSH) had conducted physical verification of stocks during the period of audit.

#### **4.3.3 Idle stock in the equipment store of LNH**

Examination of equipment stock register of LNH revealed that large quantities of equipment<sup>16</sup> purchased prior to April 2016 were not issued as of December 2021. This shows deficient stock management system of equipment in the hospital.

Government stated (November 2022) that it has initiated action to distribute the idle stock of equipment lying in Store.

#### **4.3.4 Discrepancies in Stock Registers**

Audit noted discrepancy in figures of closing balance and opening balance of medicines in Stock Register of LNH during the period 2016-17 to 2020-21 resulting in not accounting of loss of medicines from the stock. Similar discrepancies in figures of closing balance and opening balance of medicines<sup>17</sup> were also noticed in the stock registers of test checked Medicine Wards.

Stock of tablets expiring in the next financial year, were not brought forward in the opening balance for next year. As a result, 47 medicines with shelf life remaining were not taken in Stock Register and thus not accounted for in

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<sup>15</sup> Medicine & Gynaecology department of LNH and Cardiology department of RGSSH

<sup>16</sup> Adson forceps tooth (979), Adson forceps non-tooth (1054), BP Handle (257), chittle forceps (661), Metsenbaurn scissors (1086), sponge holder (93), stitch cutting scissors (47), towel clips (108), Mayo scissors (2819)

<sup>17</sup> Less shown Inj Zylistine (210) in the opening balance of 2017-18 and less shown Inj Octride (236), Inj Tazact (511), Inj Heparin (284), Inj Pantocid (746) and Inj Solumedrol (200) in the opening balance of 2020-21.

RGSSH from April 2018 to March 2021. Moreover, there was overwriting and cutting at several places in the stock register.

RGSSH stated (August 2022) that medicines were going to expire in the next year and hence entered in the expiry register. The reply is not acceptable as stock has to be debited on their expiry and not before. Closing balance of many drugs with shelf life of six to 32 months remaining were not taken into opening balance of next year which shows insensitivity towards wastage of usable medicines.

Audit further noted that drugs are issued from the main stores to various users/patient care departments as per the Indent Sheets submitted by the user departments. The day-to-day issue of drugs to various departments are noted in the consumption sheets for each month and after the end of month the total consumption of quantities are accounted for in the main Stock Register. Audit noticed mismatch of figures in the main Stock Register, Consumption Sheet and Indent Sheets in the selected months.

#### 4.3.5 Expiry of drugs due to mismanagement of stocks

Online Nirantar portal of CPA/DSHM facilitates tracking of stock balance of drugs in all health institutions of GNCTD so that the excess stock available in one health institution can be utilized by others on need basis. This would ensure optimum utilization and minimize loss due to expiry of medicines.

Audit observed from records that LNH and RGSSH were not using Nirantar portal for stock management of drugs and instead, physical registers were maintained. Due to this, excess stock in these hospitals could not be used by other hospitals on need basis and life of a large quantity of drugs had expired<sup>18</sup>.

<sup>18</sup> **LNH** - Acyclovir 200mg (31970, Date of Expiry 09/20), Acyclovir 400mg (22400, 06/20), Cephalexin 250mg (23984, 10/20), Ciprofloxacin 250 mg (38770, 09/20), Conjugated Estrogen 0.625mg(10304, 01/21), Diltiazem 60mg (25000,01/21), Fexofenadine 120mg (30000,03/21), Isotretinoin 10mg (23300, 03/21), L-Thyroxine 100mg (67700, 02/21), L-Thyroxine 25mg (18600, 12/20), L-Thyroxine 50mg (32200, 01/21), Nitrofurantoin 100mg (62300,01/21), Pheneramine Maleate (113805, 12/20), Propanolol 40mg (15500, 01/21), Rifaximin 550mg (14690,02/21), Sodium Valporate 200mg (131880,12/20), Spirolactone 25mg (19000,12/20), Tamsulosin 0.4mg (32703, 12/20), Udiliv 300 (65400, 03/21), Udiliv 150 (34050, 09/20), Allopurinol 100mg (13610,03/18), Brufen 200mg(54870, 02/18), Finasteride 1mg(189890, 11/17) and Serropeptidose 10mg(151040, 11/17).

**RGSSH** - Acebrophylline, 100 mg (16700,03/21), Alphacalcidol, 0.25 mcg Vitamin D (25675,05/20), Cilastazol, 50mg(12800,02/21), Ethamsylate, 500mg(13200,01/21), Enalapril (Envas), 5mg(17800,03/21), Glucosamine Sulphate, 750 mg(29860,01/21), Fexofenadine, 180 mg(19600,03/20), Hydroxy Chloroquine Phosphate, 200 mg(42000,11/19) and Pregabalim, 75mg(62380,03/20).

Note : In the order of Name of the medicine, quantity and month of expiry.

Moreover, it was also observed that expired medicines<sup>19</sup> were issued to indenting departments. In the case of RGSSH, gross irregularities were noticed in issuing medicines to patient care departments, OPD and Wards where the store department had issued expired medicines after changing the expiry date to a future date in the records.

CNBC was also not using Nirantar portal and instead was monitoring stock on some other online portal for drug management. It was observed that drugs worth ₹ 1.32 lakh expired as per the condemnation reports.

CNBC stated (June 2022) that due to decrease in consumption of said items and despite the best efforts taken by the departments and hospital authorities, the medicines could not be used before the expiry date.

Government replied (December 2022) that RGSSH has implemented e-hospital for maintaining stocks and for indenting process.

#### **4.3.6 Storage of drugs in LNH**

It was observed that the injection, tablet and syrup/ointment stores of LNH were not air conditioned though most of the medicines were to be kept at around 25 degrees Celsius. Shelves/Racks were not found labelled. During inspection, drugs were found stored wherein they were touching the walls.

Government accepted the facts and replied (November 2022) that the shortcomings in LNH are being addressed.

#### **4.4 Availability of Drugs and Medicines**

The requirement of drugs by hospitals were sent to CPA on quarterly basis. Findings with regard to availability of drugs are discussed below:

##### **4.4.1 Unavailability of Essential Drugs in test checked hospitals**

As discussed in para 4.2.3, CPA was not procuring drugs timely for health institutions of GNCTD. Thus, hospitals were purchasing essential drugs from local chemists for meeting their day-to-day requirements.

Scrutiny of indents for medicines received from user departments in the main stores for selected months<sup>20</sup> in test checked hospitals revealed that at the time

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<sup>19</sup> **LNH** - Levamisole 150 mg (500, 02/21, 03/21), Allendronate 35/70mg(400, 02/21, 03/21), Amino salicylic Acid (360,06/20, 09/20 to 01/21), Methergine, 0.125 mg (170, 10/19, 11/19), Asthalin 2mg(420, 05/18, 06/18), Alprazolam 0.5 mg (3130,01/18, 02 & 03/18), Asthalin 2mg(2240, 12/17, 01/18)

**RGSSH** - Framycetin 1% Cream, 30gm tube (500,06/20, 07/20), Budesonide Inhalation IP 100 mcg/dose(200,01/20, 02/20), Povidone Iodine 5% Ointment(50, 09/19, 10/19), Hydrogen peroxide(20, 05/10 & 10/19, 08/19 & 03/20) Clotrimazole Paint 1% Oral Paint 50ml(75, 10/18,12/18), Labetalol, 100 mg(2200,05/21, 06/21), Atenolol, 50mg(100, 07/20, 09/20), Azathioprine, 50 mg(2800, 04/21, 06/21), Ethamsylate, 500mg(500, 01/21,03/21), Methotrexate, 2.5 mg(1500, 03/21, 06/21), Fexofenadine, 180 mg(3800, 08/19, 12/19), Voglibose, 0.3 mg(990, 11/19, 12/19), Voriconazole, 200 mg(100, 09/19,12/19)

<sup>20</sup> October 2016, May 2017, December 2018, February 2020 and January 2021

of demand received from the patient care departments, many essential drugs were not available in the store for issue.

Further, there was delay (ranging between one month and more than one year) in procurement of drugs (Details in **Annexure IV**).

Unavailability of essential drugs indicates short-comings in the system of procurement of drugs which needs to be addressed by the Hospital/Department. CNBC stated (July 2022) that stock in the Central Store was nil or likely to be nil as the supply was still awaited. However, sufficient stock was available at sub-station /user department.

Reply is not satisfactory as the Central Store of CNBC had failed to provide essential drugs to the user department on demand in the above cases.

#### **4.4.2 Availability of Haemophilia injections in LNH not ensured**

Haemophilia is a rare disease and availability of medicines are important to reduce morbidity and mortality associated with this rare disease.

Audit noted that the monthly number of Haemophilia patients treated with inj. Factor IX ranged between 70 and 141 and number of Injections of Factor IX consumed ranged between 207 vials and 403 vials during the period from April 2016 to March 2021. Further, test check of records of Haemophilia Centre revealed that Factor IX Injection was out of stock on four occasion<sup>21</sup> during October 2018 to June 2019.

Thus, the hospital was not in a position to treat Haemophilia patients due to unavailability of injections.

The Government accepted (November 2022) the failure of CPA in ensuring supply of injections.

#### **4.4.3 Laxity in procurement of drugs prescribed for Maternal Health**

The Directorate of Family Welfare, GNCTD had instructed (November 2017) CPA to procure maternal health drugs prescribed for pregnant women by GoI. The CPA was instructed to include the items in Essential Drug List and till that time procure the items as per specifications and quantity mentioned. As per Nirantar portal, the quantity of maternal health drugs procured vis-à-vis requirement by CPA is shown in **Table 4.5**.

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<sup>21</sup> 31.10.2018 to 29.11.2018, 04.12.2018 to 12.12.2018, 27.12.2018 to 12.01.2019 and 04.5.2019 to 26.06.2019

**Table 4.5: Details of maternal health drugs procured by CPA**

Name of drug	Quantity to be procured	Quantity procured
Tab. Calcium 500 mg + vitamin D3 (250 IU)	30,00,000	Nil procurement during 2017-18 & 2018-19 4,58,155 purchased during 2019-20 4,43,925 purchased during 2020-21 27,400 purchased during 2021-22 Nil purchased during 2022-23 (upto 30.9.2022)
Tab. Folic acid 400 mg	10,00,000	Nil
Glucose sachet (75 gms) Oral swallow-able	1,00,000	Nil procurement during 2017-18 to 2019-20 2,70,500 during 2020-21 Nil purchased during 2021-22 44,500 purchased during 2022-23 (upto 30.9.2022)

In respect of test checked hospitals, LNH provides maternity services but had not procured the above said drugs during the audit period. Moreover, only 600 Glucose sachet were received from CPA during 2020-21.

This shows that CPA did not comply with GNCTD instructions indicating insensitivity towards maternal health.

#### **4.4.4 Unavailability of Anti-Rabies vaccine in Delhi Government health facilities**

Rabies is a fatal but preventable viral disease, which can spread to people and pets, if they are bitten or scratched by a rabid animal. Minister of Health, GNCTD flagged (June 2018) the issue of unavailability of anti-rabies vaccines at Delhi Government hospitals.

Audit noted that CPA had issued supply order (June 2018) for 80,900 vaccines for 22 hospitals, however, only seven hospitals received vaccines (31,100) from the suppliers. Similarly, against supply order issued by CPA for 1,15,981 vaccines (November 2019) for 20 hospitals, 18,200 were short supplied. Resultantly, vaccines were not supplied in four hospitals.

During 2020-21 and 2021-22, 2.69 lakh and 3.36 lakh anti-rabies vaccines were demanded against which only 1.13 lakh and 2.72 lakh respectively vaccines supplied.

Government attributed (February 2023) shortage of rabies vaccine to withdrawal of rate contract by the bidder, unavailability in open market and nil participation from bidders in open tenders.

#### **4.4.5 Unavailability of reserve stocks of essential medicines for TB patients**

As per Technical and operational Guidelines for Tuberculosis Control in India 2016, reserve stock of three months has to be maintained in State Drug Store.

All the drugs of TB including Cap Rifabutin and Delamanid etc were being supplied by the Central TB Division to the State TB Cell. Audit observed that the Central TB Division was sending 150 Cap Rifabutin against the average consumption of 1,642 per month and no supply of Delamanid was made. Central TB division directed State TB Cell in June 2019 that Cap Rifabutin may be purchased on their own, but medicines were purchased only on 5 September 2019, due to which Cap Rifabutin and Delamanid remained out of stock as per details shown in **Table 4.6**.

**Table 4.6: Out of Stock TB drugs**

Sl. No.	Name of the Drug	Used for	Stock-out period	Total days
1	Cap Rifabutin 150	HIV Infected TB Patients	1 April 2019 to 5 September 2019	161
2	Delamanid	Drug Resistance-TB patient	1 January 2020 to 12 May 2020 25 May 2020 to 25 August 2020	222

The unavailability of such an essential drug meant for HIV TB Patients and failure to take timely action to maintain buffer stock indicate lackadaisical approach of the department.

Department stated (June 2022) that they do not purchase tablet Delamanid as the drug is provided by Central TB Division, GoI.

The reply is not acceptable as the State TB Cell is required to keep a buffer stock or purchase the essential medicine from the market in case of delay/non delivery from the Central TB division.

**Recommendation 4.11: Department should strive to achieve availability of all essential drugs at all health facilities as envisaged by the Government.**

#### 4.5 Procurement and Availability of Equipment

##### 4.5.1 Irregularities related to procurement of Equipment by Central Procurement Agency

CPA is responsible for obtaining administrative approval from DGHS for procuring equipment<sup>22</sup> in health facilities of GNCTD (including hospitals).

Test check of records of CPA revealed the following:

- Contracts were awarded only in 24 cases (28 per cent) out of 86 tenders floated during the FYs 2016-17 to 2022-23 (till September 2022)<sup>23</sup>.
- In 12 cases<sup>24</sup> NIT was cancelled in 2017, as administrative approval of DGHS for inviting tender and uploading it on website was not obtained

<sup>22</sup> CT Simulator, Advanced Vessel Sealing Energy Device, Linear Accelerator, Surgical Examination light etc.

<sup>23</sup> 2020-2021 information not provided

<sup>24</sup> Dual Energy Linear Accelerator, C-ARM Machine, Intra Aortic Balloon Pump (IABP), Advanced Continuous Haemodynamic Monitor, 1000 mAH Radiography System, CT

by CPA. Outcome of disciplinary action recommended against erring officials by DGHS was not furnished by CPA.

- 37 tenders issued (between February 2016 and January 2017), were put on hold (January 2017) by DGHS, based on the complaint filed by Delhi Surgical and Medical Association. These tenders were finally cancelled.
- In ten cases (2016-17), bids were cancelled due to receipt of single bid. However, retendering was done in respect of only six cases wherein one tender was successful. As per information furnished, no further efforts were made by the Department in this regard.

Instead of fulfilling the obligation for timely procurement of equipment, CPA replied (June 2022) that concerned hospitals were equally competent to procure equipment/instruments as per their requirement through GeM/open tender. It also stated that no assessment was made by DGHS, GNCTD to verify as to whether the items requested by hospitals were finally purchased by hospitals for their intended use.

Government attributed (February 2023) cancellation of tenders to the requirement to procure through GeM portal and the necessity of obtaining approval from Minister of Health and Family Welfare for medical equipment worth more than rupee one crore. Regarding disciplinary cases, it was stated that the related files were with Vigilance Department.

Reply is not acceptable as the reasons furnished by the Government for not procuring equipment merely states the codal formalities to be met by CPA. Moreover, the above facts create a doubt about the actual requirement of equipment in the health facilities and also exhibit lackadaisical approach of the Department.

Office of Minister of Health directed (6 October 2015) CPA to procure 100 ventilators along with support accessories on urgent basis. Expert Committee of Maulana Azad Medical College had recommended compressor based ventilator as the other turbine based ventilators, were not considered safe for patients in case of turbine/air failure.

Audit noted that CPA/DGHS had floated a tender for procurement of 125 ventilators. Revised approval for purchasing extra 25 ventilators was not obtained from the Office of Minister of Health. Besides, the recommendation of Expert Committee for procurement of compressor-based ventilator was not brought to the notice of the special purchase committee and finally ₹ 9.38 crore was incurred (March 2016) for procurement of 125 turbine-based compressors. Thus, the input for patient safety was not taken into account.

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Simulators, Adult Flexible Intubation Fibroscope, Dual Energy Device for open and Laproscopic Abdominal Surgery, Ultrasonic Surgical Aspirator, Neurosurgery OT Table, Neurosurgery Spine drill electrical, Water Dissector for liver surgery.



#### 4.5.2 Delay in procurement of equipment by hospitals

There were many instances of inordinate delay in procurement of equipment or the demand of user departments was not fulfilled in selected hospitals. This resulted in the patient care departments functioning with no stock or limited stock, thus affecting patient care. Some of the significant cases noticed in audit are detailed in **Table 4.7**.

**Table 4.7: Instances of delay in procurement of equipment by hospitals**

Sl. No.	Name of item(Quantity)	Name of the hospital	Name of the user department	Date when requested by user department	Taken up by purchase committee	Status of procurement	Remarks
1	Ventilators (3)	LNH	Anesthesia	May 2018	Oct 2018	Not procured	In July 2019, Purchase Committee decided to call for fresh demand from the department due to slow progress in the process.
2	Ventilators (6)	LNH	Anesthesia	Aug 2019	Sept 2019	Not procured <sup>25</sup>	the Technical Evaluation Committee in May 2020 found that both the firms which had applied for tender did not have the technical qualification and accordingly, the tender was cancelled.
3	Stabilizer for Cryofuge6000i(1)	LNH	Blood Bank	26 Apr 2018	May 2018	Procured in Nov. 2018	The machine which is used for component preparation of blood was not functional for six months for want of stabilizer affecting the functioning of blood bank
4	High-Definition Camera with Monitor(1)	CNBC	ENT	Sept. 2018	Jan. 2020	Procured in Mar. 2021	In June 2020, the tender was cancelled as there was only one qualified bid. Re-tendering started in July 2020.
5	Direct Digital Flat Panel Fluoroscopy and Radiography System	CNBC	Radiology	Sept. 2015	Not available	Procured in July 2019	The CNBC in its reply stated (August 2022) that main reason for delay was return of the proposal to procure the equipment by CPA after 16 months.
6	Linear Accelerator (LINAC) machine	LNH	Radiotherapy	May 2017	Sept. 2017	Procured and installed as of Dec 2022	CPA initiated tender in Sept. 2017 and awarded the order after a lapse of two years in December 2019. LNH initiated process for Letter of Credit in February 2021, but due to shortage of fund, the letter of credit was opened only in September 2021.
7	2D Echo and colour Doppler System	LNH	Medicine	Oct. 2018	Oct. 2018	Procured in January 2022	Delay due to slow progress in bid process.
8	Advanced Respiratory Endoscopy Unit consists of 14 equipment <sup>26</sup>	RGSSH	Pulmonary	Jul 2016	Jul 2016	Procured only two items in January 2018 and March 2020	Advanced Respiratory Endoscopy unit is still not procured. Reasons not provided.
9	Seven Equipment for Pathology <sup>27</sup>	RGSSH	Pathology	Mar 2014	Mar 2014	One equipment procured in 2015, three equipment in 2020-21 <sup>28</sup>	Status of procurement of remaining equipment not available.

<sup>25</sup> Anesthesia department of LNH later received eight new ventilators from PM Care Fund during Covid period (3 in September 20 and five in March 2021)

<sup>26</sup> Jet Ventilator, bronchoscopy simulator, rigid bronchoscopy system, therapeutic video bronchoscope, Cryo system for bronchoscopy, pediatric video bronchoscope, ultrasonic endowasher, electrocautery unit with argon Plasma coagulation, portable bronchoscope etc.

<sup>27</sup> Tissue Embedding Station, Fully automated Tissue Processor, Semi-automated Rotary microtome, cryo microtome, trinocular microscope with high resolution camera, fully automated Slide Stainer and imported grossing station

<sup>28</sup> Trinocular microscope (2015) and Tissue Embedding Station, Tissue Processor and Semi Automated rotary microtome (2020-21)

LNH accepted (May 2022) the facts regarding delay in purchase of ventilators. Regarding High Definition Camera with monitor for ENT Department, CNBC stated (August 2022) that as the equipment was a high budgetary equipment, the process was completed with scrutiny at all levels, evaluation committee also took time for taking demonstration of the quoted equipment, sought clarification from the firm, evaluation of bids, rate justification and making reports. It further stated that there was lack of manpower and doctors involved in procurement process were also involved in clinical duties besides administrative duties.

The fact remained that shortage of staff delayed the completion of procedure in procuring the equipment which finally delayed the installation of equipment.

#### **4.5.3 Non-maintenance of Assets Register and weak monitoring of equipment**

As per the SoP issued by the H&FW department, the in-charge of Repair & Maintenance Section should evaluate all medical equipment at least quarterly/half yearly for the specific purpose of recommending replacements/condemnation based upon the repair history, life expectancy and condition of the equipment. The user departments have to watch the periodic repair and maintenance of the equipment and to intimate the proposal to Repair & Maintenance Section.

Audit noted that all the test checked hospitals were not maintaining Assets Register of equipment installed in the hospital. Resultantly, they were not in a position to monitor and evaluate the need of repair, maintenance, replacement, condemnation of equipment regularly and timely. Thus, centralized monitoring of the equipment was absent in the hospitals.

LNH intimated (May 2022) that action has been initiated to centralize the repair and maintenance work

#### **4.5.4 Delay in initiating tendering process to replace old machines in LNH**

LNH is maintaining some major equipment beyond the life cycle of the machine after paying enhanced AMC charges. As per the purchase agreement, major equipment are under free of cost Comprehensive Annual Maintenance Contract (CAMC) for the first five years and under paid CAMC for the next five years.

However, it was noticed that the some of the equipment<sup>29</sup> were beyond ten years and were maintained at enhanced rate of AMC without covering the replacement cost of major parts and also on best effort basis. 15 OT tables

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<sup>29</sup> Digital X Ray 2063 Digital X Ray 2068 Colour Doppler USG XRay 1000MA digital Genious 60 Xray machine60MA Mobile XRay Sonatam Definition AS CT Scan CT Scan machine Emotion 16 Anderson Gas Sterilisation system Securex Sterilisers (two nos.) Cryofuge 6000i(two machines) Stifenhofer Sterilizers (two) OT tables(15) Automated Bacterial Identification and Susceptibility System

(1990-95), two Stifhnhofer Sterilizers (87-88) and two Securex Sterilizers (1992-93) were found to be more than 25 to 30 years old.

The hospital/department has not yet initiated/finalized the tender for purchase of new equipment in place of these outdated equipment. In the case of Genius 60 Portable X ray Machine, the department had spent ₹ 2.60 lakh on its repair and maintenance whereas the cost of the machine was ₹ 1.45 lakh. Further, in the case of some of these equipment, more than 50 *per cent* of the cost of machine has already been incurred on its maintenance<sup>30</sup>.

LNH intimated (May 2022) that action has been initiated to procure new equipment and to condemn the old ones.

#### 4.5.5 Delay in issue/installation of Equipment

Equipment are purchased to enhance the efficiency of patient care on the basis of demand of the User Department. Equipment are required to be installed immediately after their receipt, for optimum utilization as well as to claim the comprehensive maintenance warranty provided by the seller. Failure to install equipment immediately after the receipt leads to blockage of Government money and denial of patient care. Further, Rule 144 (iv) of General Financial Rules 2017, envisages that care should be taken to avoid purchasing quantities in excess of requirement to avoid inventory carrying cost.

Scrutiny of Stock Registers of equipment of CNBC and LNH revealed that 156 equipment were issued with a delay ranging from four months to 8 years. 17 types (114 quantity) of equipment in LNH were issued with a delay ranging from 5 to 36 months and 10 types (42 quantity) of equipment in CNBC were issued with a delay ranging from six to 96 months.

Moreover, Stock Registers of CNBC and LNH showed that four<sup>31</sup> items in LNH and one<sup>32</sup> item in CNBC were procured in excess of their requirement and were lying unused in stock for long periods ranging from 18 months to 95 months as on 31<sup>st</sup> March 2021.

It highlights the absence of centralized monitoring mechanism to assess the requirement and manage the usage and distribution of equipment in the hospitals.

Government replied (December 2023) that the indents from departments concerned are received and recorded in the Stock Register after satisfactory installation of equipment by CNBC.

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<sup>30</sup> In the case of Securex Sterilisers, Stifhnhofer Sterilizers and CT Scan machine Emotion 16 an amount of ₹ 59.16 lakh, 52.58 lakh and ₹ 1.47 crore have been spent towards their repair and maintenance whereas the actual cost of equipment were ₹ 65.21 lakh, ₹ 86 lakh and ₹ 2.66 crore respectively.

<sup>31</sup> Two Pharmaceutical refrigerators (18 months), two infant ventilators (60 months), 17 Oscopes (58 months) and four ICU Ventilators (51 months)

<sup>32</sup> Three Examination Table (95 months)

The reply is not acceptable as the entry in the Stock Register is made immediately on receipt of the equipment and there was huge delay in installation as per the Stock Register.

#### **4.5.6 Shortage of equipment in labs/departments of MAMC and LNH**

Each department of a Medical College with 250 admissions is required to have a minimum number of equipment as per the Medical College Regulations, 1999.

- (i) It was observed that 10<sup>33</sup> essential equipment were not available in the Pathology and Biochemistry laboratories of MAMC. Further, shortage of seven<sup>34</sup> equipment was noted in these labs. Grossing Station used for cutting, sampling and for microscopic examination of tissues, purchased (January 2020) was not installed in the Pathology department.

Moreover, three equipment<sup>35</sup> in clinical laboratories of LNH were not in working condition. As per the information provided by the LNH, there was also a need of 15 different equipment in Genetic lab and six equipment in Clinical Lab which have not been made available to them yet.

- (ii) There was shortage of various equipment in Pharmacology, Community Medicine, Forensic Medicine and Anatomy Departments of MAMC as per the details given below:

- Pharmacology department had shortage of important items such as Special Drug Delivery system (10 against 25) and samples of dosage formulations (10 against 25). Pharmacology department should have a computer assisted learning laboratory with enough computers with CAL programme for teaching Experimental Pharmacology. Audit noted that computer assisted learning laboratory of Pharmacology department did not have enough computers with CAL programmes /software.
- In Community medicine department, ten<sup>36</sup> different equipment were not available. It had huge shortage of Dissecting microscope (three against 60) and Microscope oil immersion (one against five).

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<sup>33</sup> Weighing machines for cadavers, Heated paraffin embedded module, Cold plate for modular Tissue embedded system, Fully automated Flexible Cover/slipping workstation, Automated high speed Slide Scanner, Automatic Urine Analyser in Pathology and Urinometers, Chromatography unit and Glucometer in Biochemistry department.

<sup>34</sup> Autoclave ( 2 against 4), Centrifuge machine (2 against 8), Microscope for students (81 against 150), X ray viewing box ( 1 against 5) in Pathology and Student Microscope (4 against 10), Thermometer (1 against 5) and PH meter (1 against 5) in Biochemistry department.

<sup>35</sup> Fully automatic blood cell counters (2) and Lab Centrifuge Machine (1)

<sup>36</sup> Comparator(1), Extraction apparatus(1), Filter Pasteur Chamberland, Berke fed(2), Hydrometers(7), Incubator(1), Balance analytical(1), Centrifuge clinical(1), Sterilizer(2) and Autoclave(1)

- In Forensic medicine department, four<sup>37</sup> different equipment were not available. There was shortage of Microscope student type (20 against 40), X Ray view box (one against seven) and Brain knife (two against eight).
- In Anatomy Department, Drill Machine, Dissection Microscope and Incubators were not available. Further, there was shortage of tables (23 against 37), Xray viewing lobby (three against eight), articulated skeleton set (five against 10) and Bone sets (10 against 45).

Government replied (December 2023) that procurement process for purchasing the deficient equipment has been initiated.

***Recommendation 4.12: Government should ensure availability of equipment in labs/departments in Medical colleges as per Medical College Regulations.***

#### **4.5.7 Repair and Maintenance**

Many of the patient care services are essentially dependent on the equipment. Without the appropriate equipment, hospitals cannot provide desired or committed service to the patients or the community. Thus a reliable, dependable and sustainable repair and maintenance program is essential for every hospital and health care institution. The objective of the hospitals repair and maintenance programme is to keep all the medical equipment in working order through timely maintenance, repair and condemnation and replacement of the equipment in a cost effective manner.

##### **4.5.7.1 Improper Maintenance of Log Book in hospitals**

As per the terms and conditions of Comprehensive Annual Maintenance Contract (CAMC), if the downtime of the machine exceeds more than five *per cent* in a year, penalty in the form of extended CAMC period of double the number of days for which the equipment was not of service (in excess of the five *per cent* permissible limit) was applicable. However, it was noticed that neither the log books were maintained clearly indicating the number of non-functioning days of various equipment nor the calculation was ever done and taken into account while approving the renewal of contract. Further, Performance Guarantee from the firms was not taken before awarding the Annual Maintenance Contract.

##### **4.5.7.2 Delays in renewing CAMC**

In the absence of any mechanism for timely renewal of maintenance contract, it was noticed that in some instances, the CAMC was not extended after the first five years' free CAMC period resulting in delay in replacement of parts thereby effectively causing denial of service to patients.

Illustrative instances noticed during audit are mentioned in **Table 4.8**.

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<sup>37</sup> Hacksaw (4), Digital Spectrometer(1), Electric auto slide projector (1), Spectroscope lens with adjustable slit (2)

**Table 4.8: Cases of delay in finalization of AMC**

Sl. No.	Hospital	Equipment name	Date from out of CAMC	Instances of delay in repair
1	LNH (Radiology)	Ultrasound machine Acuson S2000	February 2017	Machine had malfunctioned (1 July 2017) due to problems in Transducer and was replaced on 10 October 2017.
2	LNH (Radiology)	Philips Ultrasound Machine(IU 22)	June 2017	Delay in replacement of parts (July 2021 to Nov. 2021) and April 2018 to January 2019).
3	LNH ( Blood Bank)	Two pharmaceutical refrigerators	Feb 2018	Equipment became non-functional from 30 October 2018 to 31 December 2018 and 31 January 2019 to 29 March 2019.
4	Sushruta Trauma Centre (STC), LNH	Digital X ray machine	September 2015	The machine was not operating for more than four months due to delay in getting the machine functional after its breakdown at various occasions from 2017 to 2020.
5	CNBC (Microbiology)	Medical Waste Disinfection System	September 2019	Though the CAMC expired on 9 September 2019, the department accepted the proposal of CAMC w.e.f. 30.03.2020. Audit observed that during the non CAMC period the equipment was non-functional from 25 <sup>th</sup> October 2019 to 5 <sup>th</sup> December 2019 (41 days). A payment of ₹ 6490 was made for the repair of the equipment.

#### **4.5.7.3 Delay in Repairing of Equipment in LNH**

During test check of Comprehensive Annual Maintenance Contract of sterilization equipment used in OTs, Audit noted that two high speed sterilizers located at OT-III and Gynaecology OT were not functioning since June 2016 and December 2017 respectively due to steam leakage though the Jacket and Chamber. These parts were not covered in the CAMC. There was procedural delay in decision making which resulted in unavailability of service of sterilizers in Gynaecology OT for six months and OT III for one year. The equipment was finally repaired in July 2018 and was functioning since then.

#### **4.5.7.4 Award of CAMC with Retrospective Effect**

There were numerous instances where Comprehensive Annual Maintenance Contract had been awarded with retrospective effect in hospitals.

##### **(i) LNH**

- The CAMC award letter for the period from 4 June 2016 to 3 June 2017 in respect of Stifhnohofer Sterilizers was issued in August 2017 with ex-post facto approval from the competent authority.
- In the case of Anderson ETO Gas sterilization system (purchased in August 2008) which is used for sterilization of the entire hospital including OT, ICU etc., there was delay in awarding CAMC for the period from September 2018 to August 2019. However, it was observed

that CAMC was awarded in May 2020 with retrospective effect from September 2018 and payment was made for the same.

- In the case of two high speed sterilizers used in Gynaecology OT and OT II of CSSD, CAMC was awarded in the month of August 2017 with retrospective effect for the contract period September 2016 to August 2017. Again the contract was awarded with retrospective effect in January 2019 for the period from September 2018 to August 2019.

In all these cases, it was noticed that the contracting firms were providing the services of the machines even in the absence of extension of contract, however, any sudden breakdown of the machines would have created delay in repairing the machine in the absence of a legal contract.

**(ii) RGSSH**

There were numerous instances where CAMC was awarded with retrospective effect as shown in **Table 4.9**.

**Table 4.9: List of equipment for which CAMC issued with retrospective effect**

Sl. No.	Name of equipment	CAMC start date	Date of issue of award
1	Fully Automated Integrated Urine Chemistry and Sediment Analyser	08.05.20	15.09.20
2	CO <sub>2</sub> Incubator	03.06.20	07.01.21
3	Fully automated Coagulation Analyser	01.04.20	21.10.20
4	FCR + Dry Laser Printer	14.01.20	23.03.21
5	LH 750 Analytical Station	25.06.20	07.01.21
6	Automated Immunoassay Analyser	10.07.20	16.12.20
7	Video Bronchoscope System	01.04.21	14.07.21
8	Schiller TMT Machine	10.09.20	07.07.21
9	Endobronchial Ultrasound system	01.04.21	14.07.21
10	High end Anaesthesia Machine	01.05.17	20.11.17

The above instances shows that the monitoring mechanism to ensure timely maintenance of equipment is weak in these hospitals.

**4.5.7.5 Short levy of penalty due to downtime of equipment**

As per the terms of agreement for supply of equipment, during the warranty/ guarantee, the supplier has to guarantee an uptime of 95 *per cent* of equipment failing which a penalty would be imposed equivalent to double the amount of daily cost of the unit for each day’s delay in proper functioning of the unit beyond five *per cent* down time per annum.

In CNBC, G.I. Video endoscope was non-functional for a period of 135 days during the AMC period from January 2020. The hospital levied a penalty of ₹ 32,232 based on double the cost of CMC per day instead of double the daily running cost resulting in short levy of penalty amounting to ₹ 4,42,374.

Similarly, Anaesthesia work station used in OTs revealed that the equipment was non-functional for a period of 330 days during the warranty of five years

from 20 November 2015. Thus, the equipment suffered down time period in excess of stipulated norms during warranty, for which a penalty of ₹ 8.36 lakhs should have been imposed. However, no penalty was imposed on the supplier.

Government in its reply stated (December 2023) that CNBC has since recovered ₹ 6.42 lakh out of ₹ 12.78 lakh and the remaining amount was still pending for recovery.