CHAPTER IV AVAILABILITY OF DRUGS, MEDICINES, EQUIPMENT AND OTHER CONSUMABLES

The main objective of formation of KMSCL was to avoid scarcity of drugs in hospitals at all times which can be realised only if indents are realistic and procurement of the indented quantity is effected. Audit observed that the above objective was not met resulting in stock out of drugs in hospitals during the period of Audit. The shortage of drugs in hospitals was attributable to inadequate indenting due to financial cap set, lack of response to bid, delay/ non-supply of drugs by the vendors, etc. Suppliers of around 82 *per cent* of the drugs delayed their consignment and in many instances, they were not penalised by KMSCL for the delay. The policy of subjecting only 10 *per cent* of drugs to quality check (QC) did not yield desired results as all the batches of 46 drugs and all supplies from 14 suppliers escaped QC during the audit period. Many vital medical equipment were not available in hospitals due to delay in purchase and non-maintenance of equipment. A mechanism for regular maintenance of equipment did not exist in the tertiary hospitals resulting in denial of services to patients.

Government of Kerala set up KMSCL as a fully owned Government Company in 2007 with the responsibility for procuring and distributing drugs, supplies and equipment to hospitals to meet the qualitative and quantitative needs of the end users, to avoid scarcity and losses and for optimal utilisation.

Drug Distribution and Management System (DDMS) is a web-based application used by KMSCL for managing the procurement and distribution of drugs and consumables for various health institutions. The procurement of drugs by KMSCL is effected with reference to an Essential Drug List⁴⁷ (EDL) comprising Anti-cancer drugs (ACD) and eight categories of products like generic drugs, surgical and medical supplies, X-ray films, etc. The EDL is updated every year by a high-level Technical Committee⁴⁸ and based on the updated EDL, the DHS, DME and NHM forward annual indents to KMSCL indicating requirement of drugs for effecting procurement.

4.1. Availability of essential drugs and consumables

The main objective of formation of KMSCL was to avoid scarcity of drugs in hospitals at all times which can be realised only if indents are realistic and procurement of the indented quantity is effected.

⁴⁷ Based on the National List of Essential Medicines (NLEM)

⁴⁸ As directed (November 2007) by GoK, KMSCL constituted a technical committee with five members namely, DHS, DME, Drugs Controller, HoD of Government College of Pharmaceutical Sciences and MD, KMSCL.

Audit observed that the above objective was not met, as revealed from a micro level analysis of data for the period from 2016-17 to 2021-22 relating to test-checked hospitals, shown in the succeeding paragraphs:

4.1.1. Availability of essential drugs and consumables in the test-checked GH/DHs

Audit verified the availability of essential drugs and consumables in test-checked GH/DHs, as on 31 January 2022, with reference to the EDL 2021-22 as shown in **Table 4.1**.

Table 4.1: Availability of essential drugs and consumables in the testchecked GH/ DHs

	GH Neyyattinkara	DH Nedumangad	GH Alappuzha	DH Mavelikkara	DH Tirur	GH Kalpetta	DH Mananthavady
Number of drugs and consumables required	603	603	603	603	603	603	603
Drugs and consumables available as on 31.01.2022	344	263	290	328	337	328	350
Availability of drugs and consumables (in <i>per cent</i>)	57	44	48	54	56	54	58

(Source: DDMS data of KMSCL)

It was noticed that against the requirement of 603 essential drugs and consumables in district level hospitals, the availability ranged from 44 to 58 *per cent* only.

4.1.2. Stock-out of essential drugs and consumables in the test-checked institutions

Analysis of data for the period from 2016-17 to 2021-22 relating to 67 testchecked healthcare institutions revealed that many essential drugs were out of stock on various dates in these hospitals. There were 62,826 instances of stock out of drugs and the stock out period ranged upto 1,745 days, as detailed in **Table 4.2.**

Period of stock out of drugs	Number of instances	Name of the essential drugs stocked out frequently
366 to 1745 days	4126	Multi Vitamin Tab, Vitamin C Tab IP, Thyroxine Sodium Tab IP (used to treat underactive thyroid), Bisacodyl Tab (used to treat constipation), Hydrochlorothiazide Tab/ Telmisartan Tab IP (used
101 to 365 days	21943	to treat high blood pressure), Adrenaline Bitartrate Inj IP (used in the treatment of life-threatening emergencies like severe allergic reaction and cardiac arrest), Amoxicillin and Potassium
30 to 100 days	36757	Clavulanate Tab IP (used to treat a wide variety of bacterial infections), Insulin Injection Biphasic Isophane IP 30:70 (used in the treatment of diabetes mellitus) etc.
Total	62826	

(Source: DDMS data of KMSCL)

Audit examined the reasons for stock out of drugs through an analysis of DDMS data for the period from 2016-17 to 2021-22 which revealed inadequate indenting by hospitals, non/ short ordering of drugs against indent by KMSCL, default/ delay in supply by suppliers etc., as detailed in succeeding paragraphs:

4.2. **Procurement of Drugs**

GoK issued (October 2016) guidelines for streamlining the indenting process and introduced separate financial ceiling (financial cap) for each institution. Based on the grants and also taking into account the annual value of indents/ issue/ utility relating to the previous year and the current available stock of drugs, financial cap is fixed for each hospital. KMSCL initiates procurement process on obtaining the annual indents from the hospitals, which are scrutinised at District/ State level and finalised by DHS/ DME. The gap between actual requirement and the KMSCL supply is bridged by resorting to local purchases utilising the funds received from Local Self-Government Institutions. If the required drugs are not available at Karunya Community Pharmacy (KCP)⁴⁹ / Hospital Management Committees (HMC)⁵⁰ pharmacy/ Neethi Store (NS)⁵¹, etc., they are purchased from open market. While the prices are uniform across the State in respect of the purchases through Karunya as there is a rate contract with them, purchases made from HMC, NS and open market may vary.

4.2.1. Non-availability of drugs in hospitals

4.2.1.1. Inadequate purchase of drugs against indents

Though the hospitals indented for 4,732 items of drugs, KMSCL proceeded with invitation of tenders in respect of only 4,720 items. No bids were received for 1,321 items (28 *per cent* of the tendered items). Only 536 items (11.33 *per cent*) were ordered in full quantities. In respect of 512 drugs, purchase orders (PO) were issued for less than 50 *per cent* of the indented quantity. 1,085 items of drugs were not ordered at all. Year-wise analysis of purchase orders against indents is shown in **Table 4.3**.

Year	Total number of indented items	Total number of tendered items	No bid items	Total number of fully ordered items	Items ordered in less than 50 <i>per</i> <i>cent</i> of indented quantity	Items not ordered at all
2016-17	585	585	57	23	25	58
2017-18	830	830	218	130	78	231
2018-19	825	824	274	183	80	236
2019-20	828	817	259	41	84	210
2020-21	831	831	287	124	119	182
2021-22	833	833	226	35	126	168
Total	4732	4720	1321	536	512	1085

Table 4.3: Year-wise analysis of purchase orders against indents

(Source: DDMS data of KMSCL)

⁴⁹ Karunya Community Pharmacy Services (Karunya) is the commercial division of KMSCL

⁵⁰ As per Section 173A of the Kerala Panchayat Raj Act, 1994, a Managing Committee shall be constituted consisting of not more than 15 members including the Chair for every public health institution.

⁵¹ Neethi Scheme, started as per directions of GoK in 1997, is implemented through selected primary agricultural credit societies in all the districts of Kerala for sale of consumer goods and drugs at subsidised rates. Though the Kerala State Co-operatives Consumers' Federation Ltd. is not running NSs directly, they supply provisions to societies for running the NSs.

4.2.1.2. Inadequate supply against indents

The year-wise details of supply of drugs to hospitals against the quantity of drugs indented are as shown in **Table 4.4.** Though the hospitals indented for 4,732 items of drugs, only 1,036 items (21.89 *per cent*) were supplied in full quantities. While the supply of drugs in respect of 1,313 items was below 50 *per cent* of indented quantity, 307 items of drugs were not supplied at all.

	-	against machts			
Year	Total number of indented items	Total number of fully supplied items	Items for which supply was more than 50 <i>per</i> <i>cent</i> but less than 100 <i>per</i> <i>cent</i> of indented quantity	· · · · · · · · · · · · · · · · · · ·	Items not supplied at all
2016-17	585	162	347	53	23
2017-18	830	273	310	195	52
2018-19	825	286	270	194	75
2019-20	828	185	405	179	59
2020-21	831	99	464	213	55
2021-22	833	31	280	479	43
Total	4732	1036	2076	1313	307

Table 4.4: Year-wise analysis of supply against indents

(Source: DDMS data of KMSCL)

4.2.1.3. Delay in supply of drugs against purchase orders

As per the tender conditions, the entire ordered quantity should be supplied within 60 days of issue of PO during the period from 2016-17 to 2017-18 and within 70 days during the period from 2018-19 to 2021-22.

Analysis of data for the period from 2016-17 to 2021-22 revealed that 2,975 out of 3,635 ordered drugs (81.84 *per cent*) were not supplied within the stipulated delivery period. The delay ranged upto 988 days. Year-wise analysis is shown in **Table 4.5** and range of delay is shown in **Chart 4.1**.

Year	Total no. of POs	No of POs with delayed supply	No. of drugs ordered	No. of drugs supplied with delay	Stipulated delivery period	Delay range (in days)
2016-17	2012	1365	527	490	Within 60 days	1 to 867
2017-18	1962	1401	599	547	Within 60 days	1 to 988
2018-19	2331	1056	590	458	Within 70 days	1 to 656
2019-20	1782	1011	607	488	Within 70 days	1 to 493
2020-21	1897	960	648	549	Within 70 days	1 to 315
2021-22	1706	714	664	443	Within 70 days	1 to 209
Total	11690	6507	3635	2975		

Table 4.5: Year-wise analysis of delayed supply

(Source: DDMS data of KMSCL)

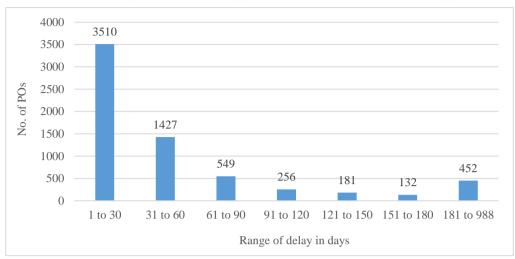


Chart 4.1: Range of delay in supply of drugs to warehouses by suppliers

The delay in supply adversely affected the availability of drugs, which resulted in stock out of drugs on various days as pointed out in **Table 4.2**.

4.2.1.4. Inadequate indenting

Audit compared quantities indented for each year that were less than 75 *per cent* of the quantity of the respective previous year's indents *vis-à-vis* the previous year's indents and the corresponding consumption in respect of each of the drugs.

The analysis revealed that there were 1,859 instances of stock out of drugs on various days directly attributable to short indenting on account of financial cap set. For instance, in one hospital as regards the indent for the drug Theophylline and Etophylline, stock out was for 212 days during 2019-20. During 2018-19, the hospital had indented 1.80 lakh numbers of this drug, of which 1.73 lakh was consumed. Due to financial cap, the hospital had to limit their indent to 18,000 during 2019-20 which resulted in the stock out. Similarly, in another hospital as regards Prednisolone Tab IP, stock out was for 128 days during 2019-20. The hospital could indent only 40,500 numbers of this drug during 2019-20 due to limited financial cap whereas it had indented and consumed 1.17 lakh and 1.12 lakh respectively during 2018-19.

Hospital authorities stated (November 2021 and February 2022) that they were compelled to restrict their indents based on the respective financial caps fixed for them, without regard to their actual requirement. Ninety *per cent* of the hospitals test-checked reported that financial cap was insufficient, which led to short indenting.

GoK stated (November 2023) that the data shown in Tables⁵² did not match with the data available in DDMS. Further, KMSCL optimised the purchase order quantities by taking into account closing stock of the items at the warehouses and institutions, anomalies in indents pointed out by user departments, slow

⁵² Under Paragraph 4.2 – Procurement of Drugs, of this Report

moving drugs etc. It was also stated that more than 28 *per cent* of items tendered was no-bidder items. KMSCL within the maximum limits, had delivered the medicines to the hospitals without wasting the public money. Regarding delay in supply against purchase orders, during 2018-19 and 2020-21, unexpected delay in the supply chain occurred due to flood and COVID 19. During 2020-21, the supply period of the purchase order was extended for a period of 40 days without any liquidated damages.

The reply is not acceptable as Audit verified the variance in data pointed out in the reply and confirmed the correctness of data provided in the Report which was based on the replies and data (dump data of DDMS) provided by KMSCL to Audit. Further, analysis of the data clearly indicates that inadequate issue of purchase orders/no bidder items/inadequate supply against indents contributed to the stock out situation. The reply on delay in supply due to COVID and flood is not tenable, as Audit noticed delay in supply of drugs throughout the audit period from 2016-2022.

Audit observed that the stock out of drugs resulted in local purchases as detailed in **Table 4.6**.

Year	Total no. of drugs issued to test-checked hospitals	No. of drugs stocked out	No. of drugs locally purchased
2016-17	585	531	82
2017-18	830	675	187
2018-19	821	668	248
2019-20	816	631	259
2020-21	820	575	278
2021-22	818	538	389

Table 4.6: Year-wise analysis of loca	l purchases and stock out of drugs
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(Source: DDMS data of KMSCL)

Audit observed that these were the consequences of inadequate financial cap and consequent short indenting by hospitals, considerable number (28 *per cent*) of no bidder items, short supply against the indents and delay in supply of drugs pointed out in the above paragraphs.

4.2.2. Non-levy of penalty for short supply

As per the tender conditions, in the event of lowest bidder's (L1) failure in supply of the required quantity in full or in part within the stipulated time, KMSCL would cancel the unexecuted quantity of POs and place POs with the matched L1 bidder or to the next bidder(s) according to the bid ranking status at the risk and cost of defaulted bidder/ supplier. In such cases, the penalty attracted is 10 *per cent* of the value of unexecuted quantity or the extra expenditure incurred for alternate purchase of the same drugs, whichever is higher.

Data analysis revealed that penalty amounting to $\gtrless 1.64$ crore in 82 instances was not levied, where supply was less than the ordered quantity.

GoK stated (November 2023) that penalty was not charged for the purchases made through Karunya Division of KMSCL (for no-bidder items), certain purchases made at the time of COVID pandemic, procurement from M/s Kerala State Drugs and Pharmaceuticals Limited (State PSU) etc, after obtaining approval from the Management/Government.

Audit, after excluding the aforementioned categories and the instances listed by GoK, found that penalty amounting to $\gtrless 69.25$ lakh still remained to be levied in 48 cases.

4.2.3. Non-levy of liquidated damages for delay in supply

KMSCL may receive supply even after expiry of the date stipulated in the purchase order, at their discretion, considering the urgency of the essential item for the hospitals. In such cases, liquidated damages (LD) should be levied at 0.50 *per cent* per day of the value of the delayed supply subject to a maximum of 10 *per cent* of value of the delayed supply.

Out of 6,092 POs⁵³ with delayed supply during the period 2016-22, LDs were collected only in respect of 5,560 POs and LDs not collected in 532 instances amounting to $\gtrless 9.91$ crore.

GoK stated (November 2023) that LD was not charged for the purchases made from Karunya Division of KMSCL (for no-bidder items), procurement from M/s. Kerala State Drugs and Pharmaceuticals Limited (State PSU), certain purchases made at the time of COVID, etc.

Audit subsequently analysed the data and found that only five cases under the above categories were included in the 532 cases of non-levy of LD pointed out by Audit. In the remaining 527 cases, LD amounting to ₹9.76 crore have not been collected.

4.2.4. Issue of drugs without following First Expiry First Out method

First Expiry First Out (FEFO) is a term used in inventory management to describe a way of dealing with the logistics of products that have a limited shelf life. These items include perishable products or consumer goods with a specified expiration date. The product which expires first has to be served first or removed from stock. During physical verification of stock of drugs in 67 test-checked hospitals, Audit noticed that in 30 hospitals, latter batches of drugs were issued before termination of former batches, which had earlier dates of expiry.

GoK concurred (November 2023) with Audit that FEFO was the best material management system. Further, during the training programme on DDMS software, KMSCL clearly mentioned that warehouses and institutions had to strictly follow FEFO method.

⁵³ Out of 6,507 POs with delayed supply during the period 2016-22, invoices were received for 6,092 POs only.

4.2.5. Probable issue of expired drugs and supplies

Analysis of data for the period from 2016-17 to 2021-22 revealed that drugs and supplies issued to wards had already exceeded the date of expiry in 60 instances in 26 hospitals. Total value of expired drugs and supplies issued to wards comes to ₹0.89 lakh in respect of these 26 hospitals. Issue and usage of expired drugs is a serious matter of concern as the change in chemical composition consequent to the expiry of drugs may put the life of patients in danger.

In respect of 530 instances in 148 hospitals, items under stop memo⁵⁴ were issued to wards. Total value of such instances comes to ₹11.69 lakh.

GoK replied (November 2023) that in any circumstances, the stopped/expired drugs cannot be issued through the DDMS software, since the stock was moved from normal stock to stopped/expired items stock. DDMS permitted the issue of items to end user only from the normal stock. The reply is not acceptable since the data in DDMS clearly showed that expired/stopped medicines were issued to wards.

4.2.6. Undue favours to a supplier by granting 100 *per cent* of purchase value as advance in violation of norms

For managing the pandemic situation, State Level Crisis Management Group (SLCMG) for management of COVID-19 decided (March 2020) to authorise KMSCL to pay upto 50 *per cent* of the purchase value as advance payment to suppliers of items needed for COVID management. In violation of the above orders, 100 *per cent* advance was paid to a firm, *viz.*, M/s San Pharma, which had offered to supply Personal Protective Equipment (PPE) kits at the highest rate of ₹1,550 per unit as stated in Paragraph 4.2.7. The firm was issued (March 2020) orders to supply 15,000 PPE kits at ₹1,550 per unit for which KMSCL paid advance amount of ₹2.32 crore (March 2020) which was the total value of the supply order and the supply was effected in May 2020.

GoK stated (November 2023) that the advance of ₹2.32 crore was paid against the Letter of Indent (LoI) quantity of 50,000 placed with the firm and that the advance amounted only to 29 *per cent* of total purchase value of the order (₹9.35 crore).

However, the contention is not acceptable as Audit observed that though the LoI quantity was for 50,000 PPE kits, orders were placed for immediate supply of 15,000 numbers only, as the company was new and the product had not been verified. Further, scrutiny of the purchase file also indicated that, on 31 March 2020, it was decided to purchase 15,000 PPE kits only. Hence, the reply of GoK that the advance was for 50,000 PPE kits is not tenable. Since it was decided to purchase only 15,000 PPE kits, the advance payment of ₹2.32 crore was for the full cost of the ordered quantity⁵⁵.

⁵⁴ Batches of drugs which were declared 'Not of Standard quality' by empanelled labs and confirmed by Drug Testing Laboratory are stopped from issue to patients.

⁵⁵ 15,000 x ₹1,550 = ₹2.32 crore

4.2.7. Irregular procurement of PPE kits leading to additional expenditure to the tune of ₹10.23 crore

GoK accorded (March 2020) special sanction to KMSCL to procure PPE kits, N 95 Masks, and other similar commodities and equipment for equipping healthcare institutions in the State to manage COVID-19 pandemic effectively. Further, in the wake of emergency requirement and scarce availability, exemption was also granted from tender/ quotation formalities. However, GoK had prescribed (March 2020) unit rates for PPE kits at ₹545 with a view to effect price control of essential commodities. The purchases were also permitted to be effected through KCP, the commercial wing of KMSCL. Further, decisions were also made in State Level Crisis Management group to place purchase orders for COVID management based on demand and criticality of situation.

Four firms⁵⁶, which included three regular suppliers to KMSCL/ Karunya division had offered rates to supply PPE kits during March 2020 at rates falling within or slightly higher than Government approved rates. Despite the availability of offers at lower price ranges from regular suppliers as well as in local markets, procurements were also made from five firms during March and April 2020 at much higher rates, as high as 300 *per cent* above the unit rate or at higher rates, compared to previous purchases made. This resulted in additional expenditure of $\gtrless10.23$ crore on the PPE kits procured during the above period. Details are given in **Table 4.7**.

SI. No.	Supplier	Unit rate offered (in ₹)	Date of Letter of indent/ supply order	Ordered quantity	Total expenditure on purchases at offered rates (₹ in crore)	Total expenditure, if purchased at prescribed rates of ₹ 545/unit (₹ in crore)	Excess expenditure incurred (₹ in crore)
1	M/s. San Pharma	1550	30.03.2020	15000	2.33	0.82	1.51
2	A&A Trading Ventures Pvt. Ltd.	1185	02.04.2020	1000	0.12	0.05	0.06
3	M/s. Innov Quotient Pvt. Ltd.	1550	06.04.2020	15000	2.33	0.82	1.51
4	BNS Health Aids Ltd.	1295	06.04.2020	25000	3.24	1.36	1.88
5	M/s. Kitex Garments	830	15.04.2020	60000	4.98	3.27	1.71
3	wi/s. Kitex Garments	800	15.04.2020	140000	11.20	7.63	3.57
	Total			256000	24.18	13.95	10.23

 Table 4.7: Details of PPE kits procured during March to May 2020

(Source: Records of KMSCL)

In this context, Audit noticed that M/s Anitha Texcot (India) Pvt. Ltd. offered (28 March 2020) to supply PPE kits at the rate of ₹550 which was close to the unit rates (₹545) prescribed by GoK. Even though KMSCL offered to procure 25,000 PPE kits from this firm, purchase orders were issued (28 March 2020) for the supply of 10,000 numbers only while the ordered quantity ranged from 15,000 to two lakh in respect of other firms which quoted rates ranging from ₹800 to ₹1,550 per unit. On receipt of supply of 50 *per cent* of the ordered quantity within 18 days of issue of supply order, the supply order was cancelled (15 April 2020) stating the reason that receipt against supply order was less. However, Audit noticed that KMSCL had not included any clause in LoI

⁵⁶ M/s Careon Healthcare Solutions Pvt Ltd (₹425 to ₹445), M/s Biomedics (₹475 + GST), M/s Anitha Texcot (India) Pvt Ltd (₹550 +GST), M/s New Care Hygiene Solutions Pvt Ltd. (₹450)

stipulating supply period and no records were available to suggest that KMSCL had set a time frame for supplying the PPE kits ordered. Besides, the suppliers who had offered substantially higher unit prices (refer **Table 4.7**), had carried out the supply 23 to 33 days after the issue of supply orders which were accepted without any cancellation of orders. Thus, it is evident that KMSCL excluded a firm that was supplying PPE kits at a lower rate in order to purchase the item at higher rates from other vendors.

GoK replied (November 2023) that GoI had issued special instructions on 27 March 2020 in view of the urgency involved in the procurement of medical and other essential supplies, for permitting procurement from more than one source. Further, the SLCMG had authorised KMSCL to buy variants of PPE kits as available in the market, based on necessity and criticality of the situation.

Though procurement was made in emergency scenario, this does not justify cancelling POs which are economical to the Government. Thus, the purchases made from suppliers who were new in market, at significantly higher rates resulted in extra expenditure of ₹10.23 crore.

4.2.8. Availability of AYUSH essential medicines

Government of Kerala vide order dated 23 December 2019 approved 174 items of drugs in the Essential Drug List (EDL) for Ayurveda. Audit verified the availability of these drugs in the ISM hospitals test-checked, as detailed in **Table 4.8**.

Sl. No.	Hospital	No. of Ayurveda drugs in EDL	Average availability of Ayurveda drugs during 2019-20 to 2021-22
1	District Ayurveda Hospital Kalpetta		71
2	Government Ayurveda Hospital Perinthalmanna		68
3	Government Ayurveda Marma Hospital Kanjiramkulam	174	41
4	Government Ayurveda Panchakarma Hospital Alappuzha		80

Table 4.8: Availability of Essential Drugs in test-checked ISM hospitals

(Source: Information furnished by test-checked hospitals)

Audit observed that out of 174 drugs in the EDL for ISM, the availability of drugs ranged from 41 to 80 drugs in the test-checked hospitals.

4.3. Quality Control

Tender conditions issued by KMSCL required that all batches of drugs supplied should carry certificates of analysis from the in-house testing laboratory of the supplier firm and from NABL⁵⁷ accredited drug testing laboratory/ central drug testing laboratory. KMSCL reserved the right to get the drug tested at laboratories of their choice for further verifications and to subject 10 *per cent*

⁵⁷ National Accreditation Board for Testing and Calibration Laboratories (NABL) is an accreditation body (a constituent Board of Quality Council of India), with its accreditation system established in accordance with ISO/ IEC 17011.

of total batches supplied in a year to quality tests on random basis, at drug testing laboratories approved under the Drugs and Cosmetics Act, 1940. It was envisaged that the distribution of such items, which fail in the analysis of empanelled laboratories (lab) would be temporarily stopped and samples forwarded to Government Drug Testing Laboratory (DTL) at Thiruvananthapuram for confirmatory analysis. If any batches were declared as not of standard quality (NSQ) by DTL, orders were to be issued to stop distribution of that particular batch of the drug. In such cases, the bidder would be liable for appropriate action as per the tender conditions and also for legal action under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. If any batch was declared as standard quality (SQ), then the same would be released for issue to patients.

4.3.1. Inappropriate exemption from subjecting to quality check

The prime objective of quality checking (QC) of drugs is to help assure that safe and effective drugs are supplied to hospitals.

However, it was observed that KMSCL exempted high value Anti-cancer drugs and specialty drugs⁵⁸ due to limited purchases, items required to be maintained in cold chain conditions due to lack of transportation facility⁵⁹, X-ray films and items for which no rates were quoted by empanelled labs,⁶⁰ etc., from quality tests.

GoK replied (November 2023) that considering the operational intricacy in testing all anti-cancer drugs and specialty drugs due to insufficient quantity of procurement/ insufficient laboratory facilities, KMSCL had taken all possible steps to strengthen procurement logistics and supply chain mechanism. Prequalification criteria for the manufacturers and suppliers were made very stringent. KMSCL had made the certificate of analysis from third party NABL accredited laboratory for each batch mandatory, in addition to in-house drug test report.

Audit noticed from details furnished by GoK that even after adopting such measures, one of the two specialty drugs and three of the 28 cold chain drugs tested on the basis of complaints received were found as NSQ, which underscores the need for quality check at Government level for protecting patients from potentially unsafe, non-effective or poor-quality drugs under the aforementioned categories.

4.3.2. Delays in quality checking of drugs at various stages

Expression of Interest stipulated that the labs have to furnish the test results within 15 days for non-sterile preparations and 30 days for sterile preparations.

⁵⁸ Anti-Cancer drugs and Specialty drugs were exempted from quality check being high value items purchased in limited quantity and consequent inability to maintain sufficient control samples

⁵⁹ KMSCL did not have cold chain transport facility (For drugs requiring storage temp 2-8°C).

⁶⁰ 53 items were exempted from QC during 2014-17, 103 items during 2017-19 and 132 items during 2019-21.

Analysis of data for the period from 2016-17 to 2021-22 revealed that 9,766 samples of drugs were picked (selected) during this period for quality check. While the laboratories took more than 30 days to furnish the test results relating to sterile preparations to KMSCL from the date of receipt in respect of 37 *per cent* of samples (376 out of 1,028 sterile samples), the maximum delay was 331 days. Of these, 19 drugs turned out to be NSQ. While the labs took more than 15 days to furnish the test results relating to non-sterile preparations to KMSCL from the date of receipt in respect of 38 *per cent* of samples (719 out of 1,876 non-sterile samples), the maximum delay was 212 days. Of these, 26 drugs turned out to be NSQ. Inordinate delay in finalising the lab test reports by DTL was also noticed. The total number of lab test reports received after 60 days during the period was 789 and the time taken for receipt of lab test report ranged up to 326 days in one case during 2020-21.

Audit also noticed inordinate delay on the part of KMSCL in other stages as shown in **Table 4.9**.

Stages involved	Norms	Remarks
Producing samples at KMSCL by		Warehouses took more than 14 days in respect
warehouses from the date of picking		of 66 per cent of samples. The maximum
(selection) samples	In the absence of	period taken was 314 days.
Producing samples at the empanelled Labs	stipulation of time limit,	KMSCL took more than 14 days, in respect of
by KMSCL from the date of placing work	Audit adopted 14 days as a	six per cent of samples and the maximum time
order with the Labs	reasonable benchmark for	taken was 176 days.
Data capture of details of test results in	analysis	Exceeded 14 days from the date of receipt of
DDMS by KMSCL from the date of		results in respect of 48 per cent of samples. The
receipt of results from the Labs		maximum time taken was 702 days.

Table 4.9: Delay in various stages of QC

(Source: DDMS data of KMSCL)

The Drugs Controller attributed (April 2022) the delay in sample reporting to testing of high-priority samples, non-availability of analytical methods/ working reference standards/ instruments and COVID pandemic.

GoK replied (November 2023) that major delay in various stages of QC had occurred due to floods during 2018-19 and COVID outbreak.

The reply is not tenable as the delay in sampling at warehouses existed throughout the Audit period.

4.3.3. Batches of drugs and suppliers escaped quality checks

Audit examined the testing methodology adopted by KMSCL to assess whether the objective of ensuring 'qualitative needs of the end users' was achieved. Audit's view on inappropriate exemption is pointed out in paragraph 4.3.1. Nevertheless, analysis of data for the period from 2016-17 to 2021-22 relating to batch-wise samples, excluding exempted drugs, subjected to QC revealed that the stipulated percentage (10 *per cent*) of the total batches received in a year was subjected to QC as shown in **Table 4.10**.

Year	Total no. of batches received	No. of batches requiring QC (excluding exempted drugs)	No. of batches sent for QC	Sample check done on required batches (<i>in per cent</i>)
2016-17	9220	8604	1080	12.55
2017-18	8843	7889	1145	14.51
2018-19	10200	7926	1124	14.18
2019-20	8983	7688	1259	16.38
2020-21	8620	7313	920	12.58
2021-22	8183	6298	3172	50.37
Total / Average	54049	45718	8700	19.03

Table 4.10: Details of batch-wise samples subjected to QC

(Source: DDMS data of KMSCL)

The objective of subjecting 10 *per cent* of drugs to QC is to ensure that all the drugs issued to patients should be of standard quality. Adopting multi-stage sampling would ensure that samples from all the batches of drugs supplied by every supplier are subjected to QC, thereby guaranteeing that the samples represent the population (entire drugs).

Audit observed that the procedure adopted to select samples is simple random sampling method. Consequently, on the one hand, considerable number of drugs escaped quality checks and on the other, several suppliers escaped from the scanner of QC as shown in **Table 4.11** and **Table 4.12**.

Year	No. of drugs received	Drugs qualified for QC (excluding exempted drugs)					
2016-17	531	412	319	93			
2017-18	586	384	295	89			
2018-19	577	364	280	84			
2019-20	610	374	329	45			
2020-21	628	373	316	57			
2021-22	674	363	306	57			

 Table 4.11: Number of drugs escaped from subjecting to QC

(Source: DDMS data of KMSCL)

Table 4.12: Number of supple	iers whose supplies	escaped from s	ubjecting to QC
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Year	No. of suppliers	No. of suppliers qualified for QC (excluding exempted drugs)	No. of suppliers whose drugs were sent for normal QC	No. of suppliers whose supplies escaped from QC		
2016-17	116	94	81	13		
2017-18	124	97	78	19		
2018-19	126	91	79	12		
2019-20	123	88	75	13		
2020-21	116	86	72	14		
2021-22	140	97	81	16		

(Source: DDMS data of KMSCL)

This included all the batches of 46 drugs, which were not subjected to QC in any of the years during the period 2016-17 to 2021-22. Further, all supplies from 14 suppliers escaped from the scanner of QC.

GoK accepted the audit observation and stated (November 2023) that KMSCL never prioritised the products or suppliers for QC random sampling. From 2021 onwards KMSCL selected 30 *per cent* of drugs for QC.

Audit however observed that though the percentage of sampling was enhanced during 2021-22, considerable number of suppliers and drugs escaped from the scanner of QC, as can be seen from **Tables 4.11 and 4.12**.

4.4. Deficiency in inventory control and improper storage of medicines

Audit conducted physical verification of the drug stores for verifying the availability of facilities in 67 test-checked hospitals as detailed in **Table 4.13**.

Description	Percentage of deficiencies	Probable impact of deficiencies
Air-conditioned pharmacy	55.22	Loss of efficacy and shelf life of drugs
Labelled shelves/ racks	28.36	High turnover time in the disbursement of drugs
Storage away from water and heat	5.97	Loss of efficacy and shelf life of drugs
Drugs stored above the floor	19.40	-do-
Drugs stored away from walls	22.39	-do-
24-hour temperature recording in cold storage	41.79	-do-
Display of instructions for storage of vaccines	29.85	-do-
Functional temperature monitoring device in freezers	19.40	-do-
Maintenance of temperature chart of deep freezers	17.91	-do-
Drugs kept under lock and key	17.91	Misuse of costly drugs
Poisons kept under lock and key	52.24	Unauthorised access to hazardous drugs
Expired drugs stored separately	22.39	Mixing of expired drugs with usable drugs

 Table 4.13: Deficiencies in drugs stores

(Source: Physical verification conducted by Audit)

It could be seen from the above that the deficiencies ranged from 5.97 to 55.22 *per cent* in the above test-checked hospitals. This carries the risk of loss of efficacy and shelf life of drugs, misuse of costly drugs and unauthorised access to hazardous drugs.

4.5. **Compliance of stipulations on prescriptions**

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 and amendment notification (October 2016) stipulate that every physician should prescribe drugs with generic names legibly and preferably in capital letters. GoK noticed violation of these stipulations and therefore issued (June 2014 and November 2015) periodical instructions to hospital authorities for strict compliance of the Regulations.

Audit conducted a test-check of prescriptions issued to outpatients which revealed persistent issue of prescriptions of branded drugs. In respect of 1,950 prescriptions issued by 65 test-checked hospitals, 15.42 *per cent* of the drugs prescribed were branded drugs. Further, 92 *per cent* of prescriptions were legible and 36 *per cent* were in capital letters. Audit also observed that the prescription of branded drugs was comparatively higher in Medical College hospitals. On scrutiny of 90 prescriptions in three Medical College hospitals

test-checked, 199 out of the 365 drugs prescribed (54.52 *per cent*) were branded drugs.

4.6. Deficiencies in IT management of DDMS

Drug Distribution and Management System (DDMS) was developed by M/s Karnataka State Electronics Development Corporation Limited and is hosted in the State Data Centre, Thiruvananthapuram. The application runs on one database server and two application servers.

The deficiencies noticed in IT management of DDMS are summarised in **Appendix 4.1**. Audit observed deficiencies in strategic IT planning at KMSCL which resulted in deficient development of DDMS, non-integration with e-procurement system of GoK, insufficiencies in operation controls, etc. Further, non-hosting of DDMS in a secure website exposed the system to possible sniffing attack.

4.7. **Procurement and supply of medical equipment**

Equipment for diagnostic/ therapeutic purposes, dialysis units, cath labs etc., were sanctioned to hospitals under the annual plan schemes by GoK and the funds were released through annual budget. GoK aims to standardise the services offered by each level of hospital through Aardram Mission and has also evolved a State level quality assurance program, the KASH to improve the quality of health care offered by the hospitals. No specific quantum of equipment required in each level of hospital has been specified under the Mission document and the accreditation standards. However, IPHS specifies the requirement of equipment in each department in each level of hospital. Hence, Audit examined the availability of equipment required under IPHS in the test-checked DH/ GHs and TH/ THQHs respectively and observed shortfall against requirement as detailed in **Table 4.14** and **Table 4.15**.

			Availability of item									
SI. No.	Type of Services	Equipment essential as per IPHS 2012	DH Mavelikkara DH Tirur		Nedumangad Mananthavady		Alappuzha	GH Neyyattinkara	GH Kalpetta	Scales determined by Audit		
			HŒ	HQ	ΗQ	HQ	GH	GH	GH	Good	Moderate	Poor
1	Imaging Equipment	12	7	7	3	9	10	4	5	> 9	6 to 9	< 6
2	X-Ray Room Accessories	8	6	5	4	3	7	3	3	> 6	4 to 6	< 4
3	Cardiopulmonary Equipment	16	12	12	8	14	12	10	11	> 12	8 to 12	< 8

 Table 4.14: Availability of equipment in test-checked DH/ GHs

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			Availability of item											
SI. No.	Type of Services	Equipment essential as per IPHS 2012	DH Mavelikkara	DH Tirur	DH Nedumangad	DH Mananthavady	GH Alappuzha	GH Neyyattinkara	GH Kalpetta	Scale	Scales determined by Audit Good Moderate Po			
4	Labour ward (LW), Neo Natal and Special Newborn Care Unit Equipment	28	22	20	21	23	No LW	24	18	> 21	14 to 21	< 14		
5	Special Newborn Care Unit	12	12	6	2	7	No LW	2	3	> 9	6 to 9	< 6		
6	Disinfection of Special Newborn Care Unit	13	11	6	3	4	No LW	б	2	>10	7 to 10	< 7		
7	Immunization Equipment	15	14	13	12	12	12	15	13	>11	8 to 11	< 8		
8	Ear Nose Throat Equipment	23	17	17	10	19	20	11	19	> 17	11 to 17	< 11		
9	Eye Equipment	27	23	21	26	26	25	21	20	> 20	13 to 20	< 13		
10	Dental Equipment	42	36	30	34	36	31	30	36	> 32	21 to 32	< 21		
11	Laboratory Equipment	87	54	43	41	33	50	37	26	> 65	43 to 65	< 43		
12	Endoscopy Equipment	8	4	2	3	5	2	2	2	> 6	4 to 6	< 4		
13	Anaesthesia Equipment	25	21	21	19	22	22	18	20	>19	13 to 19	< 13		
14	Postmortem Equipment	9	9	6	5	6	1	3	No Mortuary	>7	5 to 7	< 5		
15	Operation Theatre Equipment	29	14	10	9	16	14	13	9	> 22	15 to 22	< 15		
16	ICU equipment	10	9	7	6	7	8	No ICU	7	> 7	5 to 7	< 5		

(Source: Physical verification conducted by Audit)

Major shortfall in equipment was noticed in DH Nedumangad, GH Neyyattinkara and GH Kalpetta, where such shortfall was existing in six to eight services.

			Availability of item									
SI. No.	Type of Services	Equipment essential as per IPHS 2012	as 8 8		TH Fort	THQH Kayamkulam	THQH Tirurangadi	THQH Malayinkeezhu	THQH Vythiri	Scales determined by Audit		
1	Imaging equipment	3	2	2	0	1	1	1	2	Good > 2	Moderate 1 to 2	< 1
2	X-Ray Room Accessories	7	3	4	2	2	2	4	7	> 5	3 to 5	< 3
3	Cardiopulmonary Equipment	9	8	6	6	7	7	8	6	> 7	5 to 7	< 5
4	Labour ward and Neo Natal Equipment	18	14	15	14	15	12	No LW	14	> 14	9 to 14	< 9
5	Immunization Equipment	16	11	11	11	13	8	9	13	> 12	8 to 12	< 8
6	Ear Nose Throat Equipment	22	4	0	0	14	5	0	10	> 17	11 to 17	< 11
7	Eye Equipment	22	10	11	0	15	18	3	13	> 17	11 to 17	< 11
8	Dental equipment	4	4	4	4	4	4	4	4	> 3	2 to 3	< 2
9	Operation Theatre Equipment	24	7	6	10	15	10	No OT	9	>16	12 to 16	< 12
10	Laboratory Equipment	28	15	19	15	13	24	17	16	> 21	14 to 21	< 14
11	Surgical Equipment Sets	34	16	15	16	24	24	4	26	> 26	17 to 26	< 17
12	Endoscopy Equipment	1	0	0	0	0	1	0	0	1		0
13	Anaesthesia Equipment	19	13	9	16	17	17	0	10	> 15	9 to 15	< 9
14	Postmortem equipment	10	6	No Mortuary	No Mortuary	8	6	No Mortuary	2	> 7	5 to 7	< 5

Table 4.15: Availability of equipment in test-checked TH/ THQHs

(Source: Physical verification conducted by Audit)

It was seen from the above that Endoscopy equipment was not available in six out of the seven test-checked TH/THQHs whereas shortfall in equipment was noticed in eight services in TH Fort and THQH Malayinkeezhu. Shortage of essential equipment in the above hospitals hampered the smooth delivery of health services.

Audit examined the purchase records of the major equipment in the test-checked hospitals and found instances of delay ranging from three to nine years in procurement, defective maintenance leading to underutilisation, idling of equipment due to lack of trained staff, pending repairs, etc. as discussed below:

4.7.1. Non-purchase of vital equipment

4.7.1.1. HDR Brachy Therapy with Treatment planning System in GMC, Thiruvananthapuram

The Director of Medical Education had submitted (June 2013) a proposal to GoK for setting up Oncology and Tertiary care centres in Medical Colleges. Government approved the proposal (August 2013) and allocated \gtrless 1.75 crore to GMC, Thiruvananthapuram for the purchase of HDR Brachy Therapy with

treatment planning system⁶¹. The funds were transferred to KMSCL (January and February 2014). However, the purchase did not materialise and the amount was resumed by GoK in 2018. Though DME addressed (February 2020) GoK to sanction the revised amount of \gtrless 2.73 crore, the same has not been released by GoK.

GoK replied (November 2023) that a bunker has been constructed for the machine and on availability of funds, equipment would be procured and installed after completing the civil and electrical works inside the bunker.

4.7.1.2. Non-procurement of Brachy Therapy in GMC, Alappuzha

Ministry of Health and Family Welfare, GoI had sanctioned (September 2012) $\gtrless 4.80$ crore to GMC, Alappuzha for the purchase of HDR Brachy Therapy Unit with 3D Planning System and Conventional Simulator subject to the release of 20 *per cent* State share of $\gtrless 1.20$ crore.

The 80 *per cent* GoI share of ₹4.80 crore and ₹2.45 crore of Additional Central Assistance were credited to the SB account of the Principal, GMC and State share of ₹ 1.20 crore was credited (March 2013) to his Personal Deposit account.

Accordingly, supply order for the purchase of the machines was issued (February 2014) to the L1 quoted company for an amount of ₹4.36 crore and the sanction for opening Letter of Credit for the amount for supply of machine was issued (August 2015) by GoK. However, the company declined to supply the equipment citing the reason that the techno commercial offer was valid only upto 28 February 2014. Audit noticed that the purchase had not been made (March 2022) and the amount remained unutilized. The Hospital stated (March 2022) that the main reason for delay in procurement was the inability to meet the price hike on exchange rate variation in the price bid after finalising tender procedures.

GoK stated (October 2022) that a proposal for revised administrative sanction was received in May 2022. Further, a proposal for revalidation of the scheme from GoI was under process.

However, the fact remains that due to procedural delays and GoK resuming funds, equipment meant for cancer treatment in two tertiary hospitals in the State were not purchased, which resulted in denial of advanced treatment facilities to cancer patients.

4.7.1.3. Incinerator in GMC Thiruvananthapuram

GoK accorded (September 2016) sanction of ₹20 lakh for installation of a new incinerator⁶² in GMC Thiruvananthapuram. The amount was transferred to KMSCL (April 2017). Further, GoK sanctioned (September 2018) an amount of ₹120 lakh for construction of building to install the new incinerator. The PWD Buildings Division was requested (November 2018) to expedite the work

⁶¹ HDR Brachy Therapy with treatment planning system: High Dose Rate Brachy Therapy is a form of internal radio therapy where an oncologist places highly radioactive material inside the body for a short time and then retracts it using a remote control.

⁶² An incinerator is a furnace for burning waste.

and complete the same before 31 March 2019. Assistant Engineer, Buildings Division, PWD informed (August 2021) GMC that the first phase of the building for housing the incinerator was completed and requested to take steps to install the incinerator which was communicated to KMSCL (August 2021). Audit observed that the incinerator was not installed (April 2022) at MCH Thiruvananthapuram. GMC informed (April 2022) that necessary directions had been given to the Assistant Engineer, PWD to obtain the statutory clearance for the installation from various agencies⁶³. GMC stated (July 2022) that the waste dumped in the open area was disposed by deep burial method and in the absence of an incinerator the waste was disposed in bio-gas plants in the campus and incinerator at attached hospitals. However, Audit noticed large quantity of waste dumped in open area in hospital premises during the visit, which was detrimental to the environment as well as risky for the patients and the public in the premises.



Figure 4.1: Waste dumped in the premises of MCH, Thiruvananthapuram. Photograph taken on 07 December 2021

GoK stated (November 2023) that the incinerator was installed in October 2023. However, statutory clearances for the functioning of the incinerator were not obtained.

4.7.1.4. Delay in decommissioning of old Telecobalt machine and procurement of new Machine in GMC Alappuzha

GoK accorded (May 2017) administrative sanction (AS) for ₹2.50 crore for purchasing a new Telecobalt machine⁶⁴ for replacing the existing 27 year old one (1994) in GMC Alappuzha. The AS amount was finally revised (May 2019) to ₹3.63 crore, including the decommissioning charges of the old Telecobalt machine. The supply order was issued to the bidder (October 2019), but the supply did not materialise as vendor insisted (January 2020) for 50 *per cent* advance payment for its delivery which was not acceptable to DME.

⁶³ Thiruvananthapuram Corporation, Airports Authority, Pollution Control Board

⁶⁴ Telecobalt machine is a radiotherapy machine which uses Cobalt-60 for treatment of cancer

Subsequently, the work for decommissioning of the existing machine was awarded (May 2021) to another firm for an amount of \gtrless 26 lakh. However, this work also did not materialise as the firm demanded advance payment which was not acceptable to college authorities.

GoK stated (October 2022) that the decommissioning process was completed.

The reply does not explain the action taken to expedite the purchase. Even after five years from the date of sanction, the procurement of a new machine was not materialised and the patients were deprived of the services.

4.7.1.5. Delay in setting up Cath lab and Coronary Care Unit in General Hospital, Alappuzha

GoK sanctioned (August 2016) setting up of Cath Lab⁶⁵ and Coronary Care Unit (CCU) in GHs under Kerala Infrastructure Investment Fund Board (KIIFB) projects, one of which was for GH, Alappuzha. Though the site was handed over (March 2018) to the successful bidder, the work could not be commenced due to non-availability of required power supply of 250 KVA. GoK sanctioned (September 2018) an amount of $\overline{\mathbf{x}}$ two crore ($\overline{\mathbf{x}50}$ lakh for civil works and $\overline{\mathbf{x}150}$ lakh for electrical works) and the work was entrusted to M/s HLL.

The site for the construction of high-tension power station was handed over to the constructing authority (January 2020). However, on a visit to the hospital (February 2022), it was seen that the installation agency found the first site inappropriate and hence an alternate site was subsequently identified, which was handed over for installation in October 2021 only. The installation works in the alternate site were in progress. Thus, the Cath lab sanctioned in 2016-17 is yet to be functional even after a period of over six years. It was also noticed that Cath lab available at GMC Alappuzha was not fully functional as detailed in Paragraph 4.7.2.2 of this Report.

GoK stated (November 2023) that the building identified for the installation of Cath lab and CCU was reported to be unfit by PWD and hence the Cath lab machine was transferred to DH Mananthavady to which Cath lab was sanctioned under plan funds. It was also stated that the Cath lab and CCU can be set up at GH Alappuzha on completion of construction of pay ward building.

4.7.2. Deficiencies in maintenance of equipment by Medical Colleges

The maintenance of all bio-medical equipment in various hospitals under the DHS is executed through a service provider since 2016 under the project Bio-Medical Equipment Maintenance Program (BEMP). In the Medical Colleges functioning under DME, instead of a third-party service provider, the Bio-Medical Engineering Department undertakes the maintenance and repairs of the equipment. Audit noticed deficiencies in proper maintenance of equipment in test-checked Medical Colleges. Annual Maintenance Contracts (AMC) for

⁶⁵ A Catheterisation laboratory, commonly referred to as a cath lab is an examination room in a hospital with diagnostic imaging equipment to visualize the arteries and chambers of heart for treatment of heart diseases.

major equipment were not maintained up-to-date and no regular repairs were done resulting in frequent breakdowns and consequent denial of services to patients. The major instances noticed are discussed below:

4.7.2.1. GMC Thiruvananthapuram

In GMC, Thiruvananthapuram the Magnetic Resonance Imaging⁶⁶ • (MRI) machine which was installed in June 2010 was providing services to an average of 5,000 patients per year during 2016-17 to 2020-21. Audit observed that the machine was frequently facing operational issues due to its age and lack of servicing and was out of comprehensive AMC with effect from September 2021. It was reported (June 2020) that the MRI scanner had reached the end of its life cycle, was technologically obsolescent and needed replacement or upgradation. Out of 60 to 70 requests of service per day, around 20 cases were being carried out daily and round the clock MRI services were not available to the patients. GoK accorded AS (December 2021) for upgradation of existing MRI machine at a cost of ₹6.10 crore. However, the same was not implemented and the hospital continues to function with an MRI scanner which has reached the end of its life cycle. In the absence of MRI services in the hospital, many patients have to depend on private establishments where the rates were comparatively higher.

GoK stated that (October 2022) a decision was taken to purchase a new MRI machine. Though the decision to purchase a new equipment is a right step, a time bound action plan spelling out the source of fund is essential for implementing the project.

4.7.2.2. GMC Alappuzha

• An 800 mA Fluoroscopy machine⁶⁷ worth ₹18 lakh, necessary for diagnosing heart/ intestinal disease and to guide treatments, was idling at GMC Alappuzha for nine years. It was replied that the machine was installed in 2010 and stopped working in January 2013. Idling of the machine was reported to the Superintendent (November 2017) and the Principal (November 2018). No alternate arrangements were made (March 2022).

GoK stated (October 2022) that there was no service support by the manufacturer or the supplier. The reply reaffirms the contention of Audit that equipment is idling due to lack of adequate maintenance.

• The Cath Lab of GMC, Alappuzha, which provided 3,000 lab procedures annually did not have AMC with effect from September 2021. Audit noticed (December 2021) that one of the machines used in Cath lab for imaging purposes *viz*. IVUS+FFR costing ₹56.29 lakh was idle since

⁶⁶ MRI is a type of scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body.

⁶⁷ Fluoroscopy is a type of medical imaging that shows a continuous X-ray image on a monitor, much like an X-ray movie

2020. The Principal replied (March 2022) that the machine was idling due to non-availability of a Catheter in the Cath Lab.

GoK stated (October 2022) that agreement for comprehensive AMC for Cath Lab was under active consideration. The institution had taken steps to purchase IVUS+FFR catheters in the upcoming tender procedures.

Idling of the machine worth \gtrless 56.29 lakh due to non-availability of catheter is not justifiable.

• A Mammography Machine (₹29.61 lakh, July 2012) was idling over two years from January 2020 due to frequent repairs and was without AMC.

GoK stated (October 2022) that the maintenance of the machine was delayed due to COVID situation and following frequent breakdowns, it was made functional in June 2022, July 2022 and August 2022. The CR system in which the mammogram images are digitally processed went out of order in August 2022, spare part replacement of which was awaited. From the reply, it is evident that the Mammography machine underwent frequent breakdowns during 2022 and the mammogram studies could not be conducted as CR system was non-functional.

On an average, 500 cases per year were carried out with this machine previously. As there was no alternate machine available in the hospital, patients had to depend on private establishments.

4.7.3. Non/ underutilisation of PSA Oxygen plants

Utilising Prime Minister's Citizen Assistance and Relief in Emergency Situations fund (PM CARES fund), 26 hospitals in the State were provided with Pressure Swing Adsorption⁶⁸ (PSA) plants. Out of the five hospitals test-checked where the PSA plants were installed, Audit observed that in GH Neyyattinkara, the civil works of the plant room were completed and the plant was installed (July 2021) and inaugurated in October 2021 with a temporary LT connection. Audit noticed (January 2022) that the plant was not functional due to non-availability of generator and transformer. The hospital authorities stated (September 2022) that considering the high energy cost to be borne compared to the cost of oxygen usually procured, the operation of the PSA plant was not economical.

GoK stated (October 2022) that there was no hurdle for GH Neyyattinkara in utilising the Oxygen generator, but the hospital authorities are not showing any interest in making use of the equipment.

The reply of GoK fails in addressing the real issues behind non-functioning of the Oxygen generator, which has contributed to the idling of the plant since July 2021.

⁶⁸ The PSA plant is a source of medical grade oxygen which separates oxygen from compressed air and ensures continuous supply of oxygen.

4.7.4. Availability of ventilators for COVID-19 management

Under PM CARES fund, 480 ventilators were received and all the ventilators were distributed to different hospitals (January 2023).

4.7.5. Idling of equipment

One hundred seventy two equipment (₹7.28 crore⁶⁹) were found idling in 21 hospitals for periods ranging from one to 107 months, due to lack of manpower for its operation, pending repairs, supplied without indenting by hospital, etc. Details are furnished in **Appendix 4.2**. In GMCs Thiruvananthapuram and Alappuzha and Dental College, Thiruvananthapuram, 59 equipment worth ₹4.94 crore were lying idle for one to 107 months of which 20 items valued at ₹0.89 crore were beyond repair. DHS and DME could have explored the possibility of distributing the equipment to other needy hospitals for effective utilisation of the items procured.





Figure 4.2: Idling Blood Bank equipment in DH Tirur. Photograph taken on 24 November 2021

Figure 4.3: Idling OT table and light in CHC Edappal. Photograph taken on 30 November 2021

DHS stated that (November 2022) eight equipment valued \gtrless 14.09 lakh which were idling in three⁷⁰ hospitals were transferred to other hospitals/ put to use.

GoK stated (October 2022) that in the case of GMC Thiruvananthapuram, steps were taken to get the equipment ready to use in possible cases and for condemnation in other cases.

The reply of GoK is not tenable, as it does not set out an action plan or time frame for making the equipment functional or for condemnation. Further, the GoK reply is silent about the non-functional equipment of other hospitals.

4.7.6. Lack of infrastructure for installation of ventilators

To manage the crisis due to COVID pandemic, ICU ventilators were purchased by KMSCL and supplied to various hospitals across the State. On a visit (November 2021) to the test-checked hospitals, Audit noticed that two portable

⁶⁹ Value of 21 items are not available. It includes equipment received as donation, supplied by NHM without indent, very old items, etc.

⁷⁰ GH Neyyattinkara (one out of two), CHC Edappal (six out of 29) and CHC Thrikkannapuram (one out of three)

ventilators valued at ₹12.20 lakh supplied (October 2020) to DH, Nedumangad were not installed along bedside in ICU due to lack of sufficient space (December 2021). Though this hospital was upgraded as a district hospital (2013), the hospital was not being able to provide services as required under IPHS. To improve the facility, a new building was proposed to be constructed, but the work was abandoned as stated in **Appendix 5.1** of this Report.

Failure to ensure the availability of infrastructure before transfer of portable ventilators resulted in idling of these ventilators for over one year (December 2021). Further, no efforts were made to transfer these ventilators to some other hospital where they could have been utilised to save the lives of critical patients.

GoK stated (October 2022) that KMSCL had received installation reports from the hospital authorities and idling of the ventilators was not reported. Further, it was informed that since the ventilators are portable, they could be moved and used in any department.

Audit reiterates the fact that during field visit to the hospital, it was observed that the equipment was not utilised citing space constraint as the reason for non-utilisation.

4.8. **Recommendations**

- Government should issue necessary directions to KMSCL to take action to ensure availability of drugs in hospitals and supply should be based on the actual requirement thereby ensuring that the drugs indented are purchased without delay.
- Government should issue guidelines to be followed for purchases made during crisis situation with emphasis on improved transparency and accountability so that a better equipped public procurement system capable of helping Government to respond effectively during such situation is in place.
- Government should ensure that vital medical equipment are available in the hospitals especially in tertiary hospitals and that a proper system for maintenance and upkeep of the available equipment and condemnation of obsolete equipment is in place.