Chapter-7

Drug Management

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Accessibility, availability and affordability of good quality drugs at minimum out-of-pocket expenditure are key functions of the public health system to protect the public from the rising cost of health care.

Audit observations on various components of drug management- availability of drugs, their storage, dispensation to patients and procurement in the hospitals and CHCs are discussed in the succeeding paragraphs:

7.1. Availability of essential drugs

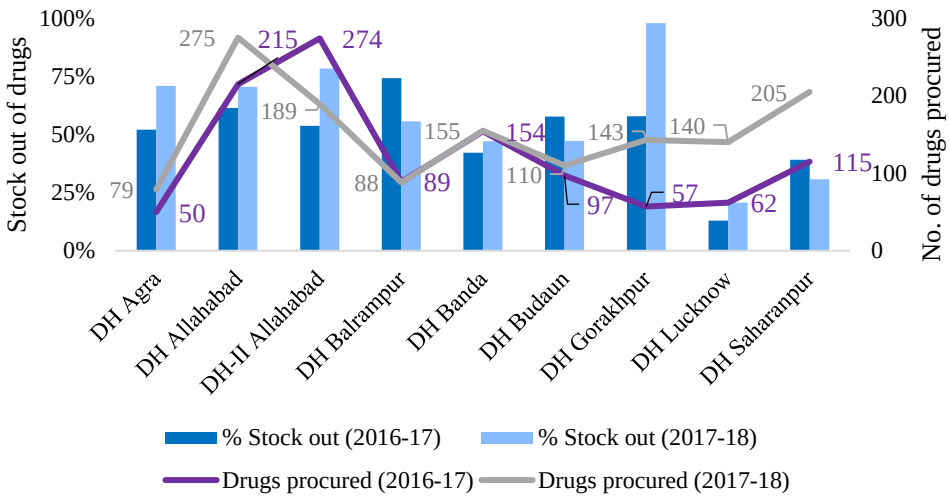
The Department has prepared an Essential Drug List (EDL) prescribing 498 drugs for CHCs and 809 and 859 drugs for the DHs[133] and DWHs/JHs respectively. Procedures for release of funds to the districts for procurement of drugs have also been put in place (October 2006) by the Department, according to which the DGMH is to obtain demands from the CMOs and CMSs based on the pattern of consumption of drugs (drug formulary) during the previous year. Accordingly, the DGMH releases funds to the CMOs and CMSs for procurement so as to ensure unbroken availability of all essential drugs in the hospitals.

Audit, however, observed that CMOs and CMSs in none of the sampled eight districts assessed the requirement of drugs as per EDL and no demands were sent to the DGMH for allotment of funds accordingly. The DGMH also did not monitor the receipt of such demands from the CMOs/CMSs. Therefore, the rationale of allocation of funds to the hospitals by the DGMH could not be ascertained.

Further, the CMOs and CMSs procured only a portion of the drugs under the EDL, ranging between 06 and 34 *per cent*, 03 and 24 *per cent*, 07 and 42 *per cent* in the test-checked DHs, DWHs/JHs and CHCs respectively during 2016-18. Also, the drugs which were procured, were inadequate in quantity due to which several of them remained out of stock for more than 30 days in a year during 2016-18 as shown in **Chart 25.**

[133] 1036 drugs for DH Lucknow

Chart 25: Drugs procured and stock out (%) in DHs



(Source: Test-checked hospitals)

Thus, the number of drugs bought in different test-checked DHs varied significantly and also were substantially less than the number of drugs required to be procured as per EDL. Further, stock out of at least 30 days during 2017-18 was observed for more than 50 *per cent* of the drugs procured in DH Agra, DH Allahabad, DH-II Allahabad, DH Balrampur and DH Gorakhpur.

Similarly, availability of drugs and stock out in DWHs/JHs/CHCs was as given in **Table 41.**

Table 41: Availability of drugs in the test-checked hospitals

Parameters	DWHs/JHs (test-checked: 10)		CHCs (test-checked: 22)	
	2016-17	2017-18	2016-17	2017-18
Number of drugs in EDL	859	859	498	498
Number of drugs not available (*per cent*)	660-835 (77-97)	652-826 (76-96)	350-460 (70-92)	289-464 (58-93)
Stock out of procured drugs				
Number of drugs not available for one to two months	1-24	1-27	1-20	1-18
Number of drugs not available for two to four months	5-36	2-38	3-25	1-22
Number of drugs not available for more than four months	8-47	11-69	2-78	11-92

(Source: Test-checked hospitals/CHCs)

It was also observed that the CMOs and CMSs did not prepare formulary on the basis of disease patterns and inflow of patients in the hospitals to support the selective procurement of drugs by them.

Due to non-procurement of full range of drugs as per EDL, even the vital drugs for IPD, OT, ICU, emergency and maternity services were not available in the hospitals to deliver the assured health services as discussed in Chapters 4 and 5.

The Government replied (May 2019) that drugs were selected by the hospitals as per the need of patients visiting the hospitals. It added that budget was allotted to the hospitals on the basis of demands raised by these hospitals and also in quest of the Government policy of distribution of free medicines to the patients.

The reply of the Government, however, was not acceptable because CMOs and CMSs in none of the test-checked districts/hospitals assessed the requirement of drugs as per EDL and sent the demands for allotment of funds to DGMH accordingly. The weak supply chains for essential medicines also potentially exposed patients to financial hardships and diminished public trust in the health system.

7.2. Storage of drugs

Drugs and Cosmetic Rules 1945 stipulate parameters for the storage of drugs in stores to maintain the efficacy of the procured drugs before issue to patients. The norms and parameters prescribed in the said Rules were, however, not adhered to as observed in audit of the test-checked hospitals as detailed in **Table 42**.

Table 42: Deficiencies in storage of drugs

Sl. No.	Parameters	Hospitals having deficiency (Test-checked: 19)	CHCs having deficiency (Test-checked: 22)	Probable impact of not adhering to parameter
1	Air-conditioned pharmacy	14	22	Loss of efficacy and shelf life of drugs
2	Labeled shelves/racks	5	9	High turnover time in the disbursement of drugs
3	Away from water and heat	0	0	Loss of efficacy and shelf life of drugs
4	Drugs stored above the floor	0	3	-do-
5	Drugs stored away from walls	1	4	-do-
6	24-hour temperature recording of cold storage area	10	8	-do-
7	Display instructions for storage of vaccines	10	7	-do-
8	Functional temperature monitoring device in freezers	1	0	-do-
9	Maintenance of temperature chart of deep freezers	9	5	-do-
10	Drugs kept under lock and key	0	2	Misuse of costly drugs
11	Poisons kept in a locked cupboard	1	2	Unauthorised access to the dangerous drugs
12	Expired drugs stored separately	7	11	Mixing of expired drugs with usable drugs

(Source: Test-checked hospitals/CHCs)

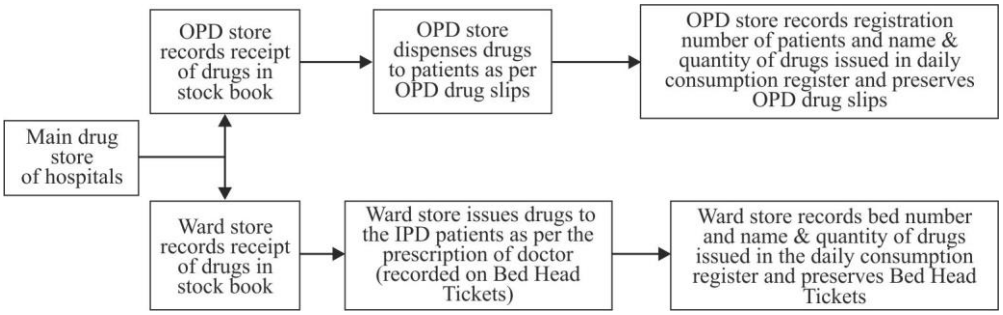
It is evident from above that several major deficiencies were present in the system of drug storage in the test-checked hospitals and CHCs; thus, the efficacy of drugs distributed to the patients could not be assured.

The Government replied that drugs, which were procured during 2013-18 by the head of the institutions, were stored by using available resources. The matter was also discussed in the Exit Conference wherein the Government responded that the deficiencies, noticed by audit in respect of the storage of drugs, would be examined and necessary corrective action taken.

7.3. Dispensing of drugs to the patients

Financial Rules, GoUP stipulate that all items received in or issued from Stores should be entered in the stock account on the dates the transactions take place.

Figure 8: Process of dispensing of drugs in a hospital



Audit observed serious discrepancies in the documentation and evidencing in respect of receipt and distribution of drugs in/from Stores, as detailed in **Table 43.**

Table 43: Documentation related to dispensing of drugs

Sl. No.	Description of records	No. of hospitals (test-checked-19) having no documentation	No. of CHCs (test-checked-22) having no documentation
1.	Section/ward-wise drug stock book	05	21
2.	Records of daily distribution	03	14
3.	OPD drug slips[134]	05	22

(Source: Test-checked hospitals/CHCs)

It is evident from the details given in Table 43 that:

- In the absence of section/ward-wise stock register, the receipt of drugs from the central drug store was not verifiable in 05 out of the 19 test-checked hospitals and 21 of the test-checked CHCs.
- Three out of the 19 test-checked hospitals and 14 out of the 22 test-checked CHCs did not record the patient-wise distribution of drugs from OPD, while 05 out of the 19 hospitals and none of the test-checked CHCs kept the OPD drug slips. Consequently, the distribution of drugs to the

[134] OPD drugs slip contains the list of drugs prescribed by the doctor along with quantity, to be dispensed to the OPD patients by the hospital pharmacy.

patients from OPD *vis-à-vis* prescriptions could not be verified in audit in the concerned hospitals/CHCs. Thus, pilferage of drugs could not be ruled out.

The Government replied that daily consumption register is maintained at the central drug store of the hospital. The reply was not tenable as daily consumption registers maintained at central drug store did not record the patient-wise dispensing of drugs, which was to be maintained at ward/section level.

In respect of non-maintenance of OPD drugs slips in the OPD store, the Government stated that drugs were issued to the patients on the basis of the prescription slips. It added that since prescription slips were retained by the patients after obtaining drugs from the store, the dispensing of drugs *vis-à-vis* prescription slips was not verifiable.

Urgent attention, therefore, requires to be given to strengthening the mechanism in this regard so as to effectively close the gap between the drugs prescribed and their actual issuance to the patients.

7.4. Grievance redressal of patients

The Drug Purchase Policy of June 2012 did not prescribe a mechanism to redress grievances related to free drug supplies to the patients and to recommend action to be undertaken within a stipulated time period. Due to this, the hospitals did not put in place a system of obtaining grievances of patients in respect of distribution of drugs. Besides, as discussed in paragraph 4.9.4.3 only two DHs (DH-II Allahabad and Lucknow) conducted patient satisfaction surveys for in-patient services during the period 2016-18, out of the 11 test-checked DHs, which included responses related to drug availability.

The Government replied that a complaint box was available in the hospitals to receive the grievances of the public. However, none of the test-checked hospitals and CHCs except for DH Agra and JH Lucknow had a system to put the grievances on record and monitor action taken.

7.5. Drug procurement management process

The Department promulgated a revised Drug Purchase Policy (DPP)[135] in June 2012 containing drug purchase procedures. Besides, the Department also issued administrative orders from time to time to regulate procurement processes.

As per DPP, the DGMH is the central procurement authority at the State level for ensuring supply of essential drugs in the hospitals at the district-level and below. The DGMH has the mandate to prepare the list of essential drugs and to conclude Rate Contracts[136] (RCs) with the manufacturing firms for

[135] No-835/five-1-2012-3(14)/04 dated 14 June 2012
[136] Rate Contracts standardise procurement prices of drugs

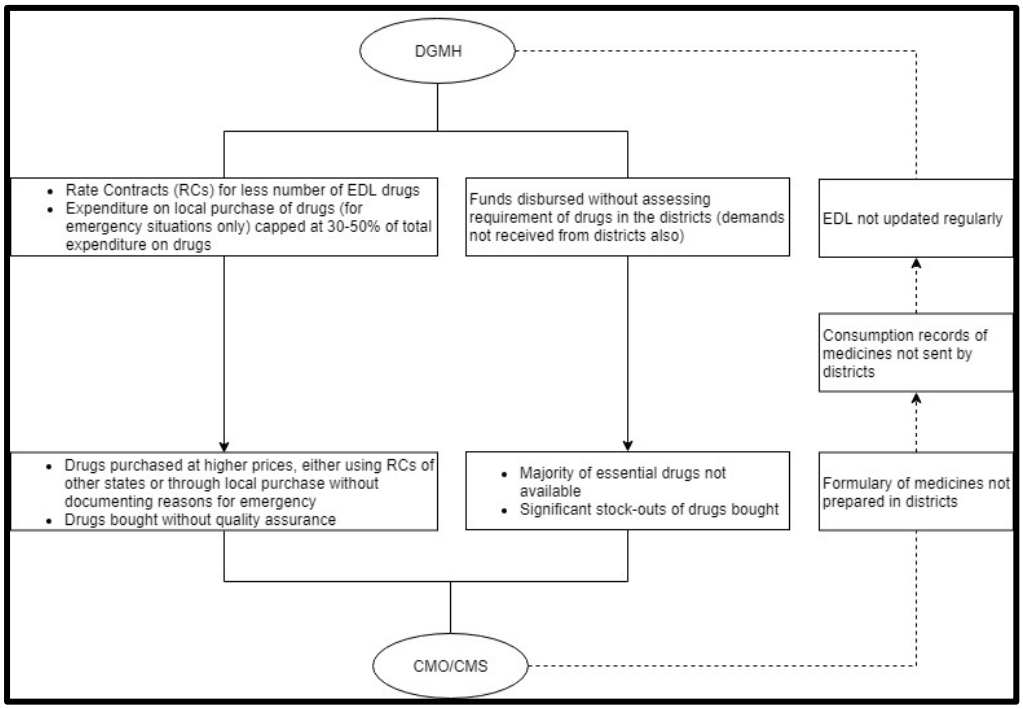
uninterrupted supply of drugs. CMOs and CMSs are to issue supply orders/indents to the contracted firms for supply of drugs as per requirement.

It is also prescribed that a drug, in respect of which RC of the Department is not available, could be procured from the firms contracted by Government of India (DGS&D/ESIC[137]) or other State Governments for supply of drugs in their respective States. Further, as per DPP, if RC is not framed for a drug and procurement is warranted in an emergency situation, the same could be procured from local vendors. A financial ceiling of 30 to 50 *per cent* of the total fund allotment has also been prescribed for CMSs of district hospitals in respect of procurement of drugs through local purchase. However, no such delegation is prescribed for CMOs.

Further, the Department prescribed an online portal 'Drug Procurement and Inventory Control System' in 2015-16 for issue of online indent of drugs to the suppliers. Subsequently, an IT-enabled Drugs and Vaccines Distribution Management System (DVDMS) with the modules for assessment of requirement of the hospitals, preparation of demand, issue of indent to suppliers, receipt of drugs, distribution of drugs to the patients, stock management, and quality control was implemented in 2017-18. However, only one module, *i.e.* online issue of indent to suppliers (under RCs), was in operation as of March 2018. Hence, the critical issues of supply chain management of drugs remained unattended.

Audit observed that the drug procurement process was marred with systemic problems as well as non-adherence to the stipulated procedures, as shown **Figure 9.**

Figure 9: Dysfunctional system of drug procurement



[137] Directorate General of Supplies and Disposals and Employees State Insurance Corporation

Major audit findings in respect of drug procurement are discussed below:

7.5.1. Inadequate coverage of drugs under RCs

The purpose of RC is to procure drugs at a fixed rate over a period of time while minimizing the order processing and inventory carrying costs. As a first step, the Drug Review Committee at the DGMH level has to collect consumption details of drugs from the hospitals and CMOs to ascertain the specifications and required quantity of drugs to be supplied to the districts. The DGMH is required to complete the process of RC for the next financial year in respect of all drugs by the end of the current financial year.

Audit, however, observed that coverage of drugs with RC was dismal because the DGMH concluded RCs in respect of only 08 to 36 *per cent* of the drugs in EDL (1036 drugs) during 2013-18, as shown in **Table 44.**

Table 44: Rate contracts in force during 2013-18

Year	Total no. of drugs in EDL	Number of NITs[138]	Number of drugs included in NITs	Number of drugs covered under RCs *(per cent)*	Shortfall *(per cent)*
2013-14	1036	Data not available		119	917 *(89)*
2014-15	1036	06	446	371	665 *(64)*
2015-16	1036	14	1032	333	703 *(68)*
2016-17	1036	23	958	83	953 *(92)*
2017-18	1036	36	1020	187	849 *(82)*

(Source: O/o DGMH)

Despite repeated requests, the DGMH did not make available the records in respect of technical and financial bidding and other related records, due to which reasons for execution of rate contracts for lesser number of drugs as compared to EDL could not be analysed. However, Audit test-checked 16 Notice Inviting Tenders (NITs) pertaining to 2013-18 and observed that none of the NITs were forwarded to Drug Manufacturing Associations (DMAs) and Drug Controllers of all States as was required in the DPP. Besides, in four cases, only 12 to 28 days were given to submit the NITs as against the minimum requirement of 30 days, thus depriving the prospective bidders of enough time to respond.

Thus, RCs for only 83 drugs (2016-17) to 371 drugs (2014-15) could be concluded during 2013-18 as depicted in **Table 44**.

The Government stated that due to many reasons, possibility of delay was expected. In respect of forwarding the NITs to drug manufacturing associations and drug controllers of all States as envisaged in DPP, it did not furnish a specific reply and stated that NITs were uploaded on the website through NIC[139] and stipulated rules were followed for the advertisement of tender process. Government further contended that desired documents and files related to rate contract were made available to Audit for evidence.

[138] NIT – Notice Inviting Tender
[139] National Informatics Centre

The reply is not acceptable, as despite request up to Principal Secretary, the records in respect of technical and financial bidding related to execution of rate contract were not provided to audit. Further, DGMH failed to adhere to the laid down provision of providing minimum 30 days to submit the bid in response to the NIT. As a result of low level of circulation of NITs and less time given to submit the bids, prospective bidders could not be drawn to participate in the bidding which ultimately led to a low coverage of drugs with RCs.

7.5.2. Capacity of bidder not analysed

DPP provides that while executing the RC, production capacity of manufacturing firms during the last three years is to be assessed.

Scrutiny of records, however, revealed that in all the 79 NITs issued during 2014-18 by DGMH, neither the details of capacity of the bidders were ascertained nor the quantity of drugs to be supplied by the bidders was mentioned. In the absence of these vital parameters, production capacity of the firms was not evaluated. Audit observed that in several cases, the contracted firms failed to supply the drugs to the districts, as discussed in paragraph 7.5.4. This was symptomatic of the distortion of the bidding process and its inability to effectively weed out firms that did not have the requisite production capacity.

The Government replied that certificate on the desired turnover and production capacity issued from the drug controller was obtained from the bidders along with the bids. The reply of the Government was not acceptable as in the 16 NITs, test-checked in audit, certificate regarding the production capacity of the bidders was not available on record. In respect of holding back mention of the quantity of drugs to be supplied by the bidders in the NITs, the Government did not furnish a reply.

7.5.3. Irregular procurement of drugs through local purchase

DPP stipulates that if drugs are not available in any RC and procurement is warranted in an emergency situation, the same could be procured from local vendors within the financial delegation of the indenting officer. To ascertain benchmark prices for local purchases (GoUP Order, 2000), CMOs and CMSs are to obtain wholesale rates from at least five manufacturing firms. The local purchases are to be made based on these benchmark prices.

Audit, however, observed that out of the total expenditure of ₹ 424.81 crore incurred on the procurement of drugs during 2013-18 in the sampled districts, drugs worth ₹ 133.02 crore (31 *per cent*) were procured by CMOs (number: 1790 drugs: cost: ₹ 36.77 crore) and CMSs (number: 4996 drugs; cost: ₹ 96.25 crore) during 2013-18 from local vendors ***(Appendix-VII).*** Local purchases of drugs were to be done in emergency situations only. Audit, however, did not find any evidence in the records of CMOs and CMSs in the sampled districts in respect of emergent requirements warranting such huge local purchases.

Further, CMOs and CMSs did not obtain rates from the five manufacturing firms, as stipulated in the Government Order (April 2000). Instead, they procured the drugs at the prices offered by the local vendors in tenders and/or quotations without ascertaining reasonableness of prices *vis-à-vis* benchmark prices. Besides, CMOs and CMSs in five out of the eight sampled districts procured 364 drugs costing ₹ 2.00 crore during 2014-18 from the local vendors though these drugs were available in the UPRCs or in the RCs of other State Governments at cheaper prices (₹ 1.17 crore).

Thus, drugs were locally purchased in an irregular manner and also without ascertaining reasonable prices.

The Government replied that local purchases are made under the Stores Purchase Rules of GoUP. The reply was not tenable as store purchase rules also stipulate that reasonableness of the quoted prices should be ascertained by the competent authority. However, CMOs and CMSs in the test-checked districts did not adopt the modalities prescribed in the Government order of April 2000 to ascertain the benchmark prices. Further, the Government did not furnish a reply in respect of documentation of requirements justifying such huge local purchases.

7.5.4. Delayed/non-supply of drugs

DPP and contract conditions stipulate that the contracted suppliers would supply the drugs to the concerned CMOs and CMSs within 30 days (15 days extendable) from the date of issue of supply order, failing which the suppliers would be liable to be imposed penalty by DGMH at the prescribed rate[140].

Scrutiny of records in the eight sampled districts[141] revealed that against 11,913 supply orders issued by the CMOs and CMSs of the concerned districts to RC firms, the firms supplied the drugs in respect of only 6,689 supply orders. Besides, in respect of 1261 supply orders, the firms supplied the drugs with delays ranging between 15 and 30 days.

Further, in none of the cases of non-supply/delayed supply of drugs was the DGMH intimated for levying penalty and taking penal action as per terms of the contracts, by the concerned CMOs and CMSs.

As several drugs were life-saving items, it was essential to have alternate suppliers available at all times. Hence, two or three RC firms were to be contracted for every drug so that in case of default of any firm, the supplies could be maintained from the other firms. It was observed in audit that for most of the drugs, only one firm was contracted and in case of default by the firm, there was no alternate firm that could be issued supply orders in order to maintain the supply chain.

[140] If the supply reaches the designated places between 5 PM of the 30th day and up to 60th day from the date of issue of the purchase order, a liquidated damage will be levied at 0.5 *per cent* per day for delayed supply up to a maximum of 15 *per cent* of the cost of supply.

[141] Records related to issue of indents to suppliers for supply of drugs were not maintained in DH Agra (2013-14), DH-II Allahabad (2013-18), DH and DWH Budaun (2013-18), DH Gorakhpur (2016-17), DH Lucknow (2013-18) and CMO Allahabad (2013-15); DH and DWH Allahabad (2013-15), CMO, DH, DWH and JH Balrampur (2013-18) and DWH Gorakhpur (2013-17) did not provide the related records.

The Government replied that delayed/non-supply of drugs against purchase orders were dealt as per the conditions mentioned in the RCs. It added that instances of non-compliance of the prescribed conditions were noticed in certain units and, thus, Divisional Additional Directors were instructed to enquire into the matter and fix responsibility.

7.6. Quality assurance of drugs

Quality control plays a major role in providing high quality drugs to the patients. DPP provides that in case, suppliers produce the quality test report issued by National Accreditation Board for Testing and Calibration Laboratories (NABL) along with the supplies, the same would be accepted. Besides, quality of drugs could also be checked through sampling by the Drug Controller (DC).

Audit observed that no provision for sampling norms, criteria and periodicity for testing of drugs for quality was provided in the DPP in the instance of absence of NABL certificates. The testing of drugs was observed to be minimal in audit given the context of non-existence of specific provisions for quality assurance. Audit examination of drugs costing ₹ 18.44 crore spent on purchase of 853 drugs from the contracted firms of DGMH in the sampled eight districts revealed that NABL certificates from the suppliers were obtained in respect of only 111 drugs (13 *per cent*), costing ₹ 1.58 crore. Accepting the drugs without obtaining the quality test reports from suppliers put patients at risk and was in contravention of the provisions of DPP.

Audit further observed that in the offices of the CMOs and CMSs of eight districts, the DCs took the samples of 429 drugs from the respective drug stores of the test-checked hospitals during 2013-18 for quality testing. It was, however, observed that the DCs submitted the test reports in respect of only 27 out of 429 sampled drugs[142]. Further examination of the test reports of the DCs disclosed that four drugs[143] in CMO Saharanpur, two drugs[144] in DH Gorakhpur, two drugs[145] in CMO Allahabad and two drugs[146] in DH-II Allahabad did not fulfil the labelling criteria rendering them unfit for consumption. However, these drugs were distributed to patients before receiving reports from the DCs.

Obtaining NABL quality test reports in respect of only 13 *per cent* drugs and minimal sampling by DCs indicated that drugs were distributed to patients without ensuring their quality.

Further, audit observed that there was no provision of quality assurance of drugs purchased locally in the DPP. Thus, drugs worth ₹ 133.02 crore were purchased locally without any quality assurance during 2013-18 by the CMOs of the sampled districts and the CMSs of the test-checked hospitals.

[142] DH Agra- 10, CMO Allahabad- 03, DH-II Allahabad- 02, DH Gorakhpur- 02, CMO Lucknow- 03 and CMO Saharanpur- 07
[143] Tab Salbutamol, Tab Chlorpheniramine maleate, Cap vitamin A & D (2014-15), Cap vitamin A & D (2015-16)
[144] Inj. Amikacin, Tab Fluconazole (2015-16)
[145] Tab Metronidazole, Tab Omeprazole 20 mg
[146] Tab Ciprofloxacin (2016-17), Inj Gentamycin (2017-18)

The Government replied that the Uttar Pradesh Medical Supplies Corporation Limited (UPMSCL) was in the process of establishing drug warehouses in every district and empanelment of 11 NABL laboratories for quality testing. After implementation of these initiatives, UPMSCL would effectively implement its drug quality policy. Government further added that the issue reported in the audit observation would be examined and necessary action would be taken to improve the drug management in hospital.

To sum up, *the Government was unsuccessful in providing an unbroken supply of essential drugs to the patients in public health facilities as per its own prescribed Essential Drug List. This would have led to significant out-of-pocket expenditure being forked out by the patients, especially the poor. The drug procurement process was riddled with systemic flaws and numerous instances of non-adherence to the Drug Procurement Policy/orders issued by the Government from time to time, consequently impacting the availability of quality drugs.*