Department of Health and Family Welfare

4.2 Deficiencies in quality assurance while procuring and distributing drugs

Poor quality assurance by the Karnataka State Drugs Logistics and Warehousing Society resulted in distribution of non-standard quality drugs. Besides, the Society did not recover ₹2.11 crore being the cost of these non-standard quality drugs.

The Karnataka State Drugs Logistics and Warehousing Society (Society) was established (2003) with the main objective of establishing an efficient, cost effective and decentralised Drug Logistics and Warehousing System in the State. The Society was procuring drugs, chemicals and miscellaneous items for use in various health institutions of the State. The procurement was through Rate Contracts (RCs) which were finalised from time to time through tender process. During 2014-15 to 2016-17, the Society procured 14,209 batches of 1,110 different drugs for ₹535.22 crore. On scrutiny of records, we observed the following:

(i) Shortfall in testing of drugs procured

In order to ensure quality of the drugs procured, the RCs of the Society for supply of drugs envisaged that the purchaser shall test each batch or batches selected at random from the consignment, either at the time of receiving the goods or at any time during the shelf life of the product, at any laboratory approved under the Drugs and Cosmetics Act, 1940, and Rules apart from the routine sampling that might be carried out by the Drugs Controller and Regulatory authorities. Since the drugs were to have active ingredients as per the specifications throughout the shelf life, the samples were to be drawn periodically throughout the shelf life. An amount equivalent to 0.5 *per cent* of the cost of drugs supplied was to be deducted from the bills at the time of payment. The Society empaneled four[46] laboratories to conduct the required number of quality tests.

The details of drugs procured and tested by the Society during 2014-15 to 2016-17 are indicated in **Table-4.4**.

Table-4.4: Details of batches of drugs procured and tested by the Society during 2014-15 to 2016-17

Sl. No.		2014-15	2015-16	2016-17	Total
1.	Batches of Drugs procured by Society	5,872	3,745	4,592	14,209
2.	Samples sent for testing	2,263	2,532	1,981	6,776
3.	Samples declared NSQ* by Society	15	4	8	27
4.	Samples declared NSQ by Drugs Controller	18	40	19	77

* Not of standard quality

[46] Standard Laboratories-Delhi; PRK Pharma Analysts-Hyderabad, Delhi Test House-Delhi, and Ozone Laboratories-Delhi.

In this regard, we observed the following:

- From the table, it was evident that out of 14,209 batches required to be tested during 2014-15 to 2016-17, only 6,776 batches of drugs (48 *per cent*) were tested. Thus, 7,433 batches of drugs were supplied to patients without testing/quality assurance.
- Out of 6,776 batches of drugs, which were tested, 27 batches of drugs worth ₹1.23 crore were declared by Society as Not of Standard Quality (NSQ).
- In addition, during 2014-15 to 2016-17, the State Drugs Controller had also declared 77 batches of drugs worth ₹4.08 crore drawn randomly from the warehouses of the Society as NSQ. This included 19 batches of drugs worth ₹0.55 crore, which were declared as Standard Quality by the empaneled laboratories of the Society. Thus, there was variance between the reports of empaneled laboratories of the Society and the State Drugs Controller.

(ii) Inordinate delay in communication of NSQ drugs to warehouses/ hospitals

Prompt communication with hospitals and warehouses is necessary to ensure that NSQ drugs are not issued to patients. However, we noticed delay while communicating NSQ details to the warehouses/hospitals as detailed in **Table-4.5** below:

Table-4.5: Delay in communication of NSQ by the Society

Delay (in days)	Number of cases
8-15	13
16-30	17
31-45	08
46-60	05
61-100	06
More than 100	01
Total	**50**

(iii) Non- replacement of drugs

As per the conditions of contract, the entire batch of any drug declared as NSQ during testing by the Society or by the Drugs Controller or by any other authority should be replaced by the suppliers irrespective of the quantity available in stock within 30 days from the date of receipt of communication. In case of default, the Society had to forfeit the Security Deposit (SD) furnished by the supplier and in respect of other damages, the Society was to take action under the existing laws to recover such loss and to blacklist the supplier. In addition, an amount equivalent to 0.5 *per cent* of the cost of batch of drugs declared as NSQ shall be recovered from the Contractor towards the expenses for its destruction.

In this regard, we observed the following:

- Out of 104 batches of drugs declared as NSQ, the drugs in respect of 12 batches were replaced. Out of balance 92 batches, recovery of loss in

respect of 73 batches of drugs which amounts to ₹4.86 crore (including cost of destruction) is yet to be made.

- Further, action was not initiated by the Society to adjust SD furnished by the suppliers in respect of 73 batches of drugs declared as NSQ. SD amount available with Society in respect of the said drugs work out to ₹0.24 crore.
- Out of 20 companies, whose drugs were declared as NSQ, four companies were blacklisted by the Society/other States. Hence, recovery of ₹69.33 lakh[47] was doubtful since the amount to be recovered was more than SD furnished by respective companies to this extent.

(iv) Blacklisting of defaulting contractors

As per the contract, if two or more than two products of a firm failed in the quality tests, then that firm was to be black listed. Further, the contractor and his establishment blacklisted by the Society or any State/Central Government will not be eligible to participate in any of the departmental tenders for subsequent five years.

During 2014-15 to 2016-17, we observed that though two or more than two drugs were declared NSQ in respect of 16 suppliers, the Society black listed only two[48] suppliers.

Thus, due to poor quality assurance by the Society, low quality drugs were not withdrawn from distribution even after they were declared as NSQ. Besides, due to poor recovery mechanism, the Society failed to recover ₹4.86 crore being the cost of these NSQ drugs.

In reply, the Government stated (September 2017) the following:

- From 2015 onwards, the successful bidders were to provide National Accreditation Board for Testing and Calibration Laboratories (NABL) report and analytical report of their own laboratory for every batch of drugs at the time of supply of consignment.

  The reply is partially acceptable. Though the system put in place had reduced the number of cases of NSQ, the ideal number should have been nil. However, it was observed that there still persisted few cases of NSQ after 2015. The Society needs to institutionalise a mechanism to address such cases.

- Due to improper storage and other related matters, drugs which were randomly drawn by the Drugs Controlling Authority failed quality tests even though they were declared as standard quality earlier by the Society.

  This indicates that the storage of drugs was poor as during 2014-15 to 2016-17, 19 batches of drugs were declared NSQ by Drugs Controller when these were declared as standard quality by Society. Thus, the Government needs to improve storage facilities.

[47] M/S.SGS Pharma-₹15.40 lakh, M/S.Mino Pharma-₹23.02 lakh, M/S.Jackson Laboratories-₹30.91 lakh, M/S.Zee Laboratories-Nil.

[48] M/S.SGS Pharma and M/S.Mino Pharma Laboratories Limited.

- While ₹2.75 crore out of ₹4.86 crore was recovered from the suppliers for issuing NSQ drugs, ₹1.26 crore would be recovered from security deposit amount of the suppliers.

  Action needs to be taken on priority to recover the said amount through SD.

- Details of NSQ drugs were forwarded immediately to all warehouses to stop usage of NSQ drugs.

  Since, there existed delay in communicating details of NSQ drugs, as already discussed, the process needs to be streamlined.

4.3 Avoidable expenditure

Karnataka State Drugs Logistics and Warehousing Society failed to insert specific clause in the tender/contract document for availing concession on Central Excise Duty. This resulted in avoidable expenditure of ₹76.55 lakh towards purchase of ambulances.

Notification No.12/2012-Central Excise dated 17 March 2012 of the Central Excise Department, Government of India, provide that excise duty on a motor vehicle registered solely for use as an ambulance shall attract a concessional duty of 12 *per cent.* Subsequently, it revised the concessional duty to eight *per cent* vide notification No.4/2014-Central excise dated 17 February 2014. Further, condition No.26 of the Notification dated 17 March 2012 provides for refund of excess duty paid on these vehicles as prescribed in the first and second schedules, which shall be refunded to the buyer through the manufacturer. The benefit of refund was available subject to production of a certificate within six months (including three months extension, which could be provided by the competent Excise Officer) from an officer authorised by the concerned State Transport Authority, to the effect that the said motor vehicle was registered for sole use as an ambulance.

Karnataka State Drugs Logistics and Warehousing Society (Society), responsible for procurement of drugs, chemicals and medical equipment for the Institutes under the Department of Health and Family Welfare, procured 398 ambulances during 2012-13 and 2013-14 under National Rural Health Mission scheme. The details of procurement are as indicated in **Table-4.6**.

Table-4.6: Details of procurement of ambulances

Sl. No.	Date of purchase order	Name of Supplier	Number of ambulances	Amount (in ₹crore)	Mode of Purchase
1	19 March 2013	Tata Motors Limited (Tata Winger)	200	12.99	DGS&D Rate Contract
2	7 May 2014	Khivraj Motors* (Force Traveler)	198	29.70	Tender
	Total		**398**	**42.69**	

*Authorised dealer of M/s Force Motors Limited, Pune

In order to avail the benefit of exemption on Central Excise Duty (CED), a specific clause was to be inserted in the tender/contract document by the