

# 7 *Drug Management*

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 are discussed in the succeeding paragraphs.

## **7.1 Drug procurement management process**

To ensure the availability and accessibility of safe, effective, good quality essential medicines to the people through an efficient selection, procurement, supply and distribution and storage system at all levels of health care facilities in the State, GoJ promulgated the Jharkhand State Drug Policy (JSDP) in June 2004 containing the procurement procedures of drugs.

As per JSDP, a State level “State Medicines Selection and Procurement Committee (SMSPC)” was made responsible for sound management practices to ensure availability and accessibility of essential medicines through proper selection, efficient procurement, improved distribution, storage and inventory control systems and promotion of rational use. SMSPC was to function with two sub-committees<sup>81</sup> having the mandate to prepare the Essential Drugs List (EDL) and to conclude Rate Contracts (RCs) with the manufacturing firms for uninterrupted supply of drugs at a reasonable cost. CS-cum-CMOs are to issue supply orders on rates approved by the Committee to the contracted firms for supply of drugs as per requirement.

The Department partially modified (August 2015) JSDP and JMHPCL<sup>82</sup> was made responsible (in place of SMSPC) for centralised procurement of medicines and equipment on the basis of consolidated indent received from the Directorate. JMHPCL was to either procure medicines or to execute Rate Contracts with manufacturers based on which CS-cum-CMOs were to

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<sup>81</sup> (i) Medicine Selection Committee responsible for identification and preparation of separate essential medicine list for primary, secondary and tertiary healthcare; and (ii) Medicine Procurement Committee responsible for tendering process, analysing of drug firms and analysing rates for the selected medicines.

<sup>82</sup> Jharkhand Medical & Health Infrastructure Development & Procurement Corporation Limited (JMHPCL) is a corporation established (April 2013) under company act which is entrusted with the work of procurement and distribution of Medicines, Equipment and Basic Infrastructure for health facilities in Jharkhand.

purchase medicines for the hospitals. Drugs not covered by the Rate Contracts could be procured from firms having Rate Contracts with GoI or other State Governments for supply of drugs. Further, as per JSDP, if Rate Contract is not framed for a drug and procurement is warranted in an emergency situation, the same could be procured from local vendors by CS-cum-CMOs.

Audit observed that the drug procurement process was marred with systemic problems as well as non-adherence to the stipulated procedures viz., expiry of medicines due to delay in testing, non-adherence of quality assurance of drugs, non-availability of Essential Drugs etc., as discussed in the succeeding paragraphs.

### 7.1.1 Utilisation of funds for drug procurement

For procurement of drugs for all healthcare facilities including DHs, JMHDPCCL received State funds amounting to ₹ 100.31<sup>83</sup> crore during 2014-16 and NHM funds amounting to ₹ 51.43<sup>84</sup> crore during 2016-19. Additionally, the Department also released State funds to CS-cum-CMOs under the Head 2210, a part of which was utilised for procurement of drugs.

Audit observed that:

➤ JMHDPCCL spent only ₹ 12.46 crore out of ₹ 100.31 crore from the State funds during 2016-18 and refunded (June 2020) the balance amount of ₹ 87.85 crore (88 per cent) to the Department. Further, only ₹ 40.54 crore (79 per cent) was spent from NHM funds during 2016-19 and the balance of ₹ 12.24<sup>85</sup> crore including interest was lying in the bank account of JMHDPCCL.

➤ The Directorate provided indents of 213 drugs during 2015-16 and 2016-17 and 354 drugs during 2018-19 required for primary and secondary health care facilities to JMHDPCCL. However, JMHDPCCL finalised the Rate Contract for only 47 drugs/medicines in November 2016 and for 48 medicines in September 2017 which was stated to be due to non-participation of firms for all the tendered medicines and single tenders for some medicines despite re-tenders. As a result, JMHDPCCL could procure drugs worth only ₹ 12.46 crore from the State funds during 2016-18.

➤ An allotment of ₹ 10.62 crore was released to test-checked DHs by the Department for purchase of medicines during 2014-19. Out of this, expenditure of ₹ 10.35 crore was incurred on the procurement of medicines from the local vendors.

Thus, inadequate procurement and supply of medicines by JMHDPCCL compelled the CS-cum-CMOs to resort to purchase of medicines from the

<sup>83</sup> 2014-15: ₹ 60.31 crore and 2015-16: ₹ 40.00 crore

<sup>84</sup> 2016-17: ₹ 1.85 crore, 2017-18: ₹ 21.55 crore and 2018-19: ₹ 28.03 crore

<sup>85</sup> Unspent balance included interest of ₹ 1.34 crore.

local vendors in the test-checked DHs during the said period.

The Department did not furnish replies to the audit observations.

### 7.1.2 Expiry of medicines due to delay in testing

As per the terms and conditions of the contract<sup>86</sup>, the vendor supplies medicines with a quality certificate. Further, JMHPCL draws samples from the supplied medicines for quality testing through empanelled laboratories and after getting satisfactory results supply is deemed to be completed. The samples which do not meet quality standards render the relevant batches liable to be rejected.

Audit noticed that purchase order for supply of 24.71 lakh tablets of Amoxicillin with Potassium Clavulanate 625 mg valuing ₹ 1.11 crore was issued (March 2017) to a vendor. The vendor supplied (June 2017) 24.47 lakh tablets in five batches, bearing manufacturing date of May 2017 and expiry date of October 2018 along with the quality certificates.

As per the provision of the contract, JMHPCL got the sample tested from an empanelled laboratory<sup>87</sup> which found (27 July 2017) all the batches “not of standard quality”. JMHPCL, however, intimated (11 September 2017) the un-satisfactory test results to the vendor after a delay of 45 days. The vendor contested (September 2017) the test report and the samples of all five batches were sent (December 2017) to the Central Drug Laboratory (CDL), Kolkata for re-testing by JMHPCL again with a delay of three months. CDL, Kolkata declared (July 2018) all the five batches “standard quality”. Ultimately, only 6.08 lakh tablets with shelf life of remaining three months was issued to the districts and balance 18.39 lakh tablets valued at ₹ 82.40 lakh expired in October 2018 and was lying in the warehouse (June 2020).

Thus, inordinate delay by JMHPCL in meeting the quality test formalities led to expiry of medicines worth ₹ 82.40 lakh.

The Department did not furnish replies to the audit observations.

## 7.2 Quality assurance of drugs

Quality control plays a major role in providing high quality drugs to the patients. As per JSDP 2004, the State is to ensure quality control of medicines through testing at Government and private laboratories. Further, good manufacturing practices (GMP<sup>88</sup>) should be promoted and inspections of the manufacturing units should be conducted at the cost of suppliers. Besides, quality of drugs should also be checked through sampling by the

<sup>86</sup> Entered into between JMHPCL and M/s. Scott Edil Pharmacia Limited (the vendor).

<sup>87</sup> Multani Pharmaceuticals Limited (Analytical Division), Haridwar, Uttarakhand.

<sup>88</sup> GMP are the practices that provide minimum requirements that a manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their intended use.

Drug Controller (DC). Audit observed that:

➤ The JMHPCL had executed (October 2017) an agreement with a vendor<sup>89</sup> for supply of 13 medicines within 60 days from the date of purchase order. According to the provisions of the agreement (Clause 6.01), the supplier was required to submit test reports from the laboratories for each batch of the drug before supply to obtain dispatch clearance of drugs at the specified locations. Further, after receipt of the supply, samples of drugs from each batch might be taken for testing/ analysis by JMHPCL.

Audit noticed that JMHPCL issued (October 2017) purchase order to the vendor for supply of 2.06 lakh vials of injection of Cefotaxime Sodium (1000 mg) at district warehouses. However, the vendor without getting dispatch clearance from JMHPCL, supplied (between January and March 2018) 2.02 lakh vials of injections of three batches (CO43705, CO43706 and CO43707) at 22 districts. As such, the vendor did not ensure supply of quality drugs by submitting quality test reports. Subsequently, JMHPCL also did not ensure quality test of supplied the injections though supply was not supported by quality test reports and paid (August 2018) ₹ 58.45 lakh to the vendor in contravention to the contractual provision stated *ibid*.

➤ Audit further noticed that in the absence of centralised purchase of medicines by JMHPCL, test-checked DHs procured medicines from local vendors which were not found supported with quality test reports and thus mechanism of quality testing before supply of drugs was compromised.

The Department accepted (January 2021) the facts in respect of DH, Hazaribag and stated that necessary quality assurance would be obtained from the empaneled laboratories from time to time. No replies were furnished in respect of other test-checked DHs.

➤ Audit noticed delays in submitting test reports of samples collected by the Drug Inspectors (DI) out of medicines available with test-checked DHs during 2014-19 as depicted in **Table 7.1**.

**Table 7.1: Details of samples collected and reported by DI**

Name of DH	Number of samples collected	Number of test reports received	Number of test reports pending
Deoghar	9	8	1
East Singhbhum	2	0	2
Hazaribag	10	7	3
Palamu	Records not available		
Ramgarh	18	11	7
Ranchi	30	22	8
<b>Total</b>	<b>69</b>	<b>48</b>	<b>21</b>

(Source: Test-checked DHs)

<sup>89</sup> M/s. Bengal Chemicals and Pharmaceuticals Limited, Kolkata (Public Sector Undertaking of the Government of India)

From **Table 7.1**, it can be seen that test reports of 21 samples collected between July 2014 and February 2019 were awaited as of March 2020.

➤ CS-cum-CMO issued (between 25 July 2018 and 23 January 2019) 17,500 vials of Dexamethasone Sodium Phosphate (Dexona) 2 ml injections to DH, Deoghar. The Drug Inspector, Deoghar collected (30 July 2018) samples of the injection of the same batch from the store of CS-cum-CMO which were found (8 March 2019) spurious by the Regional Drug Testing Laboratory, Guwahati. The samples were re-tested by CDL, Kolkata on the orders of the Civil Court, Deoghar and were again found (11 September 2019) 'not of standard quality'.

However, it was noticed that 4,185 out of 17,500 vials of injections were issued (28 July 2018 to 12 March 2019) to different wards from the store of DH, Deoghar and were administered to patients till March 2019. Audit further noticed that 309 vials were administered (between 12 March and 31 March 2019) even after the injection was detected as spurious by the Regional Drug Testing Laboratory, Guwahati as intimated (12 March 2019) by the Drug Inspector, Deoghar. The injection was further declared 'Sub-standard' by the Central Drug Laboratory, Kolkata on 11 September 2019.

The Department did not furnish replies to the audit observations.

➤ In DH, Ramgarh, Acyclovir 200 mg tablet (Batch T-15818), supplied (31 August 2018) through JMHPCL, was reported (15 March 2019) as 'not of standard quality' by the State Drug Testing Laboratory, Jharkhand. However, 140 out of supplied 5,000 tablets of the same batch were distributed (between 23 November 2018 and 27 March 2019) to OPD patients and remaining 4,860 tablets were lying in store as of February 2020.

The Department did not furnish replies to the audit observation.

➤ In DH, Ramgarh, 410 doses of hepatitis-B vaccines with shelf life up to October 2018 were administered to children between November 2018 and January 2019.

In reply, the Deputy Superintendent, DH, Ramgarh stated that wrong expiry date was recorded by mistake in the vaccine stock register. The reply is not acceptable as the same expiry date (October 2018) of the vaccine with the same batch number was also found recorded in the stock register of DH, East Singhbhum.

The Department did not furnish replies to the audit observation.

Thus, quality of medicines were not ensured during procurement as required and instances of spurious or expired medicines being administered to patients were noticed.

### 7.3 Availability of Essential Drugs

Audit observed that the EDL as prepared by the Directorate in February 2017 contained 367 drugs. Audit compared the availability of drugs in the test-checked DHs with the EDL during 2017-19 as detailed in **Table 7.2**.

**Table 7.2: Availability of drugs against EDLs**

Sl. No.	Name of DH	2017-18			2018-19		
		Number of drugs in EDL	Number of drugs available	Percentage of availability	Number of drugs in EDL	Number of drugs available	Percentage of availability
1	Deoghar	367	85	23	367	86	23
2	East Singhbhum	367	79	22	367	52	14
3	Hazaribag	367	42	11	367	41	11
4	Palamu	367	45	12	367	51	14
5	Ramgarh	367	52	14	367	56	15
6	Ranchi	367	69	19	367	70	20

(Source: Test-checked DHs)

It can be seen from **Table 7.2** that only 11 to 23 *per cent* of essential drugs were available with the test-checked DHs during 2017-19. Further, the available drugs was out of stock for a considerable period due to less procurement of drugs as compared to the requirement by CS cum CMOs as illustrated in **Table 7.3**.

**Table 7.3: Stock out of drugs**

Year	Name of DHs	Number of medicines available	Number of medicines test-checked by Audit	Total number of out of stock medicine	Stock out position (in days)			
					1-30	31-60	61-120	more than 120
2017-18	Deoghar	85	74	49	4	11	7	27
	East Singhbhum	79	37	37	1	11	8	17
	Hazaribag	42	42	21	1	3	7	10
	Palamu	45	45	21	0	0	0	21
	Ranchi	69	22	22	0	1	0	21
2018-19	Deoghar	86	72	52	16	8	15	13
	East Singhbhum	52	32	32	8	3	5	16
	Hazaribag	41	41	18	0	2	4	12
	Palamu	51	45	21	0	2	2	17
	Ranchi	70	31	28	0	2	0	26
	<b>Total</b>	<b>620</b>	<b>441</b>	<b>301</b>	<b>30</b>	<b>43</b>	<b>48</b>	<b>180</b>

(Source: Test-checked DHs)

It can be seen from **Table 7.3**, that out of the test-checked 441 essential drugs, 180 drugs (41 *per cent*) remained out of stock for more than 120 days during 2017-19 in five test-checked DHs. In DH, Ramgarh, Audit could not assess availability of essential drugs as the central stock register was not maintained.

Thus, either due to non-procurement of 77 to 89 *per cent* of essential drugs (Table 7.2) or less procurement of 11 to 23 *per cent* of drugs which also included vital drugs required for OT, ICU, Emergency and Maternity services, objective of efficient and affordable health services to needy was not ensured as discussed in **Chapters 4 and 5**.

The Department did not furnish replies to the audit observations.

#### 7.4 Storage of drugs

Jharkhand State Drug Policy, 2004 prescribes that an appropriate system of storage and stock management for medicine is to be established for adequate stocking of drugs. Further, the Drugs and Cosmetic Rules, 1945 stipulates parameters for the storage of drugs in stores to maintain the efficacy of the procured drugs before being issued to patients.

Audit noticed non-adherence to the prescribed norms and parameters (*Appendix 7.1*) by the test-checked DHs as given in **Table 7.4**.

**Table 7.4: Deficiencies in storage of drugs**

Sl. No.	Parameters	Number of test-checked DHs having deficiencies	Probable impact of not adhering to parameters
1	Air-conditioned pharmacy	5	Loss of efficacy and shelf life of drugs
2	Labelled shelves/racks	2	High Turn Over time in the disbursement of drugs
3	Away from water and heat	3	Loss of efficacy and shelf life of drugs
4	Display instructions for storage of vaccines	3	
5	Functional temperature monitoring device in freezers	1*	
6	Drugs kept under lock and key	3	Misuse of costly drugs
7	Poisons kept in a locked cupboard	4**	Unauthorised access to the dangerous drugs

\* Information not furnished by DH, Hazaribag

\*\* Information not furnished by DH, East Singhbhum

(Source: Test-checked DHs)

It is evident from **Table 7.4** that test-checked DHs were not adhering to norms in storage of drugs which were directly linked with loss of efficacy and shelf life of drugs. Prescribed safety norms were also not followed for storage of dangerous drugs. Thus, storage management of the drugs was deficient due to which reduction in efficacy of drugs cannot be ruled out.

The Department accepted the facts in respect of DH Palamu and stated that steps would be taken for proper storage of the drugs. No replies were furnished in respect of the other DHs.

*To sum up, drug procurement process was riddled with systemic flaws and instances of non-adherence to the Drug Procurement Policy which consequently impacted the availability of quality drugs. Essential drugs were not available with the test-checked DHs.*