The matter was referred (May 2018) to State Government and further reminder was issued in July 2018; their reply was awaited (May 2019).

Food and Drug Administration Department

3.5 Irregularities in collection of samples and laboratory analysis of medicines

A large number of licencees remained unchecked; sample analysis reports were issued late and where sample was found not of standard quality, action for recalling and issuing alert was initiated with inordinate delay. Destruction of substandard drugs was not monitored and subsequent batches were not checked. Risk of manufacturing, distribution and sale of substandard drugs was high with serious implications for health and even lives of general public.

The Government of Haryana established the Department of Food and Drug Administration in January 2011 for implementing Drugs and Cosmetics Act 1940 (the Act) and Rules (the Rules) framed thereunder to regulate the manufacturing, distribution and sale of drugs and cosmetics in the State and for ensuring that the quality drugs are made available to the people. The department enforces aforesaid Acts and Rules through (a) licensing and inspections of drug manufacturing units, blood banks and sale premises (b) drawal and testing of samples and (c) initiating recall of drugs declared as "Not of Standard Quality" (NSQ) and prosecuting offenders.

The Department is headed by State Drug Controller who is assisted by seven Senior Drug Control Officers (Sr. DCOs) and 18 Drug Control Officers (DCOs), against the sanctioned posts of 10 Sr. DCOs and 46 DCOs, respectively. The Department has only one drug testing laboratory at Chandigarh. Test check of records of DCOs Kurukshetra, Ambala and Panchkula for the period 2014-17 revealed the following:

3.5.1 Non-fixation of targets for sample collection

The department had not fixed targets for collection of samples by DCOs under Section 23 of the Act. It was found that out of total 1,846 licencee units in three test-checked districts, 1,244 samples from 314 units (17 *per cent*) only, were collected during 2014-17 as detailed in **Table 3.2**. Thus, 1,532 licencees (83 *per cent*) remained unchecked which was fraught with the risk of manufacturing, distribution and sale of substandard drugs and cosmetics in the State.

Table 3.2: Detail of coverage of licencee units and samples taken

District	Total licencee units	Total units covered	Coverage percentage	Sample taken
Ambala	591	103	17	483
Panchkula	733	150	20	451
Kurukshetra	522	61[24]	12	310
Total	**1,846**	**314**	**17**	**1,244**

(Source: Data compiled from information provided by the Department)

3.5.2 Delay in 'Reports of Analysis'

The quality of drug samples drawn by the DCOs were required to be analysed at the drug testing laboratory, Chandigarh. Initially, no time limit was prescribed in the rules for issuing report of analysis. In January 2017, a time limit of 60 days from the date of receipt of the sample was prescribed. There was delay in issuance of Reports of Analysis (RA) of 1,174 samples as given in **Table 3.3**.

Table 3.3: Detail of delay in issuance of report of analysis

Time period	Number of RAs received	Percentage of total samples
Within two months	70	5.63
Between two months and six months	197	15.84
Between six months and 12 months	300	24.12
Between 12 months and 24 months	340	27.33
After 24 months	25	2.00
RA still awaited (March 2018)	312	25.08
Total	**1,244**	

(Source: Data compiled from information provided by the department)

312 samples for which RA were not received as of March 2018 also included samples drawn in April 2014. Year-wise detail of samples for which RAs were awaited is given in **Table 3.4.**

Table 3.4: Detail of samples for which reports of analysis were awaited

	Samples for which RAs were awaited			
Year	**DCO Ambala**	**DCO Panchkula**	**DCO Kurukshetra**	**Total**
2014	3	6	-	9
2015	2	13	18	33
2016	63	73	22	158
2017	15	-	8	23
Date not mentioned in the register	-	-	89	89
Total	**83**	**92**	**137**	**312**

(Source: Data compiled from information provided by the department)

[24] In 37 samples, name of the licencee unit was not mentioned in the register being maintained by the Department.

It was noticed that four samples were declared NSQ in LNJP Hospital, Kurukshetra but due to delay in testing of sample and issuance of RA the drugs were consumed as depicted in **Table 3.5.**

Table 3.5: Detail of drugs consumed due to delay in reports of analysis

Drug	Azithromycin	Nephacorate (Prednisolan)	Pcm Oral Sus	Pheytion Sodium
Date of Sample	26-02-15	27-04-15	18-01-17	27-04-15
Date of issuance of test report	10-05-16	29-10-15	22-09-17	29-10-15
Delay in RA (In Days)	439	185	247	185
Quantity Received	30,000	12,300	1,000	14,730
Consumed Till RA received	30,000	3,100	491	2,070
Balance	0	9,200	509	12,660

(Source: Data compiled from information provided by the department)

Had the results of sample analysis been declared within reasonable time limit, the consumption of NSQ drugs could have been avoided. This was fraught with serious risk to health/life of patients.

In reply to the audit observation, the State Drug Controller stated (April 2018) that instructions had been issued for clearing the back log of sample analysis and measures were being taken for upgradation of laboratory. **Issuance of quality drugs is a highly critical issue. The department should have taken necessary action for ensuring this. However, it issued necessary instructions for clearing backlog of sample analysis only at the instance of audit.**

3.5.3 Delay in recall and rapid alert where sample found not of standard quality

As per Central Drug Standard Control Organisation (CDSCO) guidelines, safety alerts were to be issued to DCOs and general public for stoppage of sale and consumption of NSQ drugs. As per the guidelines, action was required to be taken immediately within 24 hours to 30 days as per categorisation of NSQ drugs[25]. Audit observed that no categorisation of NSQ drugs was done by the Department. A detailed analysis of 12 NSQs (04 from each district) out of total 25 NSQs showed huge delays in recalling and issuing rapid alert by DCOs Kurukshetra, Ambala and Panchkula.

- The DCOs had not categorised the NSQ drugs for issuing rapid safety alerts and recalling the harmful drugs for preventing serious adverse health effects.

[25] Class I recall – 24 hours to 72 hours – where probability is of serious adverse health consequences; Class II recall – within 10 days – where probability is of temporary adverse health consequences; Class III recall – within 30 days – where probability is not likely to cause adverse health consequences.

- Out of 12 samples, in 6 cases, action was initiated after 30 days. In one case, action was initiated after 275 days. Such delay in taking action was fraught with the risk of consumption of substandard drugs by public and was tantamount to playing with lives of general public.

- The department had not checked subsequent batches of drugs despite this being mandatory as per the guidelines. In two cases, the State Government of Himachal Pradesh had suspended product licences of manufacturers for 15 and 60 days on the basis of alerts issued by the Department. But subsequent batches of these manufacturers were not checked for quality assurance.

- The State Drug Control Officer had not informed the zonal offices of CDSCO regarding NSQ drugs for alerts in violation of the provisions of para 4.2 of CDSCO guidelines.

In reply to the audit observation, the State Drug Controller stated (April 2018) that all the DCOs were being informed about the NSQ drugs on receipt of such report for issuing notices to the manufacturers of these drugs. Further, NSQ drugs were destroyed by manufacturers and traders. However, the Department did not exercise adequate internal checks for having an assurance that NSQ drugs are not issued.

3.5.4 Licensing of manufacturing units and blood banks

Licence for the manufacture and sale of Allopathic and Homeopathic drugs and establishment of blood bank is required under the provisions of Drugs and Cosmetics Act-1940. For issuance of licence, the premises are jointly inspected by Central and State inspectors.

In the State, there were 219 manufacturing units of drugs, 72 blood banks and 115 manufacturing units of cosmetics. During 2014 to 2017, 15 licences were issued in the three test checked districts viz Ambala, Panchkula and Kurukshetra. **These 15 licences were issued in the time range of 13 to 323 days from the date of application for issue of licence.**

The Department (October 2018) stated that the delay had occurred due to non-compliance to observation raised during inspection and it needs to be noted that now cases are being disposed within 45 days. However, the department had taken up to 152 days for conducting inspection. Only after January 2018, all cases are being disposed within 45 days, which needs to continue.

Thus, out of a total of 1,846 licencee units in three test checked districts, samples were collected from only 314 units (17 *per cent*) during 2014-17 and 1,532 licencee (83 *per cent*) remained unchecked. No targets were fixed for

collection of samples, thus, rendering the procedure risk prone at the very outset. There was inordinate delay in issuing analysis reports of the collected samples. Analysis reports had not been issued for 312 samples so far (March 2018) which also included samples drawn in April 2014. The State Drug Controller and DCOs initiated action very late for the drugs declared 'not of standard quality' and had not checked subsequent batches. The NSQ drugs were not categorised for ensuring timely recall and issuing rapid safety alerts. This is fraught with the risk of issuing sub-standard drugs and has serious implications for health of the people. The department had not kept a record for ensuring that the NSQ drugs were destroyed by the traders and manufacturers. The working of the department left much to be desired and there were huge gaps in compliance of requisite instructions.

The matter was referred to Government in May 2018 and further reminder was issued in July 2018; their reply was awaited (May 2019).

Health Department

3.6 Procurement and Utilisation of Medicines and Medical Equipment

There were shortcomings in procurement of medicines and equipment such as delay in processing of the indents, award of rate contract to ineligible firms, inadequate price comparison leading to extra expenditure of ₹ 1.25 crore and non-levy of penalty of ₹ 1.09 crore for non-supply of medicines. Availability of medicines at medical facilities was inadequate. Procedure followed for local purchase of medicines was not uniform and lacked transparency. Further, equipment worth ₹ 1.81 crore were lying unutilised at facilities.

3.6.1 Introduction

The State Government approved Medicine Procurement and Management Policy 2012 with the objective of providing uninterrupted access to essential medicines of good quality in all Government Institutions through efficient supply chain management practices. The State Government established (January 2014) Haryana Medical Services Corporation Limited (HMSCL) for purchase of drugs, consumables and equipment (including installation and maintenance) for all District Hospitals (DHs), Sub Division Hospitals (SDHs), Community Health Centres (CHCs), Primary Health Centres (PHCs), Medical Colleges and other dispensaries. HMSCL operates "Online Drug Inventory and Supply Chain Management System". Field units make online demand for medicines through this system on the basis of which HMSCL procures medicines. In case HMSCL is unable to supply the medicines and consumables, the hospitals are allowed to