CHAPTER - II

CHAPTER II

PERFORMANCE AUDITS

Medical Education and Drugs Department

2.1 Food and Drugs Administration

Executive Summary

The Food and Drugs Administration (FDA) functions under the administrative control of Medical Education and Drugs Department (MEDD) in Maharashtra State. It is responsible for implementation of Food Safety and Standards (FSS) Act and Drugs and Cosmetics (D&C) Act as well as other Acts, Rules and orders designed to safeguard public health and to ensure quality of Drugs, Cosmetics and Food. FDA carries out important regulatory functions of granting and renewing license for drugs issued to the manufacturer/sellers in the State, investigates complaints regarding quality and overpricing of drugs, carries out inspections of the drug manufacturing and selling units, draws and tests samples of food and drugs so as to ensure quality as per standards. The FDA is also required to take legal action against the offenders.

The Performance Audit on 'Food and Drugs Administration' covered test-check of records for the period 2012-2017.

Some of the serious deficiencies noticed are as follows:

- **State Level Steering Committee required to be set up under the Food Safety and Standards Regulation, 2011 met only twice during 2012-17. Out of 30 district offices, four meetings each were held in Pune and Nanded between August 2013 and June 2017, while, in the remaining 28 district offices, District Level Steering Committee did not meet even once during 2012-17.**
- **No survey was undertaken to develop a database on Food Business Operators (FBOs). Central Advisory Committee estimated 16.86 lakh FBOs in the State of which only 9.43 lakh (56 *per cent*) were registered/licensed as of March 2017.**
- **There was shortfall of 37 *per cent* in the post of Drug Inspectors who are key personnel for effective enforcement of provisions made under different Acts for Drugs control. There was wide variation in the workload of the Drug Inspectors due to uneven distribution of Drug Inspectors among the seven Divisions in State.**
- **FDA had failed to take action to cancel the licenses of 1,535 Drug selling units whose licenses had expired, thereby posing a risk to public health by the possible sale of drugs by such units.**
- **The renewal of Drug licenses was done without inspection of the premises of the Drug selling units and thereby the requirement of adequate physical infrastructure was not ensured before grant of licenses. Inspection/survey was not done to verify that the Drug**

selling/manufacturing units were not involved in any activities during the suspension period.

- **There were serious shortfalls in the inspection of FBOs, Drugs manufacturing and selling units. The shortfall was to the extent of 35 *per cent* in the case of Drugs manufacturing units and 63 *per cent* in the case of selling units.**
- **Sampling to ensure quality showed serious deficiencies.**
  - **Samples of infant food, instant milk substitutes, meat and fish products, fruits and vegetables were not taken for testing.**
  - **Microbiological tests for food samples were not carried out as there was no microbiological division and thus, pathogenic bacteria, yeast and mould could not be tested raising serious food safety concerns. Tests to analyse the contents of metals, toxic substance and insecticides articles were also not being done due to non-availability of requisite equipment.**
  - **'Gap Analysis Report' of October 2013 based on study carried out by the FDA, brought to the fore issues relating to infrastructure, equipment, man-power in food laboratories but the Department did not initiate any action till November 2017. Of the three Food Testing Laboratories (FTLs) test-checked in audit, FTL at Mumbai only was found functional resulting in dependence on the Public Health Laboratories for testing of food samples drawn by FSOs.**
  - **Test Reports issued by Food analysts of eight selected districts, contained disclaimers stating that toxin, contaminants, residue and most of the additives were not checked.**
  - **The DCLs at Aurangabad and Mumbai issued 2,026 test reports during 2012-17, without expressing any opinion on the samples of drugs tested. Test reports on the drugs tested were issued after 90 days from the date of receipt of sample in the DCLs, in 10,501 (40 *per cent*) samples tested.**
  - **The DCLs in Aurangabad and Nagpur did not have facilities to conduct microbiological test on drugs and cosmetics and as a result all the samples were being sent to DCL, Mumbai, where they were unable to cope with the volume of work. Opportunity to strengthen and upgrade the DCLs by purchasing various modern equipment was lost despite availability of funds due to non-receipt of approvals from MEDD/Finance Department to the purchase proposals of the FDA.**
- **The delay in recalling Not of Standard Quality (NSQ) drugs resulted in consumption of the NSQ drugs by the public. In 95 (25 *per cent*) out of 375 cases scrutinised in audit, more than 50 *per cent* of the NSQ drugs were already consumed before they were recalled. Of this, in 61 cases, the entire stocks of NSQ drugs were consumed and therefore could not be recalled.**

- **The monitoring mechanism in the Department was weak in view of absence of periodical reports on various key issues as also deficiencies in the reports submitted to the Commissioner, FDA.**

The deficiencies identified above clearly indicate the failure of the Medical Education and Drugs Department in ensuring that the food consumed by the Public is of standard quality. Further, even the quality of drugs supplied is not ensured due to inadequate testing and failure to follow-up effectively.

This can have serious consequences for the health and welfare of the public.

2.1.1 Introduction

The Food and Drugs Administration (FDA) functions under the administrative control of Medical Education and Drugs Department (MEDD) in Maharashtra. It is responsible for implementation of Food Safety and Standards (FSS) Act and Drugs and Cosmetics (D&C) Act as well as other Acts, Rules and orders designed to safeguard public health and to ensure quality of Drugs, Cosmetics and Food. The Headquarters of FDA, headed by the Commissioner, is in Mumbai.

The Commissioner, FDA is assisted by 18[1] Joint Commissioners who are assisted by Assistant Commissioners (ACs)/Designated Officers[2] and Food Safety Officers[3] (FSOs). The district offices are headed by ACs[4]. In addition, three Drug Control Laboratories (DCLs) function at Aurangabad, Mumbai and Nagpur headed by Assistant Directors (except DCL, Nagpur where no posts are sanctioned) in which, testing of food and drug samples is carried out. The testing of food samples is also done at 15 laboratories under the control of the Public Health Department (PHD). An organogram of FDA is shown in **Chart 1**.

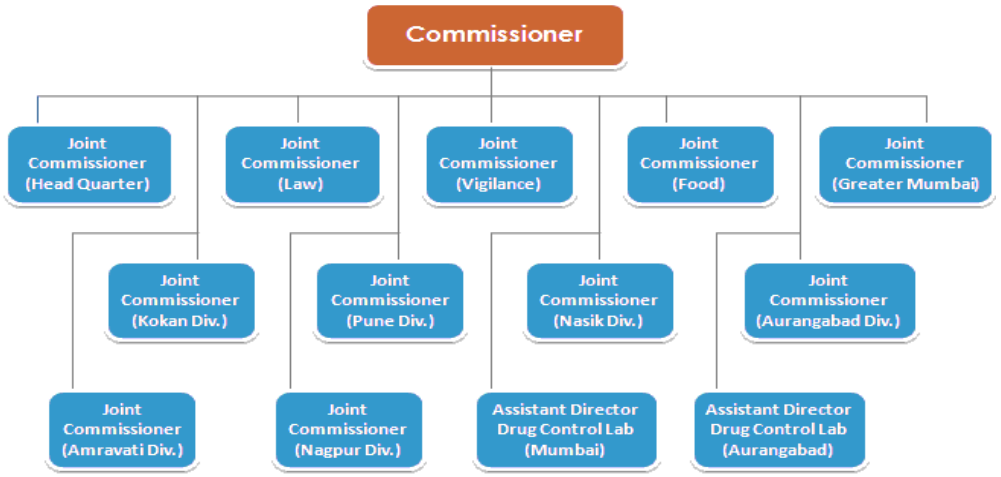
[1] Four (Joint Commissioner, Food; Joint Commissioner, Law; Joint Commissioner, Vigilance and Joint Commissioner, Headquarters at FDA headquarters) and 14 at Divisional headquarters (One Joint Commissioner each for Food and for Drugs at Amravati, Aurangabad, Greater Mumbai, Nagpur, Nashik, Pune and Thane/Kokan)

[2] An officer appointed under Section 36 of the Act who is in-charge of food safety administration and responsible for issuing of licenses to Food Business Operators (FBOs) in districts

[3] An officer appointed under Section 37 of the Act who is responsible for issuing of registration certificates to petty FBOs in the assigned local areas

[4] Except at Divisional headquarters and newly created Gondia, Hingoli, Nandurbar, Palghar and Washim districts

Chart 1: Organogram of Food and Drug Administration of Maharashtra



Source: Information furnished by the Commissioner, FDA

2.1.2 Audit objectives

The broad objectives of the Performance Audit were to assess whether:

- regulatory and Administrative mechanism was in place for implementation of the relevant Acts and Rules;
- requisite infrastructure and resources were available;
- effective mechanism was in place for creating awareness amongst consumers about substandard food, drugs and cosmetics and for grievance redressals; and
- monitoring and evaluation functions were effective in the implementation of relevant Acts/Rules.

2.1.3 Audit criteria

In order to achieve the audit objectives, the following audit criteria were adopted:

- The Drugs and Cosmetics Act, 1940 and Rules, 1945;
- The Drugs (Prices Control) Order, 1995 and 2013;
- Food Safety and Standards Act, 2006;
- Food Safety and Standards Rules, 2011;
- Food Safety and Standards Regulations, 2011;
- Circulars/ instructions/ orders/ notifications/ resolutions issued by Government of India (GoI)/ Government of Maharashtra (GoM) in respect of functioning of FDA; and
- Bombay Financial Rules, 1959 and Maharashtra Treasury Rules, 1968.

2.1.4 Audit scope and methodology

The Performance Audit covered test-check of records for the period 2012-2017. An Entry Conference was held with the Principal Secretary, MEDD (11 May 2017) and with the Commissioner, FDA (17 July 2017). The records in the offices of the Principal Secretary, MEDD, Mantralaya, Mumbai,

Commissioner, FDA, eight[5] out of 30 district offices[6] in the State for Food and eight[7] district offices for Drugs selected by adopting Simple Random Sampling Without Replacement (SRSWOR) method were test-checked. The records of all the three Drug Control Laboratories (DCLs) at Mumbai, Aurangabad and Nagpur were also test-checked. In addition, records of eight[8] laboratories connected to selected eight districts for testing of Food samples were scrutinised. Joint physical inspection of Food Business Operators (FBOs) with expired licenses was also conducted.

The reply in respect of Drugs Administration received (September 2017) from the Commissioner, FDA has been suitably incorporated in the Performance Audit. An Exit Conference to discuss the audit findings could not be held as there was no response from the Government despite constant follow-up with the Government and Commissioner, FDA.

Audit Findings

2.1.5 Regulatory and Administrative Framework

Regulatory and Administrative mechanism of FDA consists of licensing, inspections, sampling, sample testing, adjudication and prosecution functions as envisaged in relevant Acts, Rules and Regulations.

2.1.5.1 Non-availability of FDA offices in five districts

Maharashtra has 36 districts. However, only 30 district offices were found functioning as of March 2017 (for two districts of Greater Mumbai Division, one FDA office is available). Five districts *viz*., Gondia, Washim, Hingoli, Nandurbar and Palghar did not have their own district office but were attached to nearby districts. It was noticed that MEDD had given sanction (October 2009) for setting up offices in rented premises in four districts except Palghar. Accordingly, buildings were taken on rent in 2009 without posting the required staff, resulting in wasteful expenditure of ₹ 56.24[9] lakh on rent.

Reply of Government was awaited (November 2017).

2.1.5.2 State Level and District Level Steering Committees

In order to enforce the FSS Act, appropriate regulatory and administrative mechanism was required to be set up for ensuring its uniform implementation.

As per Regulation 2.1.15 of Food Safety and Standards Regulation 2011, a State Level Steering Committee (SLSC) with Chief Secretary as its Chairperson and a District Level Steering Committee (DLSC) with District Collector as its Chairperson were to be constituted to assist, aid or advice on any matter concerning food safety in the State. Both the committees were to meet once a month and decisions taken were to be forwarded to appropriate

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5 Amravati, Aurangabad, Greater Mumbai, Nagpur, Nanded, Nashik, Pune and Thane

6 District offices are not established in Gondia, Hingoli, Nandurabar, Palghar and Washim districts. One office for two districts of Greater Mumbai

7 This includes five divisions at Aurangabad, Greater Mumbai, Nagpur, Pune and Thane (Konkan) which also look after the working in divisional headquarters district including selling licenses and three districts at Jalgaon, Nanded and Yavatmal

8 Mumbai (FDA), Pune (PH), Aurangabad (FDA and PH), Nagpur (FDA and PH), Nashik (PH) and Amravati (PH). Thane and Nanded did not have laboratory

9 October 2009 to March 2017 = 90 months × Rent ₹ 62,487 per month = ₹ 56.24 lakh

authority (Food Safety and Standards Authority of India (FSSAI)/MEDD) for necessary action.

Accordingly, MEDD constituted (August 2012) SLSC at the State level and DLSC in each district. It was observed that SLSC met only twice in the months of September 2012 and October 2012 during 2012-17. Out of 30 district offices, four meetings each were held in Pune and Nanded between August 2013 and June 2017. In the remaining 28 district offices, DLSC did not meet even once during 2012-17. Thus, the objectives for constitution of these Committees were not achieved.

AC, Thane replied (September 2017) that District Level Steering Committee was not constituted in Thane.

2.1.5.3 Absence of database of Food Business Operators

While FDA had a database of drugs manufacturing and selling units, they did not have one for Food Business Operators (FBOs). As per Regulation 2.1 of FSSR, petty FBOs having an annual turnover not exceeding ₹ 12 lakh are required to register themselves by submitting an application to the FSO concerned along with self-attested declaration of adherence to the specified requirements. Other than petty FBOs, no person can commence food business without possessing a valid license. For the purpose, an application for the grant of a license is required to be made to the DO/AC (Licensing Authority) concerned.

The Central Advisory Committee[10] (CAC) which has a significant role in enforcement of the FSS Act, had recommended (February 2011) that the Food Safety and Standards Authority of India (FSSAI) would develop a database on FBOs in the country so that exact volume of FBOs and their status with regard to size, type, registration *etc*., could be estimated. Further, as per Rule 2.1.3.4 (f) of the Food Safety and Standards Regulations (FSSR), it was the responsibility of FSOs to maintain a database of all food businesses within the area assigned to them.

It was observed that no survey was undertaken by either FSSAI or by the GoM through FSOs till date. The CAC in its 17th meeting (June 2016) estimated number of FBOs operating in the State as 1.5 *per cent* of the State's population which worked out to 16,85,595 FBOs.

In further compliance with the FSS Act, all FBOs were required to be registered or licensed as per Regulation 2.1.2 of FSSR. It was observed that out of 16,85,595 estimated FBOs, only 9,42,997 FBOs (56 *per cent*) were registered/licensed as of March 2017. Therefore, almost 7,42,598 (44 *per cent*) of FBOs, remained out of the ambit of Regulations and continued to operate unauthorisedly.

[10] CAC is a Central body consisting of two members each to represent the interests of food industry, agriculture, consumers, relevant research bodies and food laboratories and all Commissioners of Food Safety

Similarly, as per Regulation 2.1.2 (3) of FSSR, license for commencing or carrying on food business, which falls under Schedule 1[11], shall be granted by the Central Licensing Authority. The required enforcement however in respect of these FBOs was the responsibility of State Licensing Authority. The Director, Central FSSA, Mumbai for Maharashtra had issued 6,027 licenses up to March 2017. However, no separate records for inspection of FBOs to whom licenses were issued by the Central Licensing Authority were maintained by the eight district offices test-checked. Thus, it could not be ascertained by audit whether the units possessing central licenses were inspected by State Authorities.

JCs, Thane, Amravati, Aurangabad and Nanded accepted (September 2017) that no FBO survey was conducted and no records were available for central licensee units. Government reply was awaited (November 2017).

2.1.5.4 Inadequate Manpower

i) Deficient Assistant Commissioners, FSOs and Food Analysts

FSS Act provides that the Commissioner, FDA shall appoint an Assistant Commissioner (AC)/Designated Officer (DO) in each district. The ACs grant/cancel license to FBOs, investigate complaints, issue prohibition orders and maintain records of inspection. The ACs also review the working of FSOs and refer prosecution cases to the Adjudicating Officer. The FSOs were responsible for inspection of registration/license holders, collecting food samples for analysis, seizing any article of food, summoning and investigating registration/license holders. The Commissioner, FDA directed (August 2011) all the FSOs to collect five food samples and to inspect 10 FBOs per month. Accordingly, the Commissioner, FDA worked out and sent (September 2012) the staff proposal to MEDD as shown in **Table 2.1.1.**

Table 2.1.1: Requirement of manpower as worked out by the Commissioner, FDA

Sr. No.	Name of Post	Total requirement	Sanctioned staff	Actual persons in position	Shortfall as compared to requirement (*Per cent*)	Persons in position in selected districts
1	AC/DO	205	62	41	164 (80)	27
2	FSO	1008	265	180	828 (82)	94

Out of 27 ACs and 94 FSOs posted in eight district offices, 22 ACs (81 *per cent*) and 68 FSOs (72 *per cent*) were posted in three district offices at Mumbai, Pune and Thane.

The CAC in its 16th meeting (January 2016) had also observed that FSOs are the most important functionaries of the Food Regulatory system and appointment of adequate number of FSOs in the State was imperative for effective enforcement. However, no action was taken by the State Government on the staff proposal. This impacted the inspection of FBOs as discussed in **paragraph 2.1.7.1**.

[11] Dairy units handling more than 50,000 litres of milk/day or 2500 MT of milk solid per annum; vegetable oil processing units with installed capacity more than 2 MT/day; slaughter houses slaughtering more than 50 large or 150 small animal; meat processing units handling 500 kg meat/day; 100 *per cent* export oriented units; all importers; FBOs operating in two or more states, food catering services under Central Government Agencies like Railway, defence *etc.*

Further, as per norms[12], there should have been 101 Food Analysts (FAs), but only 22 (22 *per cent*) were available. Of the 22 FAs available, only two FAs on rolls of Drugs Laboratory were working in FTLs while 20 FAs belonged to Public Health Laboratories.

Commissioner, FDA stated (August 2017) that the manpower proposal of September 2012 was under consideration of GoM.

ii) Absence of Licensing Authorities

Joint Commissioner (JC) at division level and Assistant Commissioner (AC) at the district level are designated as Licensing Authority for manufacturing and selling units respectively who are responsible for issuance and renewal of licenses to drugs manufacturers/sellers, inspecting units and initiating action for violation of norms.

Audit observed that in all the seven[13] Division offices, JCs were not posted and their work was being done by giving additional charge to ACs. In Ratnagiri and Wardha District office and Greater Mumbai Zones (2, 3 and 4) Drug Inspectors (DIs) were given the additional charge of ACs. This adversely affected regulatory functions as discussed in **paragraph 2.1.6.4**.

The Commissioner, FDA stated (September 2017) that now the vacant posts of Joint Commissioner (Drugs) in five Division offices *viz*. Nagpur, Thane, Pune, Greater Mumbai and Nashik were filled by promotion and transfer.

The reply is not acceptable as the vacancies in the post of JCs and ACs continued during the period covered by audit.

iii) Shortage of Drug Inspectors

DIs are key personnel for effective enforcement of provisions made under different Acts for drugs control. They are responsible for inspections of licensee units, investigation of complaints and collecting drug samples for testing. They are also responsible for follow-up action for "Not of Standard Quality" (NSQ) drugs and for initiating prosecutions for breach of the Acts and Rules. An Expert Committee under the Chairmanship of Dr. R. A. Mashelkar appointed by Ministry of Health and Family Welfare, Government of India (GoI) had recommended (2003) one DI per 50 manufacturing units and one DI per 200 sales/distribution outlets. However, the process for filling up of vacant posts and review of sanctioned strength was still stated (September 2017) to be in progress.

Against the requirement of 413 DIs as per Dr. Mashelkar Committee report, the sanctioned strength was 161 DIs. Only 101 DIs (63 *per cent*) were posted. The position in the test-checked districts is given below:

[12] As per the norm of five samples per FSO per month. 5×1008 FSOs/50 samples to be analysed by FA/month

[13] Amravati, Aurangabad, Greater Mumbai, Nagpur, Nashik, Pune and Thane (Konkan)

Table 2.1.2: Shortage of Drug inspectors in the test-checked districts as on March 2017

District	No. of units		Requirement of DIs	Sanctioned strength *vis-à-vis* requirement (Percentage)	Men in position *vis-à-vis* sanctioned strength (Percentage)	Shortage (Percentage)
	Manufacturing*	Selling				
Aurangabad	105	3017	17	7 (41)	4 (57)	3 (43)
Greater Mumbai	261	9338	52	21 (40)	15 (71)	6 (29)
Jalgaon	54	2756	15	4 (27)	3 (75)	1 (25)
Nagpur	109	4461	24	9 (38)	7 (78)	2 (22)
Nanded	38	1960	11	3 (27)	1 (33)	2 (67)
Pune	249	10108	56	16 (29)	9 (56)	7 (44)
Thane	764	10756	69	26 (38)	12 (46)	14 (54)
Yavatmal	20	1155	7	2 (29)	2 (100)	0
Total	**1580**	**43551**	**251**	**88 (35)**	**53 (60)**	**35 (40)**

Source: Information furnished by the JCs/ACs of respective Divisions/Districts
* Includes Allopathic, Ayurvedic, Homeopathic and Cosmetics manufacturing units, Blood Banks, Blood Storage Centres and Public Testing Laboratories

As seen from **Table 2.1.2** the shortage of DIs *vis-à-vis* the sanctioned strength was highest in Nanded district at 67 *per cent* among the eight test-checked districts. The impact of the shortfall was clearly evident from the fact that 1,022 out of 1,960 selling units in Nanded district were not inspected for more than one year as on March 2017.

The shortages in DIs cadre had significant impact on the regulatory activities of the FDA as discussed in **paragraphs 2.1.6.4 (iii) and 2.1.7.2**.

The Commissioner, FDA stated (September 2017) that the proposal for recruitment of Drug Inspectors was submitted to Government. Accordingly, Maharashtra Public Service Commission had taken steps to appoint the candidates but the recruitment process was challenged in Court of Law and therefore recruitment was pending.

2.1.5.5 Uneven distribution of Drug Inspectors

The position of DIs deputed in all divisions when compared to the number of manufacturing and selling units as on 31 March 2017 is given in **Table 2.1.3**.

Table 2.1.3: Division-wise number of manufacturing and selling units per Drug inspector in the State as on March 2017

Division	Drug Inspectors		No. of units			No. of units per Drug Inspector	No. of units not inspected in 2016-17 (Shortfall percentage with reference to Column 6)
	Sanctioned posts	Men in position (*per cent*)	Selling	Manufacturing	Total		
1	2	3	4	5	6	7	8
Amravati	11	8 (73)	5624	107	5731	716	2225 (39)
Aurangabad	20	10 (50)	10225	221	10446	1045	5375 (51)
Greater Mumbai	21	15 (71)	9338	278	9616	641	3841 (40)
Nagpur	15	13 (87)	7493	166	7659	589	3147 (41)
Nashik	18	13 (72)	11223	274	11497	884	6410 (56)
Pune	29	15 (52)	17798	397	18195	1213	9984 (55)
Thane	33	18 (55)	11339	952	12291	683	4421 (36)
Total	**147**	**92 (63)**	**73040**	**2395**	**75435**	**820**	**35403 (47)**

Source: Information furnished by the Commissioner, FDA

It was seen from the table that the average workload per DI was 820 units. It was highest (1,213) in Pune division and lowest (589) in Nagpur division. As

a result, Pune division did not inspect 9,984 (55 *per cent*) out of 18,195 units in 2016-17. Similarly, in Aurangabad and Nashik divisions which had workload higher than the State average of 820 units per DI, the shortfall in inspection was more than 50 *per cent*.

The Joint Commissioner (HQ), FDA stated (July 2017) that a proposal for an increase in sanctioned strength of DIs was pending at Government level since December 2016 and accepted that vacancies as compared to the sanctioned strength resulted in excess workload on the existing staff. The Commissioner, FDA stated (September 2017) that proposal for additional posts of Assistant Drug Inspector was also submitted (December 2016) to the Government for approval.

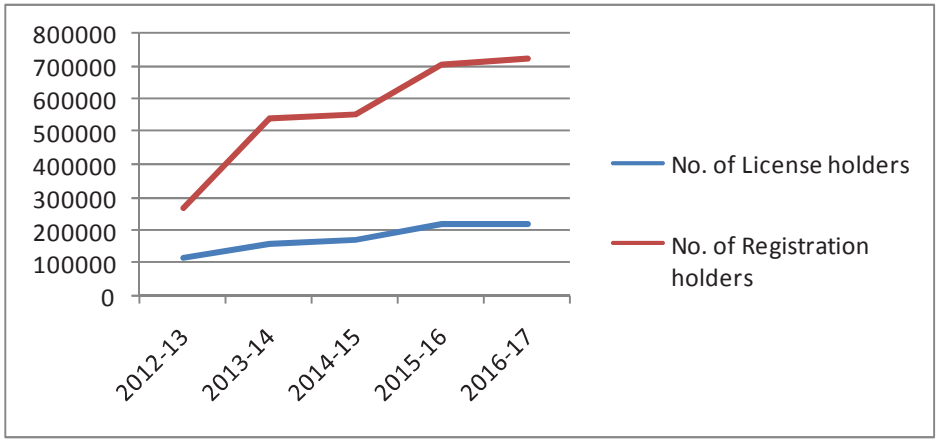
The fact remains that the regulatory functions had been hampered during the last five years whereas the proposal to fill up the posts was submitted in December 2016 only.

2.1.6 Issuance of Licenses

2.1.6.1 Licensing and Registration of Food Business Operators

In Maharashtra, against the estimated (June 2016) 16.86 lakh FBOs, 9.43 lakh FBOs (56 *per cent*) were registered/licensed as of March 2017. The remaining FBOs continued to operate the food business without registration/license in contravention to the provisions of FSS Act. The year-wise number of FBOs who have obtained registration and license in the State is shown in **Chart 2** below:

Chart 2: Year-wise details of FBOs having registration and license



Audit scrutinised 1,600 licenses[14] and 400 registrations[15] issued to FBOs in eight districts and observed the following:

- In 1,057 out of 1,600 selected cases (66 *per cent*), licenses were issued to FBOs though requisite documents[16] were not submitted.

[14] 40 licenses × 5 years (2012-17) × 8 districts = 1,600 licenses

[15] 10 registrations × 5 years (2012-17) × 8 districts = 400 registrations

[16] Layout plan, water test report, pollution control certificate issued by State Pollution Control Board, source of raw material for meat and meat processing plant, source of milk or procurement plan for milk, address proof, list of machinery *etc.*

- In 142 out of 400 selected cases (35 *per cent*), registrations were granted to FBOs though requisite declarations/documents[17] were not submitted.

- As per Regulation 2.1.1 (3) of FSSR, the FSO shall consider the application and may either grant registration or reject it with reasons or issue notice for inspection within seven days of receipt of an application. Further, as per Regulation 2.1.4 (1), a license shall be issued by the AC within a period of 60 days from the date of issue of application ID number. However, in 245 out of 1,600 licenses, delays ranging between two to 415 days were noticed in issue of licenses, while in 193 out of 400 registrations cases, the delay ranged between two to 341 days in issue of registration certificates.

- As per Regulation 2.1.7 (5) of FSSR, any registration or license for which renewal[18] has not been applied for within the period mentioned in Regulations, shall expire and the FBO shall stop all business activity at the premises. The FBO has to apply for fresh registration or license if it wants to restart the business. However, it was observed that, 764 out of 1,600 licenses and 26 out of 400 registrations had lapsed and were not renewed. But no mechanism existed with FDA to check whether the FBOs with expired licenses and registrations continued to operate in food business as evident from the case below:

GAPPL, Pune continued to supply food under ICDS despite its license getting cancelled

The Women and Child Development Department, GoM placed (February 2015) a supply order on Govardhan Ayur Pharma Private Limited, Indori, Pune (GAPPL) for supply of 20.20 lakh packets of therapeutic food (biscuits) at a total cost of ₹ five crore, under Integrated Child Development Services (ICDS) Scheme. As per conditions of supply order, GAPPL was required to submit a copy of valid FDA license to the Commissioner, ICDS Navi Mumbai. License for manufacture and supply of therapeutic food had been cancelled by AC, Pune (January 2014). FSO, Pune inspected (22 July 2015) the premises of GAPPL and collected the food samples for analysis. Laboratory reports (24 July 2015) showed that the samples were sub-standard and misbranded. Simultaneously, AC, Pune requested the Commissioner, ICDS to recall the sub-standard therapeutic food from all the anganwadis. However, the therapeutic food had already been distributed to the targeted beneficiaries. Thus, as a failure of FDA to check whether the FBOs with expired licenses and registrations continued to operate in food business, substandard food was manufactured and supplied to consumers. JC, Pune stated (July 2017) that a case was lodged with Chief Judicial Magistrate, Pune in November 2015.

- In Nagpur, during joint physical inspection of 20 FBOs (3 July 2017), whose license had expired, eight FBOs were found running their business

[17] Self-attested declaration for maintaining basic hygiene and safety requirements, ID proof, address proof *etc.*

[18] The period of validity of registration and license would vary from one to five years subject to remittance of fee applicable for the period chosen by the FBOs

while fresh licenses were issued to three FBOs after a gap of almost one year. In Mumbai, Nashik, Thane, Aurangabad, Amravati, Nanded and Pune joint physical inspection could not be conducted despite audit request. AC, Nagpur stated (July 2017) that FBOs have now applied for new licenses.

2.1.6.2 Illegal selling of drinking water in Puff jars

In Nashik, FBO units were found (September 2011) selling water in puff jars which were not colorless and transparent with tamper proof seals. The jars did not qualify as the Packaged Drinking Water and Mineral Water and contravened Rule 2.1.2 (5)[19] of (Packaging and Labeling) Regulation, 2011. Moreover, these units had written from time to time (September 2011 and January 2012) to the Commissioner, FDA, Mumbai and FDA, Nashik for issue of license for chilled water services under FSS Act. But FDA refused to issue license on the ground that there was no such category to issue license in the FSS Act. Due to inaction on part of FDA since 2011, business of manufacturing and selling of chilled water in puff jar without a license had continued. It is pertinent to mention that these puff jars are not sealed.

JC, Nashik accepted the facts and stated (July 2017) that the FSS Act specified the provisions only for packaged drinking water. Hence, no action has been initiated against these FBOs since the said business is not included in the norms prescribed for packaged drinking water. He further added that, taking these samples and seizing the stock would not be in adherence to the provisions of the Act.

	
Puff Jar	**Packaged Bottle**

The contention of the JC is not tenable as the Act provides for packaging requirements for drinking water such as clean, hygienic, colourless, transparent and tamper proof bottles/containers made of polyethylene or polyvinyl chloride for preventing possible adulteration or contamination of the water. These quality checks cannot be ensured for the water which is packed in puff jars.

Similarly, in Thane, the district authorities had identified (May 2017) 67 FBOs selling water in puff jars without license/registration but no action was initiated (November 2017). In Nanded, 13 cases were lodged in court of law by FDA during 2015-17 which were pending. When the issue was raised in

[19] As per Rule 2.1.2 (5) of (Packaging & Labeling) Regulation,2011, the packaging requirement of drinking water, it shall be packed in clean, hygienic, colorless, transparent and tamper proof bottles/containers made of polyethylene or polyvinyl chloride (PVC) or sterile glass bottles *etc.,* for preventing possible adulteration or contamination of water

other selected districts, JC, Mumbai stated (July 2017) that there were no units in Mumbai which were selling water in puff jars. JCs, Aurangabad and Amravati stated (August 2017 and September 2017) that there was no database for FBOs selling drinking water in puff jar.

2.1.6.3 On-line Food Licensing and Registration System

In order to cater to the legal requirements of the Act and increasing number of FBOs, an online Information Technology application, Food Licensing and Registration System (FLRS) was launched (April 2014) by FSSAI which was adopted by the GoM with immediate effect. However, the Management Information System (MIS) maintained manually was not discontinued. Offline records of 47,670 out of 1,26,128 licenses (38 *per cent*) and 84,866 out of 2,63,873 registrations (32 *per cent*) only were uploaded to FLRS as of March 2017. Audit observed the following deficiencies which bring out the unreliability of the data available with the Department.

i) Data discrepancy

There was wide variation in data available on FLRS and MIS in all the eight test-checked districts and noticed significant difference in four districts as shown in **Table 2.1.4**.

Table 2.1.4: Variation in Data between FLRS and MIS

District	No. of License holders		No. of Registration holders	
	FLRS	MIS	FLRS	MIS
Mumbai	23678	36036	18809	65416
Pune	16584	28705	34041	63238
Nashik	14974	6536	9290	13596
Thane	17264	45221	28627	62842

JC, Pune asked (July 2017) to consider MIS figures only, whereas JC, Nashik stated (July 2017) that figures in MIS were given on estimation. Thus, both FLRS and MIS data were found to be not reliable.

ii) Inappropriate jurisdictional areas

Each area coming under the jurisdiction of AC/FSO has been allotted a unique License/Registering Authority Code, which forms an integral part of Registration Number issued to a FBO. However, in Thane and Nashik districts, the license/registration numbers issued by two ACs and 14 FSOs respectively were not in conformity with the License/Registering Authority Codes **(Appendix 2.1.1)** resulting in flawed indication of jurisdictional area which may impact further appeals and litigations. JC, Nashik replied (August 2017) that the matter was reported to FSSAI which had power to update the system.

iii) Improper access to FLRS

In Pune, the data about licenses and registrations available in FLRS showed the combined figures for Pune district (Zone 4) and Solapur district as the DO had access to both district codes/passwords. Similarly, in Nagpur, though one AC had retired in 2015, data on licenses and registrations issued in June 2017 was shown against his name. The AC at Nashik district had access to data at Gadchiroli in addition to Nashik. Likewise, AC, Amravati was transferred in June 2016 but the licenses generated were in his name till September 2017. In

Nanded, registrations were issued in September 2017 in name of FSOs who were transferred in June 2017. JCs, Pune, Nanded and Amravati stated (July 2017) that the issue was comminicated to Commissioner, FDA/FSSAI.

iv) Dual licensing

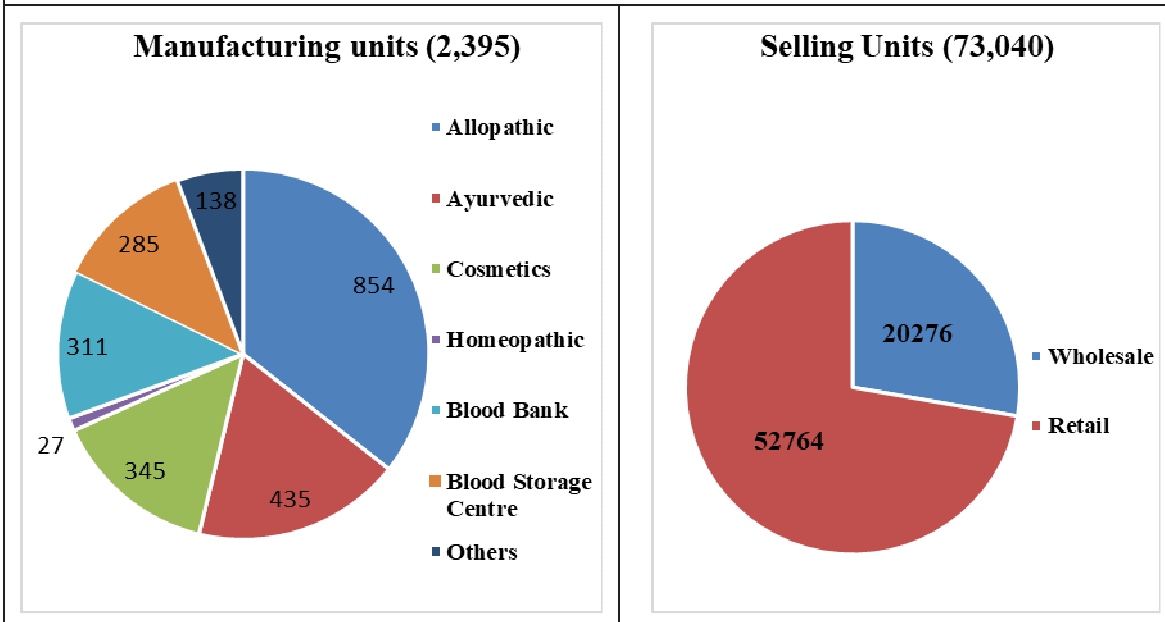
In Amravati, there were 1,697 licensed FBOs on FLRS of which 206 FBOs were allotted a separate license number which was issued manually. This was necessitated due to incorrect data entry of validity period.

Government reply was awaited (November 2017).

2.1.6.4 Licensing of Drugs manufacturing and selling units

The licensing function of the FDA as defined in Rules 63, 64, 66, 74, 85, 122(O), 143 and 159 of D&C Rules comprises issuing new manufacturing and selling licenses, renewal of licenses after inspection of premises and suspension or cancellation of the licenses for non-compliance with the licensing conditions. In the State, there were 2,395 and 73,040 licensed drug manufacturing and selling units respectively as of March 2017 as given in **Chart 3**.

Chart 3: Licensed drugs manufacturing and selling units in the State



Source: Information furnished by the Commissioner, FDA

In the case of licensing, Audit findings are discussed below:

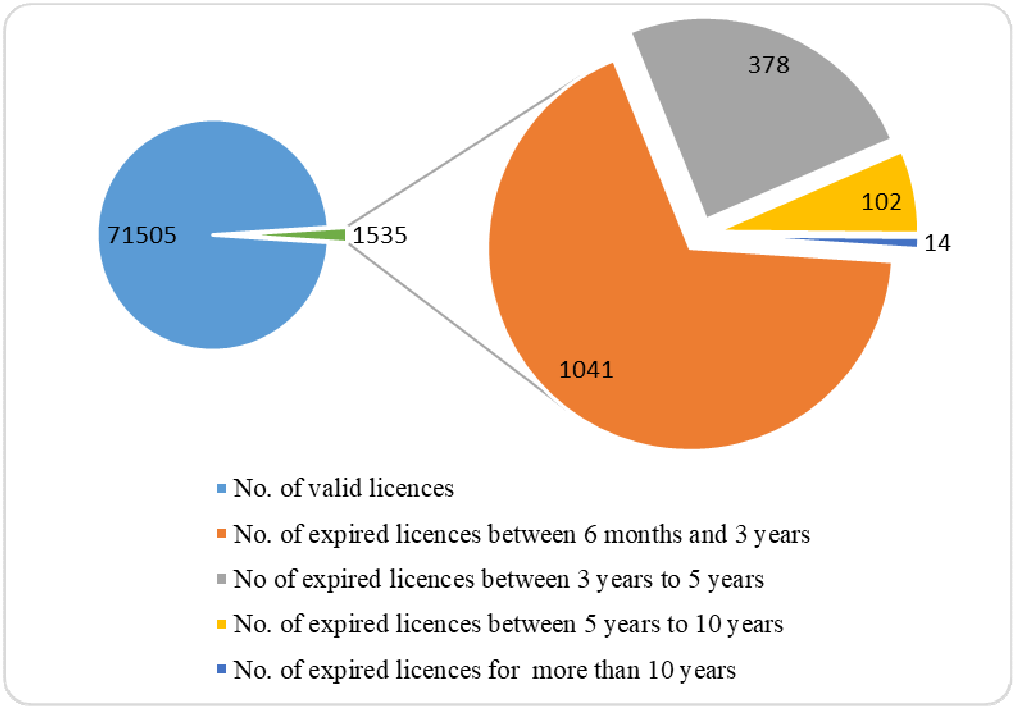
i) Expired licenses

In terms of the D&C Rules, if an application for renewal of license which is in force is made before its expiry or if an application is made within six months of its expiry, after payment of additional fee, the license shall continue to be in force until orders are passed on the application. The license shall be deemed to have expired if an application for its renewal is not made within six months after its expiry. The JC/AC heading the Division/District office is designated as the licensing authority for drugs/cosmetics manufacturing/selling units. Drugs manufacturing or selling unit may have one or more licenses for

production or sale of different types of drugs, which are required to be renewed every five years.

The FDA did not maintain any database of the status of licenses in respect of manufacturing units. However, based on the information furnished by the JC/AC in the test-checked districts it was noticed that there was no case of expired manufacturing licenses. The FDA maintains a database of the licenses issued to selling units and their expiry date. Analysis of the database by Audit revealed that licenses of 1,535 selling units in the State had expired as at the end of March 2017 but the FDA had not taken action to cancel/remove these licenses from the database after proper inspection. The age-wise break-up of the expired licenses issued to the selling units is given in **Chart 4.**

Chart 4:Age-wise analysis of expired selling licenses in the State



Source: Information furnished by the Commissioner, FDA

The status of the expired licenses of selling units in the eight test-checked districts, as on 31 March 2017 is given in **Table 2.1.5**.

Table 2.1.5: Status of expired licenses of selling units in the test-checked districts as on 31 March 2017

Name of district	Total no. of expired licenses as on September 2016	Total no. of defaulting firms	Expired since		
			Six months to three years	Three to five years	More than five years
Aurangabad	51	22	51	0	0
Greater Mumbai	19	8	16	3	0
Jalgaon	17	9	9	7	1
Nagpur	61	29	51	10	0
Nanded	0	0	0	0	0
Pune	35	13	22	13	0
Thane	300	128	234	50	16
Yavatmal	0	0	0	0	0
Total	**483**	**209**	**383**	**83**	**17**

Source: Information provided by the JCs/ACs of respective Divisions/Districts

As seen from **Table 2.1.5**, there were 483 expired licenses of selling units (209 firms) in six out of the eight test-checked districts. Of these, 300 licenses (128 firms) had expired in Thane district alone. After this was pointed out in audit, JC, Aurangabad cancelled the licenses of eight selling units whose licenses had expired more than six months to three years earlier after verifying that the same were closed permanently and agreed to take action against the remaining 14 selling units. Audit observed that the FDA had management information system showing the status of validity of the licenses. But this vital information readily available was not utilised to inspect on priority those selling units whose license had expired for cancellation of licenses or for taking appropriate action against the selling units if they were found to be operating on expired licenses.

The Commissioner, FDA stated (September 2017) that the entries of expired licenses and closed units were not updated in database system, which would be now done. No licensee was allowed to run the business without valid licenses. If any firm was found doing the business on expired licenses, strict action like prosecution was taken by the FDA.

The reply is factually incorrect as evident from the audit findings. FDA had failed to take action against the selling units whose licenses had expired. Therefore, the risk to public health by the sale of drugs by such selling units whose licenses had expired cannot be ruled out.

ii) Renewal of licenses without inspection

The D&C Rules states that a license to a selling unit shall not be granted or renewed unless the authority empowered to grant the license is satisfied that the premises in respect of which the license is to be granted or renewed are adequate, equipped with proper storage accommodation for preserving the properties of the drugs to which the license applies and are in charge of a person competent in the opinion of the licensing authority to supervise and control the sale, distribution and preservation of drugs. Thus, before renewal of licenses, the Licensing Authority should ensure that the selling units have satisfied the provisions of the Rules properly.

The FDA renews licenses of the selling units online since 2011. Audit test-checked 3,800 renewal cases out of 33,208 renewals done during 2012-17 to verify whether the licenses were renewed after inspection by the DI. The findings in this regard are given in **Table 2.1.6**.

Table 2.1.6: Renewal of licenses to selling units without inspections

District	No. of renewals	Renewal cases checked by Audit	Renewal cases in which inspections were not done (*per cent*)
Aurangabad	2513	300	147 (49)
Greater Mumbai	7756	800	259 (32)
Jalgaon	2194	300	148 (49)
Nagpur	3457	350	142 (41)
Nanded	1671	400	96 (24)
Pune	6401	650	168 (26)
Thane	7992	800	275 (34)
Yavatmal	1224	200	51 (26)
Total	**33208**	**3800**	**1286 (34)**
Source: Information furnished in the test-checked districts			

As seen from **Table 2.1.6**, in 1,286 (34 *per cent*) out of 3,800 cases test-checked, the licenses were renewed without inspection. The number of licenses renewed without inspection was maximum (49 *per cent)* in Aurangabad and Jalgaon districts. Audit also observed that the online system did not have inbuilt controls to prevent renewal of licenses, without inspection being done as required under the Rules.

The Commissioner, FDA stated (September 2017) that there was no express provision of inspection for grant or renewal of licenses of selling units. This provision was already complied with at the time of grant of license by physical verification by DI and it was verified during regular inspections of the licensed firms.

The reply is not acceptable as before renewal of licenses, the Licensing Authority should ensure that the selling units have satisfied the provisions of the Rules properly which is not possible without physical verification. Audit also observed that a large number of selling units had not been inspected as discussed in **paragraph 2.1.7.2**.

iii) Suspended licenses not monitored

The D&C Rules provide for suspension and cancellation of licenses of the manufacturing and selling units by the Licensing Authority in the case of contravention of licensing condition or if the manufactured drugs are found to be not of Standard Quality, after issuing Show Cause Notice (SCN) to the licensee.

Scrutiny in the test-checked districts revealed that during 2012-17, the Licensing Authorities had suspended licenses of selling units based on 8,276 SCNs. Test check of 343 SCN files, revealed that the licenses of the selling units were kept under suspension for periods ranging from one to 181 days.

Similarly, the Licensing Authorities had suspended the license of various manufacturing units, Blood banks and Blood Storage Centres based on 336 SCNs issued in the five Divisions *namely.* Aurangabad, Greater Mumbai, Nagpur, Pune and Thane. Test check of 47 SCN files, revealed that the licenses of the manufacturing units were kept under suspension for periods ranging from one to 127 days.

Scrutiny in Audit revealed that no records were maintained by the Licensing Authorities regarding inspection/survey done to verify that the selling/ manufacturing units were not operating during the suspension period.

The Commissioner, FDA stated (September 2017) that the monitoring on the activities of selling/manufacturing units during suspension period was done by the field officers and accepted that specific records to this effect were not available. The Commissioner cited only one case of detection in support of action taken.

The Licensing Authorities of the test-checked districts also stated (May to July 2017) that compliance with the suspension order could not be ensured due to manpower shortage.

The very purpose of suspension of license is negated if compliance with the suspension orders is not ensured.

2.1.7 Inspections

2.1.7.1 Inspection of Licensed and Registered FBOs

As per Regulation 2.1.1 (6) of Food Safety and Standards Regulations 2011, the FSOs shall carry out food safety inspections of the registered establishments at least once in a year. Further, as per Regulation 2.1.2 (5), the ACs shall ensure periodical food safety audit and inspection of the licensed establishments through FSOs or authorised agencies.

Audit observed that Commissioner, FDA had not fixed the periodicity of inspection of the licensed establishments. The number of inspections conducted in the State revealed a decreasing trend from 8.60 *per cent* in 2012-13 to 2.55 *per cent* in 2016-17. Similarly, in the test checked eight districts, only 2.5 to 13 *per cent* of registered and licensed FBOs were inspected by FSOs during 2016-17.

FDA attributed (July 2017) the failure to conduct periodical inspections to shortage of man-power. Despite being aware of the lacuna, nothing was done to improve it as discussed in **paragraph 2.1.5.4**. Government reply was awaited (November 2017).

2.1.7.2 Shortfall in inspection of drug manufacturing and selling units

Rule 52 of D&C Rules states that the DI has to inspect all premises licensed for the manufacture of drugs or cosmetics at least once a year to check if the conditions of the license and provisions of the Act and Rules are being observed. As per Rule 162 of D&C Rules, all the premises licensed for the manufacture of Ayurvedic (including Siddha) or Unani drugs have to be inspected by the DI not less than twice a year. Further, as per Rule 51 of D&C Rules, the DIs have to inspect all establishments licensed for the sale of drugs atleast once a year. Scrutiny in audit revealed the following:

The year-wise status of shortfall in the inspection of drugs manufacturing and selling units in the test-checked districts is shown in **Appendix 2.1.2**.

As seen from **Appendix 2.1.2**, there was a 35 *per cent* shortfall in inspections during 2012-17. The shortfall in inspection increased from 16 *per cent* in 2012-13 to 31 *per cent* in 2016-17 and the shortages were in category of ayurvedic, homeopathic and cosmetic units. The shortfall in inspection of manufacturing units was highest (52 *per cent*) in Greater Mumbai district during the same period.

The year-wise status of shortfall in inspection of drugs selling units in the test-checked districts are shown in **Table 2.1.7**.

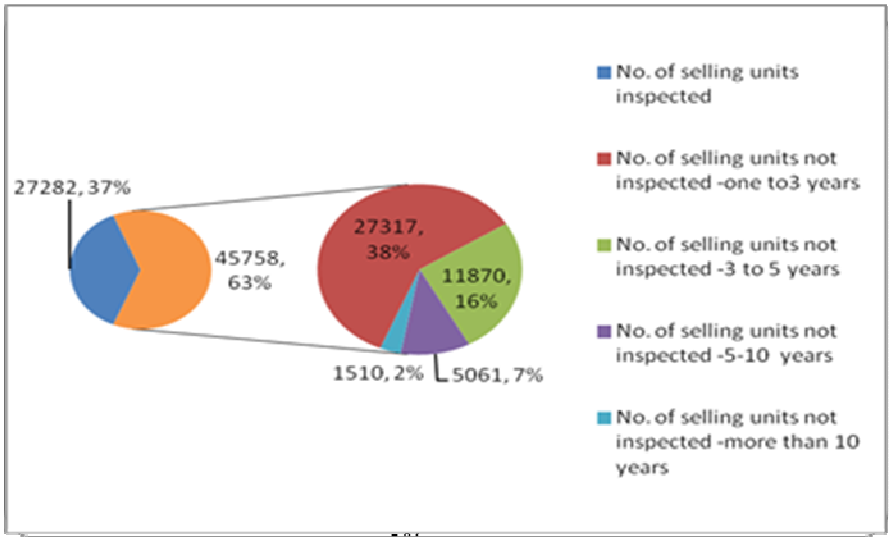
Table 2.1.7: Shortfall in inspection of selling units in the test-checked districts

Year	No. of Selling units	No. of Inspections carried out	Shortfall (Percentage)
2012-13	35977	23578	12399 (34)
2013-14	36135	24109	12026 (33)
2014-15	35985	18706	17279 (48)
2015-16	37923	14178	23745 (63)
2016-17	42494	16717	25777 (61)
Source: Information provided by the JCs/ACs of respective Divisions/Districts			

As seen from **Table 2.1.7**, the shortfall in the inspection of selling units has increased from 34 *per cent* in 2012-13 to 61 *per cent* in 2016-17. During 2016-17, the shortfall in inspection was highest in Nanded district at 87 *per cent*. Though the number of selling units had been increased from 35,977 (2012-13) to 42,494 (2016-17), the number of inspections carried out decreased.

Audit observed that 45,758 (63 *per cent*) out of 73,040 selling units in the State had not been inspected as of March 2017.

Chart 5: Age-wise analysis of selling units not inspected in the State as on 31 March 2017



Source: Information furnished by the Commissioner, FDA

The position of inspection of selling units in the test-checked districts as on 31 March 2017 is shown below: -

Table 2.1.8: Selling units not inspected in the test-checked districts as on March 2017

District	No. of units not inspected				
	One to three years	Three to five years	Five to ten years	More than ten years	Total not inspected
Aurangabad	857	428	140	15	1440
Greater Mumbai	2355	837	774	120	4086
Jalgaon	697	519	249	17	1482
Nagpur	1639	571	129	4	2343
Nanded	481	354	141	46	1022
Pune	2600	1175	609	109	4493
Thane	3380	1516	357	27	5280
Yavatmal	704	1	0	0	705
Total	**12713**	**5401**	**2399**	**338**	**20851**

Source: Information provided by the JCs/ACs of respective Divisions/Districts

As seen from **Table 2.1.8**, 5,280 selling units in Thane, 4,493 in Pune and 4,086 in Greater Mumbai districts were not inspected for more than one year as on March 2017. The FDA did not fix any internal targets for inspection of the manufacturing/selling units by the DIs after considering the risk profile of the licensing units and manpower available.

The Commissioner, FDA stated (September 2017) that the inspection of each licensed establishment at least once a year was practically not possible due to

shortage of manpower available with FDA. However, the revised staffing pattern proposal with increased number of posts had been submitted (December 2016) to Government.

Thus, an important regulatory function of inspection of the manufacturing/selling units as stipulated in the D&C Rules was not fully discharged.

The Commissioner, FDA did not offer any comment.

2.1.8 Sampling, testing and follow-up

2.1.8.1 Drawing of food samples

FSSR provide for taking samples of food and food products from the market for testing to ensure that the quality of food meets the standards. It was observed that FDA had not formulated any guidelines for drawing samples of food and food products.

In eight test-checked district offices, it was also observed that

- Samples of infant food, instant milk substitutes, meat and fish products, fruits and vegetables were not taken for testing despite Commissioner, FDA's instructions of December 2014.
- FSOs drew only samples from retail shops and no samples were drawn from manufacturers.
- FSOs could not ensure that remaining stocks of unsafe/sub-standard/ misbranded samples were not sold in market, after drawal of samples.
- Adequate space and facility for storage of samples was not available.

JC, Pune stated (July 2017) that test reports were received by FSOs after one to three months from drawal of samples and during this period the stock with the FBOs was exhausted. Meat, poultry and fish samples were not taken as deep freezer facility was not available in any of FDA offices. Thus, the entire system of sampling was defective as even the batches from which samples were drawn could not be blocked. This is further detailed in **paragraph 2.1.8.4**.

2.1.8.2 Inadequate facilities for food testing in the State

Food testing laboratories have been entrusted with the important function of carrying out complete profile analysis of food samples sent by FSOs as per the regulatory requirement. The Laboratories have to maintain high standards of accuracy and reliability. It is also mandatory for all food laboratories to be accredited with National Accreditation Board for Testing and Calibration Laboratories (NABL).

MEDD had three Food Testing Laboratories (FTLs) at Mumbai, Aurangabad and Nagpur before 2012-13. A Committee constituted (January 2012) by MEDD had proposed (March 2012) construction, strengthening and commissioning of eight FTLs at Mumbai, Aurangabad, Thane, Pune, Nagpur,

Amravati, Nashik and Kolhapur at an estimated cost of ₹ 827.70[20] crore and establishment of 37 Mobile Laboratories at a cost of ₹ 32.30 crore in the State. No action was, however, initiated by MEDD as of November 2017.

- Of the above three laboratories test-checked in audit, only FTL at Mumbai was functional. The laboratory at Aurangabad was intermittently functional from 2008 to 2012. Thereafter it became non-functional for want of Food Analyst. The FTL at Nagpur was partially functional from June 2016 to June 2017. This resulted in dependence on the Public Health Laboratories for testing of food samples drawn by FSOs. The Public Health Department's (PHD) laboratories already had enough of their own work and therefore, faced constraints in providing their resources for food testing.

- A study was conducted by FDA and State Public Health Department for 18 laboratories in the State with an objective to strengthen the food laboratory network. The 'Gap Analysis Report' brought to the fore issues relating to infrastructure, equipment, man-power which had to be addressed to bridge the gap between existing and desired outcomes in Food Laboratories.

Table 2.1.9: Prominent gap areas reported in 'Gap Analysis Report'

Particular	Proposed	Available	Gap
Human Resources (Technical)	306	Nil	306
Instruments	347	57	290
Infrastructure	73000 sqft	9500 sqft	63500 sqft

The above report was referred (October 2013) to Commissioner, FDA for further action. No action was initiated on it as of November 2017.

- During 2013-14, four mobile food testing laboratories along with allied instruments and equipment for testing of milk, milk products and other food products were purchased (March 2014) at a cost of ₹ 1.97 crore to reduce the time between sample collection, its analysis and reporting. These were stationed at Mumbai, Ahmednagar, Kolhapur and Bhandara. As no technicians were posted, three mobile laboratories could not function and one mobile lab could be put to use only for six days by taking help of technicians from district public health laboratory.

Mobile Laboratory at Aurangabad and Mumbai

[20] Cost of five laboratories at Mumbai, Aurangabad, Pune, Nagpur and Thane – ₹ 577.35 crore + cost of three laboratories at Nashik, Amravati and Kolhapur – ₹ 250.35 crore

- During the period 2012-17, the FTLs and Public Health Laboratories in the State had analysed 43,434 food samples as against the requirement of 79,500[21] samples (55 *per cent*). Of this 29,563 food samples were found to be standard and 8,101 samples were in contravention of the standards/ rules/regulations of FSS Act as detailed in **Table 2.1.10**.

Table 2.1.10: Analysis of Food Samples in FTLs and PHLs.

Year	Samples drawn	Samples found standard	Samples found contravening the Standard / Rules/ Regulations
2012-13	9076	7213	1524
2013-14	7024	5494	1630
2014-15	8305	5156	1118
2015-16	7969	5821	1441
2016-17	11060	5879	2388
Total	**43434**	**29563**	**8101**
Source: Performance Budget of MEDD for respective years and MIS data of Commissioner, FDA			

Thus, the existing FTLs in the State were not functioning fully, number of laboratories were also insufficient to cater to the testing requirements and the FDA had to rely on Public Health Laboratories which were already overburdened.

2.1.8.3 Working of Laboratories

As per Rule 2.4.2 (5) of FSSR, on receipt of the samples, the Food Analyst shall analyse the sample and the analysis report duly signed mentioning the method of analysis in Form VII A is to be sent to the DO/AC concerned within fourteen days of the receipt of the sample. Further, Rule 2.4.2 (6) of FSSR provides that in case the sample cannot be analysed within fourteen days of its receipt, the Food Analyst shall inform the DO/AC and the Commissioner of Food Safety giving reasons and specifying the time to be taken for analysis. Scrutiny of records revealed the following:

A MEDD Laboratories

Food Testing Laboratory, Mumbai

Of the three[22] laboratories only FTL at Mumbai had got accreditation for three tests namely fat, oil/fat emulsions and beverages. The laboratory did not however, have any regular manpower against the requirement of 92 posts. The staff posted at Drug Control Laboratory was also responsible for FTL. The Deputy Director, FTL, Mumbai had repeatedly requested the JC, (Food), FDA, Mumbai not to send food samples for analysis because of huge pendency and shortage of manpower. The number of samples pending for analysis increased from 69 to 906 between April 2015 and March 2017 and there was a delay of three to four months in issue of the analysis report to AC concerned. **Microbiological tests for food samples were not done as there was no microbiological division and thus, pathogenic bacteria, yeast and mould could not be tested raising serious food safety concerns. Tests to analyse the contents of metals, toxic substance and insecticides articles were also not being done due to non-availability of requisite equipment.**

[21] 265 FSOs × 60 samples per annum × 5 years = 79,500

[22] FTL at Aurangabad, Mumbai and Nagpur

There was inadequate storage facility for storing the food samples received. The walls of the building were damp due to seepage.

Food samples kept haphazardly at FTL, Mumbai.

Instruments worth ₹ 3.01 crore purchased from 2014 to 2016 were not installed due to incomplete electric works and non-availability of appropriate place for installation. As against the requirement of 53 instruments, only 25 were available in the laboratory. Annual maintenance contracts for instruments were not renewed during 2013-14, 2015-16 and 2016-17. Regular calibration of instruments was not done during 2012-17.

The Food Analyst of FTL, Mumbai accepted (May 2017) that the technical staff and supporting staff were insufficient to carry out the sample testing which led to pendency of food samples.

Food Testing Laboratory, Nagpur

- Though the food testing laboratory at Nagpur was sanctioned in November 2011, the laboratory was partially functional since June 2016. The Food Analyst posted at FTL, Mumbai was also made responsible for analysing food samples received at FTL, Nagpur. She visited Nagpur twice a month. Between June 2016 and June 2017, the Food Analyst visited Nagpur on 20 occasions and analysed only 45 out of 51 informal[23] samples. The food samples drawn by FSOs of FDA, Nagpur were tested at the Regional Public Health Laboratory.

- Though the laboratory was non-functional for a substantial period, an expenditure of ₹ 2.67 crore was incurred during November 2011 to March 2017 on rent, renovations, furniture, machinery and equipment, chemicals and other contingent expenses.

- During 2013-17, 35 instruments/equipment valuing ₹ 1.60 crore were purchased. The warranty of 16 instruments/equipment valuing ₹ 62.22 lakh however, expired before starting the laboratory. Equipment worth ₹ 31.16 lakh purchased (March 2016) for microbiology section was not installed as Air Handling Unit required for the same was not sanctioned by MEDD till November 2017.

[23] Informal samples are those samples whose test reports cannot be used for prosecution in court of law

Uninstalled machineries and equipment at FTL, Nagpur

Food Testing Laboratory, Aurangabad

- The Food Testing Laboratory at Aurangabad functioned intermittently from rented premises between May 2008 and June 2012 for 27 months with the help of a Food Analyst from Public Health Department. Thereafter, it was not functional as no Food Analyst was posted. Therefore, food samples collected by FSOs were sent to Regional Public Health Laboratory, Aurangabad for analysis.

- Under the 13th Finance Commission, equipment and instruments valuing ₹ 1.81 crore were purchased during 2015-16 for FTL, Aurangabad. These equipment and instruments were installed in Aurangabad drugs laboratory as the FTL was not functional.

Food Testing Laboratory, Nashik

- Though land for construction of FTL, Nashik was allotted in November 2011, JC, Nashik had submitted a proposal only in December 2016 to Commissioner, FDA, Mumbai for according Administrative Approval for the construction of FDA building, Testing Laboratory and Godown building at an estimated cost of ₹ 13.17 crore. This had not been sanctioned as of March 2017.

B PHD Laboratories

- Of the five PHD laboratories checked, in two laboratories at Amravati and Aurangabad, the food analyst was holding additional charge of Nagpur and Nashik respectively while there was no PHD laboratory at Nanded and Thane and food samples were sent to FTL, Mumbai and State Public Health Laboratory (SPHL), Pune for testing.

- Food samples from Integrated Child Development Service (ICDS) were not drawn by FSOs in Pune district. In Pune, the food samples sent by ICDS were tested at SPHL, Pune. It was seen that food samples received from Child Development Project Officer, ICDS did not comply with standards of FSS Act. The action initiated against the suppliers could not be ascertained in absence of records/documents.

- As per Regulation 2.10.8 of FSSR, the quality of potable water has to be tested on 51 parameters. SPHL, Pune while testing samples of packaged drinking water received from AC, Nashik, declared them as standard without

testing 12[24] of the 51 parameters. It was not confirmed whether the water was safe and fit for drinking before declaring it standard. JC, Nashik stated (July 2017) that opinion of food analyst would be sought. Similarly, in Thane, packaged drinking water samples were declared standard by testing 43 out of 51 parameters by FDA, Mumbai. In Amravati, only three samples of packaged drinking water were taken during 2012-17.

SPHL, Pune while testing food supplements taken from 22 FBOs and received from AC, Nashik, found that the nutritional values did not match the information given on the label by the manufacturers. This was in the contravention of Regulation 2.2.2 (3) of FSS (Packaging & Labelling) Regulation, 2011. JC, Nashik stated (July 2017) that the AC did not intimate FBOs nor did he take any action to recall these food supplements.

- Test Reports issued by Food analysts of eight selected districts contained disclaimer stating that toxin, contaminants, residue and most of additives were not checked. FTL, Mumbai and Public Health Laboratories at Aurangabad, Nagpur and Nashik stated (July 2017) that due to shortage of equipment, these tests were not conducted. Thus, it was not ensured that the food samples tested were safe for human consumption.

2.1.8.4 Follow-up action under FSS Act

(i) Recall of unsafe/substandard/misbranded material

FSS Act (Section 28) provided that if a food product is unsafe/ sub-standard/misbranded, FBO shall immediately initiate procedures to withdraw the same from the market, inform the competent authorities and consumers indicating reasons for its withdrawal. Further, as per Section 38 of the FSS Act, the FSO may seize any article of food which appears to be in contravention of the Act and keep in safe custody of the FBO by executing a bond for a sum of money equal to the value of such articles with one or more sureties as the FSO deems fit.

In eight selected districts, 2,992 food samples were found unsafe/ sub-standard/misbranded during 2012-17; but there were no documents to show that FBOs had taken action to withdraw sub-standard food products from market. Also, there was no document to show that FSOs had executed a bond for keeping food products in safe custody of FBOs for articles of food.

JCs, Pune, Aurangabad, Thane and Nanded replied (July 2017, August 2017 and September 2017) that no FBO had recalled the substandard products/material and no bond was executed by FSOs. JC, Nashik and Nagpur stated (July 2017) that the said information was not available. JC, Amravati stated (September 2017) that in some cases, notices were issued to FBOs to recall the material but there was no such record of recalled material.

(ii) Adjudication

The FSS Act provided that the State Government may notify an officer as Adjudicating Officer (AO). The State Government notified (2011), JCs as

[24] Tests for Phenolic Compounds, Manganese, Nickel, Silver, Arsenic, Chromium, Mercury, Selenium, Poly Nuclear Aromatic Hydrocarbons, Polychlorinated hydrocarbons, Polychlorinated Biphenyl and mineral oil

AOs. In seven divisional offices, of the 5,902 adjudication cases registered, 1,741 cases were pending as of March 2017. Though penalty amount of ₹ 185.89 lakh out of ₹ 904.08 lakh levied by AOs could not be recovered in 583 cases, their licenses were not suspended as required under Section 6 of the Act. The details are shown in **Table 2.1.11.**

Table 2.1.11: Details of Adjudication cases and pending recovery towards penalty

District	Total number of adjudication cases	Number of disposed cases with penalty	Amount of penalty levied (₹ in lakh)	Number of cases where penalty was recovered	Amount of penalty recovered (₹ in lakh)	Number of cases disposed off but penalty not recovered	Amount of penalty not recovered (₹ in lakh)
Mumbai	520	395	151.66	291	65.73	104	67.41
Pune	1724	1375	219.08	1294	165.55	81	53.59
Nagpur	736	487	70.30	445	57.66	42	12.63
Nashik	850	673	42.27	374	14.27	299	28.00
Aurangabad	561	319	215.94	295	199.67	24	16.26
Thane	1235	702	165.54	702	165.54	0	0
Amravati	276	210	39.29	177	31.29	33	8.00
Total	**5902**	**4161**	**904.08**	**3578**	**699.71**	**583**	**185.89**

- In Nagpur, due to non-accreditation of the food laboratories with NABL, non-appointment of food analysts, delay in filing the cases, test reports not in prescribed format, 108 cases of adjudication were dismissed/acquitted by AO.

- In respect of Sun Feast Yippee Magic Masala Noodles, the test reports were found to be adverse. The AO, Nagpur however, dismissed seven cases on the grounds that the test reports were not in the correct format and also not signed by Food Analyst. Besides noodle was considered to be a proprietary food, for which no standard was prescribed under the Act and Rule.

- In Amravati, during 2015 out of seven adjudication cases of substandard milk, the AO upheld test report of food analyst in two cases while in five cases challenged the food analyst report though same method of testing had been adopted by the food analyst in all the seven cases.

- In Amravati, a separate current bank account was opened on 01 October 2015 in the name of AO and fine/penalty collected in the form of demand drafts was deposited in this account. Between October 2015 and July 2017, fine/penalty amounting to ₹ 11.79 lakh was collected of which ₹ 9.50 lakh was remitted into government account after a delay of three to nine months. Further, FDA, Amravati had seized 26,514 kg of soyabean oil valuing ₹ 21.97 lakh from an FBO which was found unfit for human consumption. The AO directed to sell the oil in presence of FSO and deposit the amount in AO's bank account.

- In Thane, the AO returned 146 number of cases during 2012-14 to FSOs without any action for not complying Rule 3.1.1(3)[25] of the Act.

[25] On receipt of the communication from the AC authorising the filling of the adjudication application, the FSO shall file the application for adjudication with the AO for adjudication of the offence/contravention alleged to have been committed.

- Rule 3.1.1(9) of the FSSR 2011 provides that the AO shall pass the final order within 90 days from the date of first hearing. However, in Nanded, 20 cases were pending for want of first hearing with the AO for the period 2015-17.

(iii) Failure to prosecute FBOs for supplying unsafe/ banned food products

- Section 30 (2) (a) of the FSS Act empowers the Commissioner, FDA to prohibit in the interest of public health, manufacturing, storage, distribution or sale of any article of food, *gutka* or *pan masala*, containing either tobacco and/or nicotine or magnesium carbonate as ingredients, by whatsoever name available in the market and any other products marketed separately having *gutka* or *pan masala*. Further, Sections 41 and 42 of the Act lay down powers and procedure for conducting search, seizure, investigation and prosecution. The procedure for launching prosecution involves inspection, drawing of samples and sending it to laboratory for analysis and based on analysis report, the ACs/Commissioner decide to prosecute the FBOs either before the Adjudicating Officer or Court of Law.

The FSOs seized *gutka* and *pan masala* valuing ₹ 101.86 crore from 5,693 FBOs for violating the prohibition notification during 2012-17. Though FIRs were lodged against 3,973 FBOs, for involvement in unsafe and banned products, no sample was drawn from the seized products for its analysis in the laboratory. Audit observed that 21 FBOs filed (2015) writ petitions in Aurangabad High Court. The Court found that due process was not followed for establishing the fact that seized product was unsafe for human consumption and quashed (March 2016) the criminal cases filed by police against 21 FBOs. Thus, the failure of the FSOs to follow the due process resulted in inability to take action to its finality.

- As per section 59 of the Act, any person who, whether by himself or by any other person on his behalf, manufactures for sale or stores or sells or distributes or imports any article of food for human consumption which is unsafe, shall be punished.

In Nanded, the Maharashtra State Co-operative Consumer Federation, Amravati had supplied (September 2015) peanut (450 Kg) to Ashram school, Sarkhani, Taluka Kinwat. The sample was sent to SPHL, Pune for analysis (December 2015) and the same was reported unsafe (January 2016) for human consumption. FDA, Nanded destroyed (April 2016) the unsafe material but by that time 252 Kg of peanut had been consumed by the inmates. The case was referred to Commissioner, FDA in November 2016 for seeking sanction to prosecute the supplier. No action was however initiated till November 2017 for want of sanction from Commissioner, FDA. Reply of Commissioner, FDA was awaited (November 2017).

2.1.8.5 Drawing of Drug samples

The drawing of samples, testing and follow-up action of drugs is extremely important to ensure that spurious drugs are not consumed by the public. However, audit of the system in Maharashtra has revealed serious discrepancies at almost every stage as detailed below:

As per Section 22 (1) (b) of D&C Act, DIs have power to take samples of any drug or cosmetic (i) which is being manufactured or being sold or is stocked or exhibited or offered for sale or is being distributed, (ii) from any person who is conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee.

In five out of eight test-checked districts, 5,810 drug samples were drawn by the DIs during 2012-17 against the target of 5,956 samples resulting in shortfall of 146 samples. Greater Mumbai, Nagpur and Thane districts did not furnish the information.

Further, the DIs did not collect samples of medical devices such as stents, orthopaedic implants, heart valves during 2012-17 as discussed in **paragraph 2.1.8.6 (v).**

2.1.8.6 Laboratory testing of drugs and cosmetics

Three Drug Control Laboratories (DCLs) were functioning at Aurangabad, Mumbai and Nagpur under the administrative control of FDA for testing of drugs samples. Availability of adequate technical and non-technical manpower, instruments and chemicals is essential for carrying out complete and timely analysis of the drug samples. Audit scrutiny revealed the following:

i) Shortfall of staff in Drug Control Laboratories

The Assistant Director (AD) is the head of the DCL and was responsible for overall functioning of the laboratory. The posts of AD at DCLs, Mumbai and Aurangabad were lying vacant since April 2016. In DCL, Nagpur (functioning from July 2016) though no posts have been sanctioned by the Government, the work was done by appointing officials[26] on deputation from DCL, Aurangabad.

The details of men-in-position *vis-a-vis* sanctioned strength in DCLs Mumabi and Aurangabad as on 31 March 2017 is shown in **Table 2.1.12**.

Table 2.1.12: Men-in-position *vis-à-vis* sanctioned strength as on 31 March 2017

Particulars	DCL, Mumbai				DCL, Aurangabad			
	Sanctioned posts	Men-in-position	Vacancy	Percentage of vacancy	Sanctioned posts	Men-in-position	Vacancy	Percentage of vacancy
Assistant Director	1	0	1	100	1	0	1	100
Sr. Scientific Officer	5	0	5	100	3	0	3	100
Scientific Officer	23	12	11	48	12	7	5	42
Analytical Chemist	20	20	0	0	12	8	4	33
Sr. Technical Asstt.	21	17	4	19	12	12	0	0
Administrative Officer	1	0	1	100	1	0	1	100
Other staff	44	29	15	34	7	3	4	57
Source: Information provided by the DCLs								

The shortage in the key posts of Sr. Scientific Officers and Scientific Officers was alarming and was one of the reasons for the delay in testing of drugs as

[26] Scientific officer:1; Analytical Chemist:2; Senior Technical Assistant:1; Junior clerk cum typist:1

discussed in **paragraph 2.1.8.6 (iii).** Audit also observed that apart from the shortage of manpower, the laboratory staff of Aurangabad and Nagpur DCLs was also not provided training to upgrade their skills. This could affect the ability of the staff to carry out testing properly and on time. However, the laboratory staff of DCL, Mumbai was provided training.

The Commissioner, FDA stated (September 2017) that the proposal for the additional manpower of 176 posts for laboratories was sent (September 2016) to Government and the same was under the consideration of Government.

ii) Issue of test reports without expressing opinion on the quality

As per Section 25(1) of D&C Act read with Rule 46 and 163(5) of D&C Rules, the Government Analyst to whom a sample of drug or cosmetic has been submitted for test or analysis shall submit to the Inspector a signed report indicating whether the sample is of Standard Quality (SQ) or Not of Standard Quality (NSQ). Audit observed that the test reports issued by DCLs contained three categories *viz.* Standard Quality (SQ), Not of Standard Quality (NSQ) and No Opinion (NOP). Details of samples received, analysed and results issued by DCL, Mumbai, Aurangabad and Nagpur during 2012-17 (other than homeopathic[27]) is shown in **Table 2.1.13**.

Table 2.1.13: Details of samples of drugs and cosmetics tested in the DCL during 2012-17

Year	No. of samples pending at the beginning of the year	No. of samples received during the year	Total	No. of samples tested during the year	Result of sample testing done during the year			No. of samples pending at the end of the year
					SQ	NSQ	NOP	
DCL, Mumbai								
2012-13	693	6266	6959	5641	4926	324	391	1318
2013-14	1318	3548	4866	4844	4143	352	349	22
2014-15	22	3104	3126	2969	2469	317	183	157
2015-16	157	3242	3399	2946	2504	244	198	453
2016-17	453	2965	3418	2929	2408	239	282	489
Total		**19125**		**19329**	**16450**	**1476**	**1403**	
DCL, Aurangabad								
2012-13	294	1982	2276	1854	1545	102	207	422
2013-14	422	1144	1566	1472	1214	115	143	94
2014-15	94	1406	1500	1329	1119	134	76	171
2015-16	171	1302	1473	1153	956	122	75	320
2016-17	320	1249	1569	1212	976	119	117	357
Total		**7083**		**7020**	**5810**	**592**	**618**	
DCL, Nagpur								
2016-17	0	140	140	88	76	7	5	52
Total		**140**		**88**	**76**	**7**	**5**	**52**
Grand Total		**26348**		**26437**	**22336**	**2075**	**2026**	

Source: Information furnished by the DCLs

As seen from **Table 2.1.13**, in 2,026 test reports (eight *per cent*) no opinion was given on the samples. 1,589 samples pertained to ayurvedic drugs and 434 samples pertained to other than Ayurvedic drugs.

The Commissioner, FDA stated (September 2017) that unlabelled, informal, Ayurvedic, new and orphaned[28] drugs samples were the reasons for NOP. Due

[27] Samples of homeopathic drugs is not tested in DCLs but tested in laboratory at Gaziabad which is notified by Government of Maharashtra

[28] An orphan drug is a pharmaceutical agent that has been developed specifically to treat a rare medical condition, the condition itself being referred to as an orphan disease

to non-availability of required infrastructure for testing of these drugs in the laboratory, the complete analysis could not be done and inference could not be drawn for its quality.

The fact remained that the issue of test report with no opinion expressed on the quality of drugs tested, was not only in violation of the D&C Act but also handicapped the Licensing Authorities since they cannot take any action on the basis of such test reports.

iii) Delays in testing of drugs and cosmetics

Timely testing of samples is necessary to prevent consumption of NSQ drugs and for initiating action against the errant manufacturers. As per the Standard Operating Procedure prescribed by the Commissioner, FDA, the test reports have to be issued within 90 days of the receipt of samples. The delay in issue of test report noticed in the three DCLs during 2012-17 is given in **Table 2.1.14**.

Table 2.1.14: Delay in issue of test reports during 2012-17

DCL	No. of samples tested	No. of test reports issued		No. of NSQ reports issued after 90 days	Range of delay in respect of NSQ reports (in days)
		Within 90 days	After 90 days		
Mumbai	19329	10745	8584	724	1-370
Aurangabad	7020	5123	1897	117	2-194
Nagpur	88	68	20	0	-
Total	**26437**	**15936**	**10501**	**841**	**1-370**
Source: Information provided by the DCLs					

As seen from **Table 2.1.14**, 10,501 (40 *per cent*) of the test reports were issued after 90 days from the date of receipt of sample in the DCL. The percentage of test reports issued after 90 days was highest in DCL, Mumbai at 44 *per cent*.

The delay in issue of NSQ test reports ranged between one day and 370 days. Analysis in audit revealed that 49 *per cent* of the NSQ test reports *i.e.* 409 out of 841 NSQ test reports were issued with a delay of more than 60 days.

Delayed reporting of NSQ drugs results in consumption of the drugs during the intervening period which could cause a major health hazard to the public. Such delays resulted in high percentage of NSQ drugs being consumed as discussed in **paragraph 2.1.8.7 (A).**

The Commissioner, FDA stated (September 2017) that the reasons for delayed reporting were lengthy coding process, uneven flow of samples, non-availability of testing method, impurity standards, necessary infrastructure and shortage of manpower. The Commissioner further stated that corrective measures such as modifying the process of coding, developing software for inventory control of standards, methods and chemicals, revision in sample drawing methodology and proposal for additional manpower were being taken.

iv) Deficiencies in sample testing

Section 17B (d) and 33EEA (d) of D&C Act provided that a drug shall be deemed to be spurious if it has been substituted wholly or in part by another drug or substance.

The DCLs, Aurangabad and Mumbai reported that the content of active ingredients was less than the prescribed limits in 92 (50 *per cent*) out of 183 NSQ drug test reports[29] test-checked in audit. These samples were, however, not analysed further to ascertain whether the active ingredients were substituted. In the absence of further analysis, a drug could be reported as NSQ, instead of spurious drug which as per Section 36-AC of the D&C Act is a cognizable offence.

The Commissioner, FDA stated (September 2017) that the laboratories were engaged in quality control of Drugs and Cosmetics which included testing of parameters prescribed in the specification. Hence if the quantum of active ingredient was lower than the prescribed limit, it was not further investigated as this required sophisticated and well developed, dedicated research unit. When signs of spurious drugs were visible, investigation/ research for substituted drug was carried out and many spurious cases were detected.

The reply only confirms that samples in the cases test-checked by Audit were not analysed further to ascertain whether the drugs were substituted by another drug or substance to meet the short fall in active ingredients.

Audit also observed that in 193 (23 *per cent*) out of 835 SQ drug test reports test-checked in audit, as per the laboratory protocol, the samples were declared as of SQ without carrying out various tests such as Microbial content/ limit, related substances and uniformity of weight. This was due to lack of working standards[30] from the manufacturer, technical facilities and sufficient quantity of sample. Thus, complete testing was not ensured by the DCLs before issuing the SQ drug reports.

The Commissioner, FDA stated (September 2017) that the testing of samples which remained pending for longer time (due to unavailability of methods, impurity standards, working standards) was carried out as per the specification laid down in Schedule V of Drugs and Cosmetics Act. It was also mentioned in the report that the report for standard for quality was given on the basis of test and assay carried out as given in protocol.

The reply only confirms that the DCLs did not ensure complete testing before issue of SQ drug test reports.

As per Rule 169 of D&C Rules, excipients *i.e.,* additives, preservatives, antioxidants, flavouring agents *etc.,* as per the Indian Pharmacopoeia, Prevention of Food Adulteration Act, 1954 and Bureau of Indian Standard Act, 1986 are permitted for use in Ayurvedic drugs. Scrutiny in audit revealed that during 2012-17, Aurangabad and Mumbai DCLs tested 1,760 samples of Ayurvedic drugs. However, in none of the samples, the use of permitted excipients was tested against the standards, in violation of the D&C Rules.

The Commissioner, FDA stated (September 2017) that neither the methodology nor procedure was available to test excipient/additives in the final formulation. Further, Rule 169 (5) stated that manufacturer shall be

[29] NSQ drugs test reports issued by the DCLs in the month of January of each year from 2013 to 2017 were test-checked

[30] A drug substance of established quality and purity as shown by comparison to the reference standards material and used as reference working substance for routine quality control

responsible to assure rationality, safety and quantity used of various excipients in the formulation.

The reply confirms the Audit finding. In regard to manufacturer's responsibility, the FDA is also responsible to ensure rationality, safety and quantity used of various excipients in the formulation.

v) Absence of adequate infrastructure facilities in the Laboratories

Audit observed that in none of the DCLs medical devices such as stents, orthopaedic implants, heart valves, were tested/analysed during 2012-17. The exception was a few samples of orthopaedic implants which were tested in DCL, Mumbai in February 2017 for corrosion resistance only.

The Commissioner, FDA stated (September 2017) that the DCLs tested the drugs samples received from DIs working in Maharashtra. Medical devices such as stents, orthopaedic implants and heart valves were recently notified as a drug as per notification no. 78(E), dated 31 January 2017 and should be tested in the laboratory notified by Central Government as per notification under Chapter 1.

The reply is not acceptable as the medical devices were already notified by GoI in October 2005. Hence, ensuring the standards prescribed in the D&C Act was an important regulatory function of FDA which was not discharged.

The DCLs in Aurangabad and Nagpur did not have facilities to conduct microbiological test on drugs and cosmetics requiring such tests. DCL, Mumbai alone had the facility to conduct microbiological tests. Due to shifting of all workload to DCL, Mumbai, there was maximum delay in issue of test reports as mentioned in **paragraph 2.1.8.6 (iii)**.

The Commissioner, FDA stated (September 2017) that DCLs, Aurangabad and Nagpur did not have facility to conduct microbiological test, because Aurangabad laboratory was established in a rented premises and open sewage line was flowing adjacent to the building. It was further stated that separate independent building for laboratory was under construction which would be provided with the facility of microbiological testing within a year. Nagpur laboratory was established in rented premises and did not have facility of microbiological testing. The Government had however, also sanctioned funds for separate laboratory building at Nagpur.

In DCL, Aurangabad, 150 batteries connected to UPS which was used for providing power supply to computers and equipment in the event of power failure became unserviceable. The DCL, Aurangabad's proposal (November 2014) for the purchase of new batteries for ₹ 28.47 lakh was pending with the Commissioner, FDA for more than 32 months. Due to non-availability of power backup, risk of damage to equipment on sudden power failure could not be ruled out.

Audit observed that the FDA lost an opportunity to strengthen and upgrade the Laboratories due to non-receipt of approval from MEDD/Finance Department to the proposals submitted by the Commissioner, FDA for purchase of various equipment resulting in surrender of funds of ₹ 30.31 crore during 2012-17 as discussed in **paragraph 2.1.10**.

The Commissioner, FDA stated (September 2017) that the proposal to make the grant available for 120 wet batteries and 154 dry batteries was received from AD, DCL, Aurangabad in May 2015. Accordingly, proposal was sent to Government in September 2015 which is pending for approval.

2.1.8.7 Follow-up of drugs and cosmetics

A Non-recall of "Not of Standard Quality" drugs

The Commissioner, FDA issued (June 2010) guidelines for taking action on Drug samples declared as "Not of Standard Quality" (NSQ) on the basis of GoI guidelines issued (August 2009) on the subject. As per Para 5 of the guidelines, all JCs, ACs and DIs of respective area in whose jurisdiction NSQ Drug manufacturer is located shall take proper steps for effective withdrawal of sub-standard drugs from the market and quick action against erring manufacturers. On receipt of NSQ drug reports from the DCL or from the outside the State, the Licensing Authority issues show cause notice to the manufacturer directing it to recall the NSQ drugs. Accordingly, the manufacturer is expected to recall the drugs and submit compliance to the Licensing Authority. Thus, the NSQ drugs are required to be withdrawn immediately to stop further sale in the market as it poses numerous health hazards to the public.

i) The details of NSQ drug cases reported by Drug Controllers of other States and DCLs of the State during 2012-17, NSQ cases scrutinised in audit and the cases in which more than 50 *per cent* of the NSQ drugs were consumed are given in **Table 2.1.15**.

Table 2.1.15: Details of NSQ cases reported and NSQ drugs consumed in the test-checked districts during 2012-17

District	No. of NSQ cases reported by		No. of NSQ cases scrutinised in audit		No. of cases where more than 50 *per cent* of the NSQ drugs were consumed	
	Drug Controllers of other States	DCLs of Maharashtra State	Drug Controllers of other States	DCLs of Maharashtra State	Drug Controllers of other States	DCLs of Maharashtra State
Aurangabad	51	29	30	25	7	10
Greater Mumbai	0	301	0	80	0	18
Jalgaon	0	48	0	10	0	5
Nagpur	106	313	50	50	8	7
Nanded	0	31	0	20	0	7
Pune	18	48	15	30	6	8
Thane	Not furnished	Not furnished	20	15	5	5
Yavatmal	0	61	0	30	0	9
Total	**175**	**831**	**115**	**260**	**26**	**69**
	1006		**375**		**95**	
Source: Information furnished by the JCs/ACs of respective Divisions/Districts						

Analysis in audit revealed that in 95 (25 *per cent*) out of 375 cases scrutinised in audit, more than 50 *per cent* of the NSQ drugs were already consumed before they were recalled. Of this, in 61 cases, the entire stocks of NSQ drugs were consumed and therefore could not be recalled. Audit observed that in respect of NSQ reports received from Drug Controllers of other States, there was delay even in sending the NSQ reports from the Commissioner, FDA's office to the Licensing Authority concerned in the districts to take action for recalling the NSQ drugs. The time taken in sending the NSQ report in respect

of 25 out of 26 cases scrutinised in audit ranged between 17 days and 196 days.

Licensing Authorities in the test-checked districts accepted (April to July 2017) that due to late receipt of test reports, manpower shortage and lack of infrastructure, recall of entire quantity of NSQ drugs was not possible.

The Commissioner, FDA did not offer specific comment.

ii) Out of 95 NSQ cases in which consumption by the public was more than 50 *per cent*, audit noticed that in 34 NSQ cases the drugs comprising of tablets, syrups, capsules, injections were recalled. The Licensing Authority however, relied on the compliance report submitted by the manufacturer regarding recall of the NSQ drugs without checking the stock recalled by inspecting the manufacturing units. Further, no report of the DIs was available regarding destruction of the recalled drugs.

The Commissioner, FDA did not offer any comment.

B Ineffective pursuance of prosecution cases

As per Rule 51 (5) and 52 (5) of D&C Rules, it shall be the duty of Inspector to institute prosecutions in case of breaches of the Act and Rules thereunder. The details of prosecution cases filed and decided during 2012-17 in the test-checked districts is shown in **Table 2.1.16.**

Table 2.1.16: Details of prosecution cases filed and decided in test-checked districts during 2012-17

District	No. of prosecution cases pending as on 01 April 2012	No. of prosecution cases filed during 2012-17	No. of prosecution cases decided during 2012-17	No. of prosecution cases decided during 2012-17		
				Conviction	Acquittal	Discharge
Aurangabad	45	29	9	0	3	6
Greater Mumbai	476	212	97	31	43	23
Jalgaon	29	15	13	2	7	4
Nagpur	217	62	25	17	2	6
Nanded	19	7	0	0	0	0
Pune	143	62	55	17	4	34
Thane	424	174	75	20	36	19
Yavatmal	23	15	5	0	5	0
Total	**1376**	**576**	**279**	**87**	**100**	**92**
Source: Information furnished by the JCs/ACs of respective Divisions/Districts						

As seen from **Table 2.1.16**, in the test-checked districts, the percentage of cases resulting in acquittal and discharge was very high at 69 *per cent*.

Audit scrutiny of 60[31] out of the total 192 acquittal and discharge cases decided during 2012-17 revealed that the acquittals were mainly because the charges were not proved beyond reasonable doubt, the complainant absent, lack of sufficient evidence, drug found to be of standard quality on testing in Central Drug Laboratory, Kolkata, failure to establish that the samples seized were effectively sealed, no evidence to prove that proper procedure while testing the drugs and its storage was followed and lack of independent witnesses.

[31] 30 Acquittal cases and 30 Discharged cases

The cases discharged were due to non-follow up of cases and because these were pending for a long time *etc.* The reasons for acquittal and discharge indicated that the FDA failed to effectivelly pursue the cases. Further, the MEDD did not have a separate legal cell which resulted in ineffective pursuance of prosecution cases.

The Licensing Authorities in the test-checked districts attributed the low rate of convictions to insufficient manpower, shortage of inspectors for carrying out quality inspections and raids and lack of knowledge of the legal proceedings.

The reply only confirms the need to adequately train the DIs and the FDA may consider a dedicated Legal Cell to provide legal assistance to the staff, required for handling prosecution cases in the Courts.

The Commissioner, FDA did not offer any comment.

2.1.9 Physical Infrastructure

2.1.9.1 Absence of adequate storage space for seized and confiscated drugs

As per Section 23 (5), 23 (6), 31 and 33 (K) of D&C Act read with Rule 58 and 58-A of D&C Rules, the DIs while conducting inspection/ search of any manufacturing and selling unit may also seize stock of drugs, inform the Judicial Magistrate and take his orders for the custody of the same. On conviction of the person for contravening any provision of the Act or any Rule made thereunder, the stock of drugs is liable to be confiscated. As per Court order, the stock of drugs has to be destroyed if the same was not of standard quality or distributed to hospital or dispensary maintained or supported by Government or by Charitable institutions if found to be of standard quality.

Safe custody of seized/confiscated stock of drugs is of paramount importance to prevent its theft, *etc*, loss till its final disposal as per Court order. For this purpose, adequate and safe storage facility is required to keep the seized/confiscated drugs. Proper records have also to be maintained to keep track of the seized/confiscated stock of drugs till its final disposal. The Commissioner, FDA had instructed (March 2015) all heads of FDA offices to provide separate godowns for stocking of seized and confiscated goods and to rent godowns if separate godowns were not available.

Audit observed that two districts (Aurangabad and Yavatmal) out of the eight test-checked districts did not have separate godowns; in the remaining six districts (Pune, Greater Mumbai, Thane, Nanded, Jalgaon and Nagpur) though separate godowns existed, they did not have sufficient space for stocking seized and confiscated drugs. In the absence of separate godowns, seized and confiscated drugs were kept in corridors, lift area, staff area, toilet area, *etc.,* as revealed during joint inspection by audit with FDA officers as shown in the picture below:

Thane

Greater Mumbai

Based on the information furnished by test-checked districts, during the period 2012-17, the FDA seized and confiscated drugs valuing ₹ 24.94 crore. However, proper records showing the storage and disposal were not maintained in any of the test-checked districts. Audit could not ascertain whether the drugs seized/confiscated were available or the same were disposed off as per the Court orders. Further, the Commissioner, FDA did not prescribe a system of periodical physical verification of the seized and confiscated stock of drugs.

It is pertinent to mention that Thane Division office (Drugs) was functioning in dilapidated rented premises. There were heavy leakages during monsoon. Thane Municipal Corporation declared (July 2016) the building as dangerous. The JC requested the Collector, Thane (August 2016) and Commissioner, Thane Municipal Corporation (September 2016) to provide office accommodation but did not succeed in obtaining alternative accommodation. Office staff and visiting stakeholders were exposed to grave risk to their life besides the risk of loss of property kept in the premises.

Deteriorated condition of FDA, Thane (Drugs) office building

The Commissioner, FDA did not offer any comments.

2.1.10 Funding

For proper implementation of the FSS Act, availability of adequate financial resources is imperative. During 2012-17, the Commissioner, FDA demanded ₹ 242.19 crore for Food administration. Against this, FDA received

₹ 89.45 crore only and incurred an expenditure of ₹ 75.48 crore. Funds received for office expenditure, travel, rent, material supply, advertisement and publicity, vigilance activity were not adequate, hampering the critical activities as described in **paragraphs 2.1.8.2 and 2.1.8.3.**

During 2012-17, funds amounting to ₹ 7.45 crore received under 13th Finance Commission grant were released to FDA for strengthening of food testing laboratories. The FDA could however, utilise only ₹ 4.15 crore (56 *per cent*), and the balance amount of ₹ 3.30 crore was surrendered. Under utilisation of funds was attributed to non-completion of *e*-Tendering process and non-receipt of administrative approval from MEDD/Finance Department.

In addition, budget provision of ₹ 53 crore was made for strengthening and upgradation of infrastructure for Drug Control Laboratories (DCLs) during 2012-17, the grants received were ₹ 40.13 crore, however, the FDA was not able to spend ₹ 30.31 crore due to non-receipt of approval of the MEDD/Finance Department to the proposals for purchase of various equipment required for the DCLs. The poor spending in 2016-17 affected the strengthening and upgradation of the Laboratories as discussed in **paragraph 2.1.8.6 (v)**. Administrative approval (AA) of ₹ 5.30 crore was given by MEDD (July 2016) for purchase of instruments/equipment. But the *e*-Tendering process was completed (February 2016) even before obtaining AA.

Audit also observed that the FDA had demanded ₹ 243.50 crore during 2012-17 for construction of FDA administrative office buildings in ten districts[32]. As against demand, Government had approved budget provisions of ₹ 37 crore only. Of this, only ₹ 1.64 crore was received and utilised. The non-provisioning/ release of funds as demanded in various districts has resulted in poor/ inadequate physical infrastructure for the Department as discussed in **paragraph 2.1.9.**

The Commissioner, FDA did not offer any comment on the above.

2.1.11 Information, Education and Communication

2.1.11.1 Information, Education and Communication Activities

In the 8th CAC meeting held in July 2012, the Chief Executive Officer (CEO) of FSSAI highlighted that Information, Education and Communication (IEC) activities provide for a strong base to create awareness and enforce the FSS Act. In the same meeting, the CEO, FSSAI also recommended that Food Safety Commissioners should take up the matter, insisting that the State Governments should plough back at least 75 *per cent* of fees collected through grant of registrations/licenses to FBOs for carrying out IEC activities. It was observed that during 2011-16, GoM realised ₹ 185.04 crore on the above account, but no funds were earmarked for the purpose of IEC.

Due to lack of any IEC activities in the State, educating the society on food safety standards was ineffective.

[32] Amravati, Akola, Aurangabad, Kolhapur, Mumbai, Nagpur, Nashik, Pune, Thane and Washim

2.1.11.2 Lack of effective mechanism for creating consumer awareness

Though the FDA is vested with powers to ensure the quality of drugs, sale of drugs at authorised prices *etc*., consumer awareness about substandard drugs and cosmetics, misleading advertisements, overcharging of prices more than the maximum retail price plays an important role and supplements the efforts of the Department to a great extent. To ensure this, regular dissemination of information though print, electronic media *etc.*, is of vital importance. Further, to protect consumer interest in view of the proliferation of e-Commerce and internet selling of various kinds of Drugs through misleading advertisements, creating consumer awareness assumes even greater significance.

Scrutiny in audit revealed that the FDA did not have an effective mechanism for creating consumer awareness in terms of plans for dissemination of information through print, electronic and other mass media, the nature of information to be disseminated, the periodicity of disseminating the information *etc.*

The Commissioner, FDA stated (September 2017) that mechanism for creating consumer awareness was being prepared and a proposal for comprehensive media plan had been submitted (July 2017) to the Directorate General of Information and Public Relations (DGIPR), GoM. Separate fund allocation of ₹ two crore was also made for this purpose.

The reply confirms that the FDA did not have an effective mechanism for creating consumer awareness.

2.1.12 Monitoring and evaluation

2.1.12.1 Submission of Annual Returns

Food Safety and Standards Rules provide that every manufacturer shall submit annual returns on or before 31 May of each year. Every licensee engaged in manufacturing of milk and/or milk products shall file half yearly returns in the months of October and April.

JC, Mumbai stated (August 2017) that no FBO was submitting the returns. The remaining JCs in test checked districts replied that FBOs were submitting the returns.

The monitoring mechanism was weak as the State and District Level Steering Committees barely held any meetings during 2012-17 as discussed in **paragraph 2.1.5.2.**

2.1.12.2 Deficiencies in monitoring mechanism

Existence of effective monitoring mechanism to ensure the implementation of the relevant Acts and Rules is crucial to detect any deviation and take corrective action for future planning. The Commissioner receives monthly reports from the field offices regarding licenses issued/renewed to manufacturing/selling units, inspection of manufacturing/selling units, action taken on the basis of inspection conducted, prosecution cases pending and preferred, details of sample drawn *etc.* Scrutiny in audit revealed following deficiencies in the monthly reports:

- The monthly reports did not indicate the manufacturing/selling units which have not been inspected for more than one year so as to identify the districts which are lagging behind in inspection, for appropriate action.
- The stock of seized/confiscated drugs held, physical verification of such drugs, the status of its destruction or distribution to Government hospital/Charitable institutions as per Court order, were not indicated.

Further, there was no Management Information System in respect of the following key issues:

- The time taken by the three DCLs in issue of test reports on the drug samples along with the reasons for the delay.
- Number of manufacturing/selling units whose licenses have expired, number of licenses suspended, inspection done or pending in respect of such expired/suspended licenses.
- Number of licenses which were renewed without inspections.

The above deficiencies therefore indicated weaknesses in the monitoring mechanism.

The Commissioner, FDA did not offer specific comments.

2.1.13 Conclusion

The Performance Audit on 'Food and Drugs Administration' covered test-check of records for the period 2012-2017. Audit emphasised on the functional presence of the requisite infrastructure, resources with an adequate administrative and regulatory framework for implementation of the relevant Acts.

Audit revealed that important areas of Food and Drugs Administration (FDA) required immediate attention of Government and prompt remedial action for an effective management of citizens' health. The important findings are highlighted below:

- **State Level Steering Committee under the Food Safety and Standards Regulations 2011, met only twice during 2012-17. Of 30 district offices, meetings were not held in 28 district offices during 2012-17.**
- **Survey was not undertaken to develop a database on Food Business Operators (FBOs). Against the estimated 16.86 lakh FBOs in the State, only 9.43 lakh (56 *per cent*) were registered/licensed as of March 2017.**
- **Only 20 *per cent* Assistant Commissioners (Food) and 18 *per cent* Food Safety Officers (FSOs) were on establishment as against the requirement assessed by Commissioner, FDA for the State.**
- **The Drugs Division offices were functioning by giving additional charge to Assistant Commissioners while Drug Inspectors were also given additional charge of Assistant Commissioners. There was shortfall of 37 *per cent* in the post of Drug Inspectors.**
- **FDA had failed to take action to cancel the licenses of 1,535 Drug selling units whose licenses had expired, thereby posing a risk to public health by the possible sale of drugs by such units.**

- **The renewal of Drug selling licenses was done without inspection of the premises of the selling units. Inspection/survey was not done to verify that the Drug selling/manufacturing units were not involved in any activities during the suspension period.**
- **There were serious shortfalls in the inspection of FBOs, Drugs manufacturing and selling units. The shortfall was to the extent of 35 *per cent* in the case of Drugs manufacturing units and 63 *per cent* in the case of selling units.**
- **Sampling to ensure quality showed serious deficiencies.**
  - **Samples of infant food, instant milk substitutes, meat and fish products, fruits and vegetables were not taken for testing.**
  - **Microbiological tests for food samples were not carried out as there was no microbiological division and thus, pathogenic bacteria, yeast and mould could not be tested raising serious food safety concerns. Tests to analyse the contents of metals, toxic substance and insecticides articles were also not being done due to non-availability of requisite equipment.**
  - **'Gap Analysis Report' of October 2013 based on study carried out by the FDA, brought to the fore issues relating to infrastructure, equipment, man-power in food laboratories but the Department did not initiate any action till November 2017. Of the three Food Testing Laboratories (FTLs) test-checked in audit, FTL at Mumbai only was found functional resulting in dependence on the Public Health Laboratories for testing of food samples drawn by FSOs.**
  - **Test Reports issued by Food analysts of eight selected districts, contained disclaimers stating that toxin, contaminants, residue and most of the additives were not checked.**
  - **The DCLs at Aurangabad and Mumbai issued 2,026 test reports during 2012-17, without expressing any opinion on the samples of drugs tested. Test reports on the drugs tested were issued after 90 days from the date of receipt of sample in the DCLs, in 10,501 (40 *per cent*) samples tested.**
  - **The DCLs in Aurangabad and Nagpur did not have facilities to conduct microbiological test on drugs and cosmetics and as a result all the samples were being sent to DCL, Mumbai, where they were unable to cope with the volume of work. Opportunity to strengthen and upgrade the DCLs by purchasing various modern equipment was lost despite availability of funds due to non-receipt of approvals from MEDD/Finance Department to the purchase proposals of the FDA.**
- **The delay in recalling Not of Standard Quality (NSQ) drugs resulted in consumption of the NSQ drugs by the public. In 95 (25 *per cent*) out of 375 cases scrutinised in audit, more than 50 *per cent* of the NSQ drugs were already consumed before they were recalled. Of this, in 61 cases, the entire stocks of NSQ drugs were consumed and therefore could not be recalled.**

- **The monitoring mechanism was weak in view of absence of periodical reports on various key issues as also deficiencies in the reports submitted to the Commissioner, FDA. The percentage of cases resulting in acquittal and discharge of offenders was very high at 69 *per cent*.**

The deficiencies identified above clearly indicate the failure of the Medical Education and Drugs Department in ensuring that the food consumed by the Public is of standard quality. Further, even the quality of drugs supplied is not ensured due to inadequate testing and failure to follow-up effectively.

This can have serious consequences for the health and welfare of the public.

2.1.14 Recommendations

- **The State Government may conduct a survey and create a database of FBOs which should be updated periodically so as to bring maximum FBOs within the ambit of the FSS Act. The Government may also strengthen the enforcement structure for effectively carrying out regulatory functions by duly addressing the issues of staff shortages on priority.**
- **The Government may streamline the procedure of licensing and registration. The State Government may ensure strict monitoring of license holders whose licenses have expired or suspended. The State Government may ensure that internal targets for inspection of the licensing units are fixed considering the risk profile and also ensure that the licensed units do not remain uninspected for a long period of time.**
- **The Government may establish additional food testing laboratories to meet the requirement of entire state and also ensure that non-functional food testing laboratories are made functional with requisite equipment, infrastructure and manpower for effective implementation of the Act.**
- **The State Government may ensure that testing of drugs and cosmetics is done expeditiously by providing the required manpower, equipment and material for conducting the tests. The Government may also ensure safety, efficacy, purity and quality of drugs and cosmetics by carrying out all the required tests through well-equipped Drug Control Laboratories.**
- **The Government may review the reasons for delay and take concrete steps for timely recall of Not of Standard Quality Drugs to minimise the risk of its consumption by public. The Government may also consider setting up of a dedicated Legal Cell to provide legal assistance to the staff for handling prosecution cases in the Courts to ensure maximum convictions.**

School Education and Sports Department

2.2 Management of Sports Infrastructure in Maharashtra

Executive Summary

The State Government formulated the new Sports Policy, 2012 revising the earlier policy of 2001 for preserving the rich sports culture of the State and to equip the sportspersons in the State to face the challenges at international level.

A Performance Audit of Management of Sports Infrastructure in Maharashtra of School Education and Sports Department for the period 2012-17 revealed that though the Government of Maharashtra had formulated the Sports Policy 2012, it was yet to be translated into action plan. No long term plan was prepared for implementation of the Policy. There were delays in execution of schemes due to non-acquisition of land, change in design/scope of works and short or late-release of funds. There was short-release of funds for maintenance and repairs too. As a result, the infrastructure created could not be optimally utilized. The functioning of sports academies also suffered from number of problems *viz.*, less intake, inadequate coaching, lack of sports facilities and basic amenities and this impacted the performance at National, State and International level games. Though emphasis was given on creation of sports infrastructure, in absence of qualified and capable coaches and focused training, it failed to yield the desired outcome. The release of funds was significantly less than the demands made.

The deficiencies mentioned above indicated that even after incurring huge expenditure of ₹ 576 crore, the Sports Department was unable to create adequate sports infrastructure, its proper maintenance and coaching facilities to the sportspersons thereby compromising performance of the sportspersons.

2.2.1 Introduction

For preserving the rich sports culture of the State and for facing the challenges at international level, the State Government formulated new Sports Policy, 2012 revising the earlier policy of 2001. There were 10 main elements of this sports policy namely, (i) creation of basic sports infrastructure; (ii) preparation of national/international players and financial assistance for advanced training; (iii) incentives and felicitation of sportspersons, (iv) creation of sports atmosphere; (v) organisation of sports festivals, (vi) development of technical manpower; (vii) establishment of sports university; (viii) incentives to the institutions working for development of sports in the State; (ix) promotion of adventure sports in the State; and (x) establishment of high power committee for implementation of the policy.

2.2.2 Organisational set-up

The Principal Secretary, School Education and Sports Department (SESD) is the administrative head of the Department. The Director of Sports and Youth Services, Pune (DSYS) is responsible for implementation of various sports

schemes. He is assisted by one Joint Director and three Deputy Directors at Pune. There are eight Deputy Directors responsible for management of sports infrastructure at division level. At district level, the responsibility of sports related affairs is vested with District Sports Officer (DSO). The Deputy Directors and DSOs report directly to the Director of Sports and Youth Services, Pune. The DSOs are assisted by Taluka Sports Officers.

2.2.3 Audit objectives

The objectives of the performance audit were to assess whether:

- the plans formulated by the Department for implementation of Sports Policy, 2012 were comprehensive; and factored in the emerging requirements;
- creation, maintenance and utilisation of physical infrastructure was efficient and effective;
- functioning of sports academies along with coaching and training facilities led to creation of a high quality pool of players; and
- sound financial practices were followed in release and utilisation of funds.

2.2.4 Audit criteria

The audit findings were benchmarked against criteria derived from the following sources:

- Sports Policy 2001; and Sports Policy 2012;
- Maharashtra Treasury Rules (MTR), 1968 and Maharashtra Public Works Manual (MPWM), 1984;
- Government resolutions (GRs), orders, guidelines *etc.*

2.2.5 Audit scope and methodology

A performance audit on "Management of Sports Infrastructure in Maharashtra" was conducted between January and July 2017 covering period of five years from 2012-13 to 2016-17. Audit examined the effectiveness in implementation of New Sports Policy 2012 with reference to the four features, out of total ten features, namely (i) creation of basic sports infrastructure, (ii) preparation of national/international players and financial assistance for advanced training, (iii) organisation of sports festivals, (iv) development of technical manpower. Records maintained by the SESD, Mumbai; DSYS, Pune, eight divisions[1] and eight districts[2] selected by Stratified Random Sampling Method were scrutinised during the course of audit. Besides, records of selected Taluka Sports Complexes (TSCs) and Sports Academies falling under the selected eight districts were also scrutinised with joint inspections of selected sports facilities along with the departmental officials.

An entry conference with the Principal Secretary, School Education and Sports Department (SESD), Government of Maharashtra (GoM) was held on 7 February 2017 wherein the audit objectives, scope and audit methodology of the PA were discussed. The draft performance report was issued to the State

[1] Nagpur, Amaravati, Aurangabad, Latur, Nashik, Pune, Kolhapur and Mumbai
[2] Nagpur, Amaravati, Aurangabad, Nanded, Nashik, Pune, Ratnagiri and Thane

Government in August 2017. The audit findings were discussed with the Principal Secretary (SESD) in an exit conference held on 9 November 2017. During exit conference, the Principal Secretary, SESD accepted all the recommendations suggested by audit.

Audit findings

2.2.6 Policy and planning

In order to achieve the objectives envisaged in the Sports Policy 2012 (Policy), a well-thought out plan specifying the objectives, allocation of limited resources in accordance to the priorities, fixing of schedule of execution and periodical targets was a pre requisite. The Sports Policy 2012, stipulated that the Sports Department should conduct a survey to collect the information on available facilities like gymnasium, playgrounds, swimming pool, playfields of different sports. The information was to serve as input for future planning of projects. Further, in order to implement the Policy, Government Resolutions (GRs) containing detailed instructions were required to be issued for each feature of the policy.

However, it was observed that

- GoM did not prepare any long term plan for implementation of Sports Policy 2012.
- a Government Resolution for conducting survey was issued only in February 2014. In none of the eight selected districts, the district-wise information on sports facilities, games and players prepared and consolidated.
- although five years had elapsed since the Policy came into force, GRs on only 33 out of 66 sub-points of the policy had been issued. Out of the remaining sub-points, GRs on 18 sub-points were under process while for 15 sub-points like Construction of sports complexes and their maintenance, Adventure Sports, participation of schools in competitions, *etc*., no proposal had been initiated by the Department as of March 2017.

  Thus, the policy, in its entirety, was yet to be translated into administrative action. Audit findings are discussed in the succeeding paragraphs.

During exit conference, the Principal Secretary, SESD, stated (November 2017) that a High Level Committee had been set up under the Chairmanship of Chief Minister and also stated that necessary action would be taken at Government level.

2.2.7 Creation of Infrastructure

2.2.7.1 Development of Sports Complexes

The status of Sports Complexes in the state is shown in the **Table 2.2.1.**

Table 2.2.1: Status of Sports Complexes in Maharashtra State

Type of Sports Complex	Target	Total cost (₹ in crore)	Achievement (No.)			Cost of completion (₹ in crore)
			Completed Complexes (2012-17)	Work in progress	Not yet started	
Divisional	9*	216[3]	3	4	2	140.62
District	31[4]	248[5]	18	11	2	179.47
Taluka	381	381[6]	70	138	173	150.46
Total	**421**	**845**	**91**	**153**	**177**	**470.55**

Source: Information submitted by Director, Pune
* Note: Out of 9 divisional sports complexes, one sports complex of Navi Mumbai was not sanctioned by GoM.

As of July 2017, only 91 Sports complexes were completed as against the target of 421. In selected divisions, districts and talukas, the work on sports complexes at all three levels was found to be delayed or incomplete due to non-release of funds, non-availability of land, incorrect site selection and contractual issues. Audit findings are discussed below:

Non-release of funds

- Sports complexes with basic sports amenities were to be developed for meeting National and International Standards at Divisions, Districts and Talukas. An amount of ₹ 33 crore was earmarked (March 2009) for the construction of the same. It was noticed that the GoM had released the grants to the Deputy Directors/District Sports Officers concerned in instalments. Due to this, there were delays in completing the construction works.

At taluka level, in 20 talukas of 14 districts, the construction of TSCs could not commence due to non-release of funds by the GoM even though these works were administratively approved by the competent authority. On the other hand, grant of ₹ 9.57 crore was released to 26 TSC committees although land had not been acquired. The entire grant was, therefore, lying unutilised as of December 2016.

During exit conference, the Principal Secretary, SESD, accepted the facts and stated (November 2017) that grants were released as per availability of funds.

Non-availability of land

- In Aurangabad division, instead of selecting revenue-free land for construction of divisional sports complex, the land of Co-operative Spinning Mill Society (28 Acre) having a liability of ₹ 8.78 crore was selected. An amount of ₹ 32.78 crore[7] was granted to the divisional sports complex committee.

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3 @ ₹ 24 crore for each divisional sports complex
4 Out of 36 districts, GoM had sanctioned only 31 districts for construction of sports complexes
5 @ ₹ 8 crore for each district sports complex
6 @ ₹ 1 crore for each taluka sports complex
7 Clearing the liability of ₹ 8.49 crore and constructing the complex at ₹ 24 crore

- The Divisional Sports Complex Committee, Mumbai had decided (March 2013) to construct the sports complex at Shimpoli, Mumbai on the land handed over by Maharashtra Housing and Area Development Authority (MHADA). Accordingly, project cost was estimated at ₹ 177.94 crore against which the Committee received (January 2014) ₹ 11.86 crore from the GoM. But work could not commence due to demand of ₹ 55.47 crore by MHADA on account of lease rent. As of March 2017, the issue had not been resolved.
- As per GR (December 2005), it was mandatory for the Sports Department to sign a memorandum of undertaking (MoU) with the Government entity whose land was being acquired prior to taking up construction so as to prevent any future dispute on land or created assets. However, it was noticed that in Nanded, the work of District Sports Complex was started (2000) without signing MoU with Nanded Municipal Corporation. An expenditure of ₹ 6.61 crore was incurred by the sports department on the above land for various sports infrastructure. In the absence of MoU, the Municipal Corporation took over the possession of the open stadium and constructed a cricket ground at the same site despite having issued a no objection certificate for the construction of sports complex. The DSO, Nanded took up (February 2017) the matter with the Sports Complex Committee to recover the amount of ₹ 2.75 crore from Nanded Municipal Corporation. However, there has been no further action.
- Out of 273 TSCs administratively sanctioned by Government, 25 TSCs in 15 districts remained incomplete or were abandoned due to non-acquisition of land and court cases. Only 3.86 *per cent* work was executed as of December 2016 after incurring an expenditure of ₹ 3.70 crore out of total grant of ₹ 17.89 crore released by the GoM. The remaining grant of ₹ 14.18 crore was lying unspent with the TSC committee account concerned.

During exit conference, the Principal Secretary, SESD stated (November 2017) that due to non-availability of revenue free land and the selected land falling in the prime location of city, the land of spinning mill was acquired. In case of Mumbai, necessary correspondence with MHADA was in progress. He further stated that due to non-execution of MoU, Corporation took away the possession of the open stadium in Nanded and also stated that the proposal for revision of construction cost of TSCs is being submitted which is under consideration in respect of all the sports complexes.

Incorrect site selection

- With a view to construct District Sports Complex and International Sports University in Thane, land admeasuring 195.823 sqm was handed over (September 2011) by Revenue & Forests Department (GoM) to the Sports Department. Thereafter, State Sports Development Committee decided (July 2012) to construct a compound wall so as to avoid any encroachment on the said land. As against the total area of 3700 meters, construction work of 400 meters was completed by incurring expenditure of ₹ 78 lakh. However, based on a decision taken by GoM in meeting (January 2015) the afore mentioned land was to be taken up for assessing its viability for

development of Central Business District. Thus, decision on use of land for constructing DSC was still in limbo as of March 2017.

- In violation of GoM instructions to construct sports complex in district headquarter, an amount of ₹ eight crore was sanctioned (March 2016) to construct district sports complex at Gada, Kamptee taluka at Nagpur district which was 30 Km away from Nagpur with a population of 15,000.

  Out of 25 test-checked talukas in selected eight districts, in two[8] talukas *viz*. Bhokar in Nanded and Phulambri in Aurangabad, the selected sites were not appropriate for construction of TSCs due to hilly terrain and inaccessibility of the sites as seen from the photographs below:

	
Hilly land selected for construction of complex at Bhokar taluka	***Hilly land selected for construction of complex at Phulambri taluka***

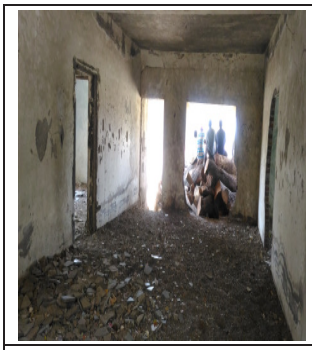
During exit conference, the Principal Secretary, SESD stated (November 2017) that necessary action in this regard was in progress.

Contractual issues

- In Amravati divisional sports complex, synthetic sports flooring system in badminton hall was not executed by the original contractor, though it was one of the tendered items. Later the work was executed by another contractor at a rate, higher by ₹ 0.27 crore.
- In Nashik, the work of divisional sports complex was awarded (July 2009) to a contractor at a tendered cost of ₹ 15.89 crore. However, due to slow progress, the contract was terminated in January 2014. The balance work of ₹ 1.65 crore was retendered at a cost of ₹ 8.23 crore through twelve different agreements during 2014-15 and was yet to be completed as of July 2017.
- In Kolhapur, the work of divisional sports complex was awarded (July 2009) to a contractor at a cost of ₹ 18.01 crore with a stipulated date of completion as January 2011. An expenditure of ₹ 15.57 crore was incurred upto September 2015 *i.e*. the extended period. This included ₹ 3.19 crore spent on swimming pool. But, the swimming pool could not be put to use due to design fault leading to accumulation of rain-water. However, the work was yet to be rectified as of July 2017 even after a lapse of eight years.

[8] Bhokar (Nanded) and Phulambri (Aurangabad)

- In 11[9] talukas, the works on complexes were 90 *per cent* complete after spending ₹ 8.20 crore. The works were left incomplete owing to rise in rates and contractors' reluctance to execute the work as per tendered rates. As a result, the complexes were lying unutilised and in a deteriorated condition as can be seen from the pictures taken during field visit by the audit team during March, May and July 2017 respectively:

		
TSC Khultabad (Aurangabad)	*TSC, Mulshi (Pune)*	*TSC, Guhagar (Ratnagiri)*

During exit conference, the Principal Secretary, SESD, stated (November 2017) that as per public demand the rollable mats were installed in the badminton court in Amravati. He further stated that the review of sports complexes would be conducted and necessary instructions for rectification would be issued to concerned contractors. In respect of Nashik the security deposit of the original contractor has been deposited with divisional sports complex committee and at present 90 *per cent* work was completed. The reply is not acceptable as only ₹ 3.19 crore was recovered against the total recoverable amount of ₹ 6.58 crore from the contractor.

Development of Playgrounds

GoM released 'District Planning and Development Council' (DPDC) grant of ₹ 53.88 crore to 1,220 institutions during the period 2012-17, for development of playgrounds. Test-check of 81 cases (25 *per cent*) out of 323 cases in selected eight districts revealed omissions/ irregularities in 23 cases involving an amount of ₹ 1.04 crore, as shown in **Table 2.2.2**:

Table 2.2.2: Details of omissions/irregularities noticed in 23 cases

District	No. of cases	Nature of omission/ irregularities
Aurangabad (2), Nanded (2), Nashik (3), Thane (1)	8	Grants for playground development were released to the institute/ organisations having no playfield.
Aurangabad (2), Nanded (4), Nashik (2), Thane (2), Pune (1)	11	Beneficiaries/ institutes utilised the grants for other purposes.
Nanded (1), Nashik (1), Thane (1), Pune (1)	4	In spite of release of grant the institute/ beneficiaries have not constructed/ completed playground.

[9] Tiwasa (Amravati); Khultabad (Aurangabad); Kannad, Kandhar, Loha (Nanded); Chandwad; Mulshi, Haveli (Pune); Guhagar, Chiplun (Ratnagiri); and Sinner (Nashik)

Development of Gymnasia

For development of gymnasia, GoM released DPDC grant of ₹ 88.32 crore to 1956 institutions which benefited under the scheme during the period 2012-17. Test check of 113 cases, out of 453 cases in selected eight districts, revealed omissions/irregularities in 33 cases involving an amount of ₹ 1.82 crore, as shown in **Table 2.2.3**.

Table 2.2.3: Details omissions/ irregularities noticed in 33 cases

District/No. of cases	No. of cases	Nature of omission/ irregularities
Amravati (2), Nasik (1), Pune (5), Nagpur (2)	10	The equipment supplied were stored in a room without utilisation
Aurangabad (1), Nanded (1), Nasik (1)	3	Grant given for construction of gymnasium hall was utilised for other construction.
Nanded (2), Nasik (1)	3	Incomplete gymnasium hall in-spite of grants released two years back
Aurangabad (1), Nasik (1)	2	Constructed gymnasium hall used for class room by the educational institutions
Aurangabad (1)	1	Grants for construction of gymnasium hall was given to the school having classes only upto IVth standard
Aurangabad (1)	1	The grant was sanctioned for gymnasium on the land where lease period is less than 30 years
Ratnagiri (1), Nasik (1) Pune (2), Nagpur (3)	7	Grants were released for construction where the construction area was below/against the norms
Thane (2), Pune (2), Nagpur (2)	6	Short/non supply of equipments against the release order

During exit conference, the Principal Secretary, SESD, stated (November 2017) that the state level squad would be prepared the issues of playground and gymnasia would be reviewed and accordingly appropriate action taken.

2.2.8 Working of Sports Academies

Sports Academies are meant to give specialised training, nutritious diet, and adequate and modern sports facilities for creating international level sportspersons.

2.2.8.1 Residential sports academies

Government established 11 residential sports academies[10] in the State with intake capacity of 1,045 players including the academy at Pune which controls the functioning of remaining ten academies. Accordingly, boys and girls between eight to 14 age groups are selected through a selection process formulated by the Sports Authority of India comprising a "Battery of Tests" (BT). All the selected players are provided with sports training as well as school education and the expenditure thereof is borne by the State Government.

[10] Pune, Sangli, Kolhapur, Thane, Nashik, Akola, Pravaranagar, Aurangabad, Amravati, Gadchiroli and Nagpur

Out of 11 sports academies, Sports Academy at Pune catered to the needs of all 11[11] disciplines while six academies had coaching for two disciplines and remaining four academies had coaching for only one discipline.

Test check of records in six[12] selected sports academies revealed the following discrepancies:

- The Sports Academy, Amravati, identified for specific training in archery did not have range required as provided in the Sports Authority of India (SAI) guidelines *i.e.* 70 meters along with 20 meters space of safety zone and 20 meters behind shooting line; instead the academy had provided a small space without observing safety norms. Also, the required equipment and teaching aid for archery game was not provided during the review period.
- The Sports Academy at Aurangabad has been identified (2013-14) for training in hockey and athletics. The academy, however, has not been provided with the synthetic track along with sport equipment required for athletics practice as per type plan for sports complexes. Also, hockey ground was not established in the academy.
- In Sports Academy at Thane, accommodation to players was provided under the staircase of spectator's gallery of the Municipal Corporation's stadium. The rooms had seepage and were used to store gymnasium equipment. Though the Academy was identified for specific training in badminton and athletics, there was no coach for either of the games since 2015-16.

Students accommodated under staircase of stadium and Sports equipment dumped in hostel room at Thane academy

- As per Sports Academy Guidelines, 1997, room for kitchen and dining shall be separate, however, in Sports Academy at Nashik, it was observed that the kitchen and dining activities were carried out in one small room.
- Common diet was provided to all players, instead of game-specific diet except in Sports Academy, Pune.
- As per Sports Academy Guidelines, 1997, Sports Medical Officers were required to visit the academies; however, audit observed that except in

[11] Athletics, swimming, Judo, gymnastic, hockey, shooting, football, triathlon, cycling, table-tennis and weight lifting

[12] Amravati, Aurangabad, Nagpur, Nashik, Pune and Thane

Pune out of six academies, Sports Medical Officers had not visited the academies for examining periodical physical progress of sportspersons.

- As per Sports Academy Guidelines, 1997, advance training by experts to be given by appointing coaches of international repute for high performance at International level. However, this was not done. No facility of medical room and necessary first aid kit was found readily available in the hostel except Pune.
- As per Sports Academy Guidelines, 1997, insurance of trainees had to be taken from the Insurance companies for medical expenses. However, it was noticed that no insurance was taken for trainees' medical expenses.

During exit conference, the Principal Secretary, SESD stated (November 2017) that a proposal to provide separate range for archery was in consideration of Amravati. He further stated that necessary action had been initiated in respect of Aurangabad and Thane. Diet would be provided as per games and proposal for necessary supporting staff is under consideration.

2.2.8.2 Underutilisation of Sports Academies

As against the total intake capacity of 1045 players in 11 sports academies, during 2012-17, actual intake was between 563 (2014-15) and 771 (2012-13); intake ranged between 54 *per cent* and 74 *per cent*. The main reason for lower intake was found to be the BT under which capability and talent of players was assessed through nine rigorous tests and pupils securing at least 63 *per cent* were given admission in the academy.

Considering the under utilisation of sports academies, Sports Policy 2012 had proposed to relax the selection process and to appoint an Expert Committee for revaluation of BT. Accordingly, Committee for examining the BT and suggesting modifications, was appointed in September 2012. The Committee submitted its report in March 2015. However, no action has been taken by the Government on the report of committee.

During exit conference, the Principal Secretary, SESD, accepted the facts and stated (November 2017) that to enhance the number of players from this seasons, two separate tests with BT had also been included.

2.2.8.3 Non-residential Sports Academies

The Sports Policy 2012 and the GR of September 2013 envisaged establishment of non-residential sports academies in the existing residential sports academies on priority basis. It was also permitted to start non-residential sports academies by voluntary organisations where the facilities of sports academy or facilities for a particular game are not available. One non-residential academy was required to be opened in every district with maximum of 25 players. The monthly honorarium of ₹ 15,000 to Coaches and daily diet expenses ₹ 50 was payable to players. The players were also entitled to get sports uniform, sports kit and other expenses *viz.* travelling, daily allowances for taking part in competitions. It was observed that out of 11 existing sports academies, non-residential sports academies were started only in five academies at Akola, Amravati, Kolhapur, Nashik and Pune. During the year 2013-14, no grant was received for non-residential academies due to late submission of proposal for grant. In 2015-16, grant amounting to

₹ 0.21 crore was surrendered. Thus, in absence of concerted efforts to publicise the non-residential facility along with lack of regular fund-flow, the desired outcome was not achieved.

The performance of the sportspersons from the Academies displayed a downward trend from 252 medals in 2012-13 to 81 medals in 2016-17 at National level games. The percentage of medals won by inmates of Sports Academies compared to the total medals won by State went down from 33 *per cent* in 2012-13 to 13 *per cent* in 2016-17. Further, at International level, the academy students could win only one bronze medal at Asian Games and three in Commonwealth Games during the review period.

During exit conference, the Principal Secretary, SESD stated (November 2017) that the action has been initiated to start non-residential academies by giving wide publicity and sufficient funds.

2.2.9 Coaching camps

The Sports Policy 2012 proposed to prepare action programme for improving the performance of players through providing expert guidance of Indian/Foreign coaches, balanced diet, regular training and organising two State level training camps of 30 days in a year. Accordingly, GoM issued (February 2014) instructions for organising two State level camps for 15 games, for the players excelling at national and international levels. An estimated grant of ₹ 1.96 crore was also to be sanctioned for this purpose. For organising minimum 10 day training camp at district level twice a year by utilizing the facilities available in the taluka and district complexes. A grant of ₹ 0.14 crore was to be provided to every such training centre for organising two camps a year for 50 players each (50×2 = 100 players).

It was observed that during 2014-15, as against 15 games, the state level camps were organised for 12 games, except Sailing, Rowing and Lawn tennis. As against the required participation of 1,183 players, only 579 players participated in the games. An expenditure of ₹ 0.55 crore was incurred and grant of ₹ 0.63 crore was surrendered during the year 2015-16 as against 15 games, camp for 12 games was organised with participation of only 401 players against the entitled 1,183 players, expenditure of ₹ 0.37 crore was incurred against sanctioned grant of ₹ 0.96 crore and grant of ₹ 0.59 crore was surrendered. The grant for organising camp for the year 2016-17 amounting to ₹ 1.57 crore was received on 30 January 2017. However, the camps could not be organised due to election and board exams.

Similarly, no grants were released for organising district camps in 2014-15. In the year 2015-16 against the provision of ₹ 5.07 crore for 35 districts, Government released only ₹ 2.48 crore due to which the Directorate could cater to the requirement of only 25 districts. Out of nine districts, proposals were received from six districts but Directorate, Pune could not distribute the grant. In 2016-17, Government released only ₹ 3.21 crore to 34 districts. However, in six selected districts, the grant was neither utilised nor surrendered in the same financial year.

Thus, despite availability of funds, the camps for required number of games were not being organised regularly. The participation of players in the camp was much less than the expected turn-out. As a result, the purpose of

providing an edge to the potential players through focused training in camps could not be achieved.

During exit conference, the Principal Secretary, SESD, stated (November 2017) that necessary efforts will be taken to encourage the players for participation in District and State level camps.

2.2.10 Coaching Centres

District coaching centres (DCC) were established across the State with a view to inculcate sports culture, provide coaching facilities and sports infrastructure for various games to boys and girls in the rural and urban areas and to promote sports in the State. The departmental coaches impart training to the sportspersons and prepare them for State competitions in various disciplines in these centres on a regular basis. Similarly, it was decided (March 2003) that Taluka Coaching Centres should be a part of TSCs. Each TSC was to have one Taluka Sports Officer (TSO), two coaches, one sports officer, one junior clerk, one peon and one ground man/watchman.

It was observed that though 117 coaches were shown on rolls of 117 DCCs, 23 of them were posted in the sports academies; thereby bringing the effective number to 94 coaches. Regular coaches were not appointed at Washim, Hingoli, Nandurbar and newly formed Palghar district. The services of 153 coaches appointed on honorarium basis were discontinued in June 2015. There were wide variations in the number of disciplines available for coaching across DCCs. While Akola and Dhule had coaching centres for six discipline, Pune had four disciplines whereas Ratnagiri, Sindhudurg, Jalna and Beed had centres for only two disciplines. Further, transfer and posting of coaches at DCCs was not linked to trainees or disciplines offered for a particular game/sport. A coach of a particular game was transferred and replaced by a coach of different game. It was seen that Cricket coach was replaced by badminton coach, athletics coach replaced by khokho coach and gymnastics coach replaced by swimming coach. As a result, the training in that particular discipline was affected and due to lack of continuity, the trainee already undergoing training in that particular game had to leave the centre midway, adversely affecting the progress.

It is pertinent to mention here that Directorate, Pune had submitted (May 2017) proposal to Government for granting exemption to coaches from transfer policy and fix a minimum period of eight years so as to ensure continuity in the performance of players.

In respect of Talukas, out of 381 talukas in State, only 135 TSCs were used for coaching purpose. In 65 TSCs out of 135, the sports facilities were inadequate since the construction work was in progress in these talukas. Only 18 TSOs were appointed against the sanctioned strength of 97 TSOs on regular basis. Out of completed 70 TSCs and 138 ongoing TSCs, sports officers were not appointed in any of the TSCs.

Further, 224 coaches, 93 junior clerks, 98 peons and 94 security guards were appointed on honorarium basis at a meagre monthly remuneration of ₹ 5,000 to coaches, ₹ 1,000 each to Jr. Clerk, peon and watchman. Moreover, it was being paid in lump sum at the end of the year. Hence, due to less remuneration

and delayed payment, no qualified staff was willing to join these centres which adversely affected the performance of players at taluka level.

Thus, the very purpose of activating coaching centres for imparting regular training was defeated.

During exit conference, the Principal Secretary, SESD stated (November 2017) that the new policy for appointment of coaches was under consideration.

2.2.11 Maintenance of sports complexes

Maintenance grant

Considering the significance of regular maintenance and upkeep of the created assets, GoM prescribed (March 2009) maintenance grants[13] for sports complexes. Test-check of eight districts one each in eight divisions, and 25 TSCs revealed that maintenance grants of ₹ 0.28 crore and ₹ 0.15 crore respectively were released when divisional sports complex of Nashik and Kolhapur were being constructed resulting in the grants lying unutilised as of June 2017. However, no grants were released to Aurangabad divisional sports complex by GoM. As a result, the upkeep of sports complexes was adversely affected.

During exit conference, the Principal Secretary, SESD, accepted the facts and stated (November 2017) that the maintenance grant was released to the sports complex committees as per their demand.

The reply is not tenable as GoM had already prescribed the quantum of grants for upkeep and regular maintenance of created assets, the same should have been released as already prescribed by GoM. Evidently, monitoring was also poor.

Maintenance of Sports Complex

To encourage self-sustenance, GoM instructed (March 2003) creation of own sources of income for maintenance and repairs of complexes from the initial stage. It was observed that the income generated by the complex committees was insufficient in sampled divisions/districts as discussed below:

- In Pune, the facilities of Golf and Cricket Training and Practice Centres at divisional sports complex were leased (January 2007) on BOT basis to a private partner at an annual lease rent of ₹ nine lakh and ₹ three lakh respectively upto 30 August 2008 and lease rent for both was fixed as ₹ one lakh per month. It was observed that as of March 2017, as against the total receivable lease rent of ₹ 1.57 crore, only ₹ 26 lakh was received. Further, development of facilities at Golf Training and Practice Centre were incomplete as of May 2017.
- In Aurangabad, the facilities of five lawn tennis courts and gymnasium at divisional sports complex were leased (August 2008) on BOT basis to a private partner for a period of 30 years. Of total earnings from these sports

[13] The maintenance grant prescribed by GoM for Divisional Sports Complex was ₹ 15 lakh, ₹ 13 lakh and ₹ 10 lakh; for District Sports Complex: ₹ 10 lakh, ₹ 8 lakh and ₹ 5 lakh for first, second and third year respectively and for Taluka Sports Complex: ₹ 3 lakh only for first three years

facilities, 30 *per cent* would be payable to the Divisional Sports Complex Committee, Aurangabad. It was however, noticed that income of ₹ 4.57 crore was realised during 2010-11 to 2016-17 from the above facilities. Of this, ₹ 1.37 crore was to be paid to the Divisional Sports Complex Committee. However, nothing has been paid to the Divisional Sports Complex Committee as of March 2017.

Joint physical verification of the divisional sports complexes in sampled divisions revealed the following:

i) In Aurangabad, the drainage line, ceiling and wooden flooring of multipurpose indoor stadium, jogging track were found in damaged condition. The toilets were dirty.

ii) In Nashik, the cleanliness in the sports complex was not maintained and there were bushes around the ground and garbage inside the stadium. The drainage line was not cleaned, as shown in the pictures below:

		
Shabby work in front of toilets of multipurpose hall (Amravati)	**Damaged drainage line and cement grill with big hole (Aurangabad)**	**Uncleaned drainage line (Nashik)**

During exit conference, the Principal Secretary, SESD stated (November 2017) that in respect of Aurangabad DSC, the matter would be taken up with Sports Complex Committee for appropriate action. He further stated that to make the complexes self-sustainable, the Government had instructed revision of the fees and reduction of the expenses of all the complex committees.

It is pertinent to mention here that State Level Expert Committee headed by Commissioner, Sports and Youth Services was constituted (September 2015) to prepare a comprehensive sports policy on speedy completion of sports complex, their utilisation, day to day maintenance and management and to overcome the technical and administrative problems arising therein. The recommendations of the Committee were submitted to the GoM in January 2016, however, action was awaited as of July 2017.

The Principal Secretary, SESD stated (July 2017) that the suggestions made by the Expert Committee were under consideration.

2.2.12 Sports activities

Sports Policy, 2012 and GRs issued by the Government had earmarked, ₹ 50 lakh annually for games like Wrestling and Volleyball in selected divisions. GoM also failed to organise Mini-Olympic games at State level and creation of Talim Kushti Kendras at taluka level. The audit findings are discussed below:

2.2.12.1 Competitions for Wrestling and Volleyball

In three[14] out of eight selected divisions, the Deputy Directors failed to organise these competitions even after sanction and release of grants by the Government. The details are indicated in **Table 2.2.4.**

Table 2.2.4: Details of grant released by GoM and status of competitions

(₹ in crore)

Name of division	Name of competition	Year	Grant released	Expenditure incurred	Status of Grant
Aurangabad	Chhatrapati Shivaji Chashak Kabaddi & Volleyball	2015-16	0.28	0	Amount kept in 'Savings' bank account of Deputy Director
Nashik	Khashaba Jadhav Wrestling competitions	2016-17	0.35	₹ 0.15 crore for providing lunch and other facilities to the committee members and the participants	₹ 0.20 crore kept in bank account of Deputy Director
Pune (Solapur)	Khashaba Jadhav Wrestling competitions	2014-15	0.50	0	Amount surrendered in May 2017 with interest of ₹ 0.03 crore

During exit conference, the Principal Secretary, SESD, accepted the facts and stated (November 2017) that necessary action will be taken in this regard.

2.2.12.2 Mini-Olympic games at village level

For encouraging sports at village level, the Maharashtra Olympic Association (MOA) and the Department proposed (March 2014) to organise Mini Olympics in the State, for the year 2013-14. Accordingly, grant of ₹ 4.06 crore was released by GoM in July 2014 against the estimated expenditure of ₹ 5.08 crore. The event could not be conducted in 2014-15 owing to Vidhansabha elections and was postponed (May 2015) to 2015-16. However, the amount was credited (March 2014) to Personal Ledger Account (PLA) of DSYS to avoid its lapse. It was surrendered to Government in December 2015 by DSYS, Pune without conducting the events on the ground of board examinations and national sports competition.

Thus, despite availability of funds, the mini-olympics could not be conducted in the subsequent year, thereby denying the benefits to sports talent in villages.

During exit conference, the Secretary, SESD, accepted the facts and stated (November 2017) that the Mini-Olympic would be considered.

2.2.12.3 Development of *Talims* and *Kushti Kendras*

The Sports policy proposed to upgrade and provide modern facilities in *Akhadas/Talims* by providing financial assistance of ₹ 0.07 crore for construction and repairs of clay *Akhadas* and purchase of wrestling mats to registered organisations working in the field of developing the sport of wrestling. Accordingly, GR was issued in March 2014 and provisions of

[14] Aurangabad, Pune and Nashik

₹ 4.90 crore and ₹ 1.00 crore for 2015-16 and 2016-17 respectively were made by GoM for this purpose.

It was observed that no proposal was sanctioned in 2015-16. During 2016-17, 12 proposals were sanctioned by SESD. DSYS, Pune withdrew (March 2017) amount of ₹ 0.79 crore for distribution to the 12 *Akhadas/Talims*. The amount was not disbursed to the identified *Akhadas/Talims* as of March 2017 as the beneficiaries failed to submit the required documents for finalisation of the proposals. The money was lying in a bank account of DSYS.

During exit conference, the Principal Secretary, SESD, accepted the facts and stated (November 2017) that necessary steps will be taken to upgrade the facilities.

2.2.13 Financial Management

2.2.13.1 Short allocation and under utilisation of funds

Budget outlay for the Sports Department compared to the total budget outlay of the State during 2012-17 ranged between 0.44 *per cent* and 0.57 *per cent*.

The expenditure incurred for development of sports and physical education in the State by the Sports Department *vis-a-vis* budget provision made during the period 2012-17 is detailed in **Table 2.2.5.**

Table 2.2.5:- Budget allotment and expenditure incurred by Sports Department

(₹ in crore)

Year	Central		State (Plan)		Total	
	Grant released	Expenditure incurred	Grant released	Expenditure incurred	Grant released	Expenditure incurred
2012-13	3	3	128	109	131	112
2013-14	0	0	140	139	140	139
2014-15	0	0	134	35	134	35
2015-16	0	0	130	129	130	129
2016-17	0	0	198	161	198	161
Total	**3**	**3**	**730**	**573**	**733**	**576**
Source: Information furnished by Mantralaya, Mumbai						

- As per the Sports Policy 2012, to implement various schemes for development of sports, financial assistance of ₹ 1,434.71 crore was to be made during 12th State Five Year Plan (2012-17). As against the proposed provision, the State Government released ₹ 730 crore (51 *per cent*) during 2012-17.
- During 2012-17, against the total released grant of ₹ 733 crore (both Central and State), an expenditure of ₹ 576 crore (78 *per cent*) was incurred. During 2014-15, as against the grant of ₹ 134 crore, released only ₹ 35 crore (26 *per cent*) grant was utilised.

Thus, in spite of availability of funds, players were deprived of the opportunities to improve their skills, performance and to compete as discussed in following paragraphs.

During exit conference, the Principal Secretary, SESD, stated (November 2017) that funds were not released in accordance with the demands.

2.2.13.2 State Sports Development Fund

State Sports Development Fund (SSDF) was created (September 2003) for development of sports facilities, making available services of foreign coaches to sportspersons in the State, providing sports equipment of international standards and giving financial aid to renowned sportsmen in the State. In order to augment the SSDF, as envisaged in the Sports Policy 2012, it was proposed to undertake measures like contribution of grant of ₹ three crore per annum from the State Government, raise income from special sports lottery, accept donations from industrial and commercial establishments and assign one day's income from horse racing. As of May 2017 there was a balance of only ₹ 1.70 crore in SSDF account and the books of accounts and audited statement of SSDF were not made available to audit. It was further observed that

- GR for augmenting SSDF was not issued (August 2017) as envisaged in Sports Policy 2012. Adequate steps were not taken by the department to raise money from above mentioned sources for creation and empowerment of SSDF. Income from one day's racing (Mumbai race) per year, amounting to ₹ 1.73 crore was also not collected by SESD during 2012-17;
- the contribution made to SSDF by the Government during 2012-13 to 2016-17 was only ₹ 0.64 crore against ₹ 15 crore proposed; and
- though 250 proposals for providing financial assistance to Sportspersons from SSDF were submitted (between 2014-15 and 2016-17) by the Directorate, Pune to the Government, no financial assistance was disbursed as the Controlling Committee meeting to take decision in this regard was not held after October 2014;

During exit conference, the Principal Secretary, SESD, accepted the facts and stated (November 2017) that immediate action will be taken to collect the income from above sources.

2.2.13.3 Delay in release of incentive grant to schools

To encourage schools to participate in district level sports GoM made (February 2014) provisions for incentive grant of ₹ one lakh, ₹ 75,000 and ₹ 50,000 respectively to the schools winning 1st, 2nd and 3rd ranks in individual/team sports.

It was noticed that as the incentive grant was being released by Government at the end of the year during the period 2013-17, it could not be disbursed and utilised in time. As a result, incentive grants of ₹ 1.21 crore released in March 2015 were utilised in the year 2015-16. Further, the grant of ₹ 1.95 crore released (8 March 2017) in 2016-17 could not be utilised as the list of beneficiaries was under preparation as of June 2017. During the year 2016-17, out of 19,231 secondary school, 11,433 (59 *per cent*) of schools did not participate in competitions organised by Sports Department.

During exit conference, the Principal Secretary, SESD, accepted the facts and stated (November 2017) that necessary precautions will be taken for prompt release of grant.

2.2.14 Conclusion

The objectives of the Sports Policy, 2012 which aimed at empowering sports in Maharashtra were not achieved fully as:

- there was lack of initiatives and comprehensive planning;
- creation of sports complexes at divisional, district and taluka level was much below the target;
- the work on remaining sports complexes could either not commence for want of land or was lying incomplete due to financial crunch;
- the functioning of sports academies also suffered from number of problems *viz.* less intake, inadequate coaching, lack of sports facilities and basic amenities; this impacted the performance at National, State and International level games;
- though emphasis was given on creation of sports infrastructure, in absence of qualified and capable coaches and focused training, it failed to yield the desired outcome;
- utilisation, maintenance and upkeep of sports complexes was another area of concern where participation of non-Government institutions failed to produce intended benefits; and
- fund flow was erratic and was found not in consonance with the intended objectives of the Sports Policy. The share of Sports Department in the total budget outlay for the State was only between 0.44 *per cent* and 0.57 *per cent*.

The deficiencies mentioned above indicated that even after incurring huge expenditure, the Sports Department was unable to create and maintain adequate sports infrastructure as well as coaching facilities thereby affecting the performance of the sportspersons.

2.2.15 Recommendations

- **The Government may prepare a comprehensive plan duly conducting a survey on existing sports facilities and on future requirements. Government resolutions on all actionable points of the Sports Policy may be issued at the earliest.**
- **The State Government may ensure that adequate funds are released in a timely manner and the same are utilised efficiently and effectively.**
- **A proper schedule needs to be chalked out for early completion of the sports complexes at division, district and taluka level. Optimal use of the facilities created at sports complexes should be ensured.**
- **The Government needs to streamline the procedure for organising coaching camps for improving the performance of the players.**