

# **CHAPTER III**

## **COMPLIANCE AUDIT**



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### COMPLIANCE AUDIT

This Chapter presents the results of Compliance Audit of various Departments of the Government, their field formations, Local and Autonomous Bodies. Instances of lapses in the management of resources and failures in observance of the norms of regularity, propriety and economy have been presented in the succeeding paragraphs.

#### 3.1 Overpayment

##### *HEALTH AND FAMILY WELFARE SERVICES DEPARTMENT*

##### 3.1.1 Overpayment of service charges

**Failure to verify the genuineness of the claims submitted by the firm for providing hospital management services, resulted in an overpayment of ` 1.14 crore.**

Rule 74 of Contract Labour (Regulation and Abolition) Central Rules, 1971, requires that every principal employer should maintain a register of contractors which should contain names of the contractors, nature of work contract, period of contract and maximum number of workmen employed by the contractor.

The Health and Family Welfare Services Department (Department) had invited tenders for outsourcing hospital management services in Rajiv Gandhi Government Women and Children Hospital (Hospital) (July 2010). The firms participating in the tender were required to quote the number of persons to be deployed in each area of work in their respective bids, based on which their tenders would be technically evaluated, among other criteria.

Twenty one firms participated in the tender, out of which one firm, which had quoted lowest rate, was selected (January 2011). The firm was to deploy 267 persons to carry out all the eight hospital management services<sup>1</sup> for ` 26.62 lakh per month. The Director, Health and Family Welfare Services entered (February 2011) into a Memorandum of Understanding (MoU) with the firm for providing hospital management services.

<sup>1</sup> Electrical and plumbing maintenance (19), cleaning and sanitary (106), security (34), tailoring (1), maintenance of landscaping and interior garden (5), supply of diet (81), laundry services (10) and front desk management (11)

According to the MoU, the firm had to maintain panel of persons (267), as mentioned by it in the technical bid document. The agreement period was for two years, which could be extended for a further period of one year on mutually agreed terms.

On completion of the three year period in January 2014, the firm was allowed to continue its operation with the approval of the UT Government, up to November 2016. The firm raised monthly invoices for all the 267 persons along with supporting Muster Roll (MR) for respective months. As of June 2016, ₹ 17.77 crore was paid as service charges for the period January 2011-December 2015, on certification by the Resident Medical Officer that services provided by the firm were satisfactory and that firm had deployed 267 persons for carrying out the services.

Audit scrutiny of the MR and other records in the hospital during February 2016 revealed the following:

(i) As per the tender bid document, the firm had to engage 81 staff for diet service. Though the firm had engaged 81 staff as per the agreement, it was noticed that actually 38 staff were deployed for diet service and the remaining 43 had been diverted to cleaning and sanitary service from February 2012 to December 2015. However, the firm claimed service charges in respect of 43 diverted staff under diet service itself (₹ 10,761 per person)<sup>2</sup>, which was higher than the service charges (₹ 7,970 per person)<sup>3</sup> for staff who were actually engaged in cleaning and sanitary service. The hospital, without restricting the service charge to cleaning and sanitary service in respect of 43 staff diverted, continued to make payment as per the rate applicable for diet service. The excess amount, thus, paid in respect of the wrong claim worked out to ₹ 60.20 lakh<sup>4</sup> for the period February 2012 to December 2015.

(ii) Scrutiny of MRs further revealed that during August 2013 to December 2015, twenty one persons were shown as deployed in more than one services<sup>5</sup>, leading to duplication of staff in MRs in respect of four services. The incorrect monthly claims raised and paid on account of the above duplication worked out to ₹ 45.39 lakh<sup>6</sup>.

(iii) Further, in respect of diet service, three names were repeated twice, which again indicated duplication of staff under the same service and

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<sup>2</sup> Revised as ₹ 11,512 from 25 January 2013 and ₹ 12,375 from April 2015

<sup>3</sup> Revised as ₹ 8,526 from 25 January 2013 and ₹ 9,166 from April 2015

<sup>4</sup> Excess service charge for 43 staff for 47 months at an average of ₹ 2,979 per month

<sup>5</sup> Twenty one staff shown in MR of cleaning and sanitary service were also shown in the MRs of diet service (16), landscaping and maintenance (4) and tailoring (1)

<sup>6</sup> Service charge for 21 staff for 27 months (excluding January and November 2015, for which details were not available) at an average of ₹ 8,006 per month

incorrect monthly claims raised and paid in that regard worked out to ` 7.99 lakh<sup>7</sup>.

When attendance records were called for by us to verify the correctness of the number and names of the staff deployed, the Hospital authorities forwarded the reply of the firm, which stated (May 2016) that biometric attendance system maintained, was corrupted and hence, no data could be retrieved.

(iv) Though the firm had claimed in its monthly bills that 267 staff were deployed for various services in Hospital, cross verification of half yearly returns submitted (July 2014 and June 2015) by the firm under Rule 82 (1) of Contract Labour (Regulation and Abolition) Central Rules, 1971 to the Labour department revealed that the firm had engaged only 157 and 161 employees respectively during those years. Thus, without actually deploying all 267 persons as per the agreement, the firm continued to raise monthly claims for all 267 persons.

Thus, hospital authorities, without ensuring whether the persons were deployed as per conditions accepted by the firm, continued to make payments which resulted in an overpayment of ` 1.14 crore<sup>8</sup> to the firm during February 2012 to December 2015, on account of diversion and duplication of persons as discussed above.

The UT Government replied (September 2016) that MoU did not indicate specific clause on the numerical data of manpower and that the outsourcing was a new concept due to which, they faced certain difficulties. The UT Government further stated that they had taken note of the audit observation and assured that the numerical data of manpower to be deployed would be included as a specific clause in MoUs to be executed in future.

The UT Government's reply was not acceptable, as it had been clearly mentioned in the MoU that the firm had to maintain panel of staff as indicated in the technical bid.

Thus, due to the failure of the hospital authorities to maintain a register as specified in Rule 74 of the Contract Labour (Regulation and Abolition) Central Rules, 1971 coupled with their failure to exercise necessary checks while passing firm's invoices for payments against the terms and conditions of the agreement resulted in an overpayment to the firm, for which UT Government may take appropriate action against the defaulting officials of the hospital as also against the firm for claiming overpayments and submitting fabricated data about deployment of persons not only to the hospital but also to the Labour Department in its returns for taking undue financial benefit.

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<sup>7</sup> Service charge for three staff for 27 months (excluding January and November 2015, for which details were not available) at an average of ` 9,867 per month

<sup>8</sup> ` 60.20 lakh + ` 45.39 lakh + ` 7.99 lakh

## 3.2 Avoidable expenditure

### ADI-DRAVIDAR WELFARE DEPARTMENT

#### 3.2.1 Avoidable expenditure on payment of interest

**Delay in depositing the enhanced compensation amount for land acquisition in the Court, resulted in an avoidable interest payment of ₹ 0.93 crore.**

As per Section 34 of the Land Acquisition Act, 1894 (Act), if compensation or any part thereof is not paid or deposited within a period of one year from the date of possession of land, interest at the rate of 15 *per cent* per annum shall be payable from the date of expiry of one year on the amount of compensation or part thereof.

The UT Government had accorded (June 2008) administrative approval to Adi-Dravidar Welfare Department (Department) for acquisition of land to an extent of 02-08-00 hectares<sup>9</sup> in Kirumampakkam village for allotment of free house sites to Scheduled Caste and Other Economically Backward Class people. Land acquisition proceedings were initiated as per provisions of the Act and the Land Acquisition Officer (LAO) had passed (January 2011) an award of ₹ 4.70 crore as compensation (at the rate of ₹ 150 per square feet) to land owners. The possession was taken on 26 May 2011, after making payment to the land owners (May 2011). Since the land owners were not satisfied with the amount of land compensation received, they had requested the LAO for enhancement in the amount of land compensation. The LAO referred the case to the District Court, as provided in Section 18 of the Act<sup>10</sup>. The Court revised the rate per square feet as ₹ 300 and awarded (August 2012) ₹ 4.70 crore as enhanced compensation along with interest (in addition to the award of ₹ 4.70 crore already passed by LAO), which had to be paid at the rate of 15 *per cent* with effect from 26 May 2012<sup>11</sup>.

The audit scrutiny of the records revealed that the LAO had sought (October 2012) the opinion of Law department for preferring an appeal against the decision of the District Court. The Law department, however, had opined (November 2012) that the case was not fit for appeal. In the circumstances, the amount of the enhanced land compensation, as awarded by the Court, had to be paid to the landowners without any delay, to avoid

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<sup>9</sup> 2.24 lakh square feet

<sup>10</sup> Any person interested who has not accepted the award may, by written application to the Collector, require that the matter be referred by the Collector for the determination of the Court, whether his objection be to the measurement of the land, the amount of the compensation, the person whom it is payable, or the apportionment of the compensation among the persons interested

<sup>11</sup> Reckoned from the date on which one year period was completed after taking possession of the land on 26 May 2011

additional burden on the Government exchequer by way of accrual of interest on the amount of compensation.

In this regard, we further observed that the LAO had requested (December 2012) the Department to deposit the enhanced compensation (including interest upto December 2012) in the Court. As the Department had not provided funds, the LAO issued (February 2013, September 2013 and February 2014) reminders to the Department for expediting release of funds, as the liability for the payment on account of the payment of interest on the amount of land compensation was accruing day by day and demanded an amount of ` 6.37 crore<sup>12</sup> including interest upto February 2014. After protracted correspondence by the LAO, the Department provided funds in March 2014 and the LAO deposited the same in the Court (April 2014), which was paid to the land owners in October 2014. It was further noticed that the Department had taken 16 months (January 2013 - April 2014) to provide funds for making payment of enhanced land compensation to the land owners concerned.

Thus, we observed that due to delay in making payment of the amount of enhanced land compensation, the UT Government had to pay an interest of ` 1.36 crore<sup>13</sup> (**Appendix 3.1**) on the amount of enhanced compensation, which could have been limited to ` 0.43 crore, had the Department provided funds in December 2012 itself, when LAO had initially requested the Department to deposit the amount of enhanced compensation.

While accepting the audit observation, the UT Government stated (October 2016) that the delay in providing funds was due to mingling of original files in question with some other old files and hence, the compensation amount could not be settled in time. The UT Government further assured that such claims would be settled in time in future. Thus, delay in depositing enhanced compensation amount in the Court, resulted in an avoidable interest payment of ` 0.93 crore for which the UT Government needs to take appropriate action about streamlining procedure for ensuring release of funds in a timely manner to avoid reoccurrence of such happenings in future as also action against the persons for delay in release of funds causing loss to Government exchequer after investigation in the matter.

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<sup>12</sup> ` 6.37 crore - ` 4.71 crore compensation and ` 1.66 crore interest

<sup>13</sup> Includes ` 11.59 lakh pertaining to two months (March and April 2014), which is yet to be paid to the land owners

**REVENUE AND DISASTER MANAGEMENT DEPARTMENT**

**3.2.2 Avoidable expenditure on Customs Duty**

**Failure of the Project Implementation Agency to avail of the customs duty exemption resulted in avoidable expenditure of ` 56.16 lakh.**

As per Notification Number 84/97-Customs dated 11 November 1997, the Central Government exempted all the goods imported into India for execution of projects financed by the United Nations or an International Organisation and approved by the GOI, from the payment of custom duty leviable thereon under First Schedule to the Customs Tariff Act, 1975 (51 of 1975), on production of a certificate from Project Implementation Authority that the goods were required for execution of the project. The GOI allocated (2014-15) to UT Government of Puducherry ` 188 crore under Coastal Disaster Risk Reduction Project (CDRRP), approved and financially assisted by World Bank, which was released to Project Implementation Agency (PIA) during September 2014 – March 2015 for undertaking various works under the CDRRP.

Under the Project, Fire Services Department proposed (June 2014) to purchase Aerial ladder platform and other fire safety equipment and PIA accorded (January 2015) administrative approval for an estimated cost of ` 11.17 crore. Though all these items were eligible for customs duty exemption, as they were being purchased and imported under CDRRP scheme financed by World Bank, PIA failed to take note of this and entered into an agreement with M/s Brijbasi Fire Safety System Private Limited, Mumbai (firm) for supply of these items, at a cost inclusive of customs duty. As a result, PIA had to make payment of ` 56.16 lakh towards Customs Duty on purchase (October and November 2015) of seven Smoke Exhausters, five Jumping Cushions, an Aerial Ladder Platform and five Thermal Imaging Cameras.

While accepting their lapse in making payment of the customs duty, which was not actually payable in terms of the above notification, the UT Government stated (November 2016) that suitable provisions were incorporated in the subsequent tender (August 2016) to avail the exemption.

Thus, the failure of PIA to ascertain and include appropriate clause in the agreement with the firm regarding exemption of customs duty, resulted in avoidable payment of ` 56.16 lakh.



### 3.3 Idle expenditure

#### TOWN AND COUNTRY PLANNING DEPARTMENT

##### 3.3.1 Defective planning resulting in idle expenditure on construction of tenements

**Sixty three tenements were constructed without proper planning and without identifying beneficiaries of the scheme. There were also delays in allotment of tenements to eligible beneficiaries despite spending ` 3.72 crore.**

As a best practice, before embarking upon the construction of any housing project for allotment to the intended beneficiaries, it is imperative for the authorities concerned to identify the eligible beneficiaries. Thus, proper planning about the number of houses to be constructed for allotment to the beneficiaries should be in place before execution of housing projects as these entail huge capital investment apart from fulfillment of the Government's commitment towards welfare measures meant for the socially and economically disadvantaged groups especially in a scenario when financial resources are scarce. Further, it is incumbent on the Government to ensure that the rules governing the eligibility criteria for identification of the beneficiaries are in place before execution of any project meant for the beneficiaries so that the benefits of the Government schemes are derived in a timely manner.

The Puducherry Slum Clearance Board (PSCB) was entrusted (August 2008) with the work of "Construction of 432 tenements at Karaikovilpatthu, Karaikal" at an estimated cost of ` 17.03 crore<sup>14</sup> under the Integrated Housing and Slum Development Programme of Jawaharlal Nehru National Urban Renewal Mission (JNNURM) for accommodating roadside encroachers and platform and slum dwellers belonging to three constituencies<sup>15</sup> of UT of Puducherry. The scheme guidelines stipulated a minimum of 12 *per cent* of the cost of the dwelling unit as beneficiary contribution. In the case of beneficiaries belonging to SC, ST, BC, OBC, PH and other weaker sections, the contribution was fixed at 10 *per cent*. The Town and Country Planning Department was the State Level Nodal Agency (SLNA) for administering the Project and selection of beneficiaries.

The PSCB commenced (September 2009) construction of 216 tenements<sup>16</sup> at a tendered cost of ` 13.16 crore in a phased manner. As of May 2016, 72 tenements were completed (November 2013) in all respects and works relating to 144 tenements were under progress against an amount of ` 12.74 crore released to PSCB during March 2008-October 2014. Out of

<sup>14</sup> Includes GOI share of ` 5.48 crore and UT Government share of ` 11.55 crore

<sup>15</sup> Karaikal North (150), Karaikal South (160) and Kottucherry (122)

<sup>16</sup> Construction of remaining 216 (432-216) tenements was not taken up

72 tenements completed at a cost of ₹ 4.25 crore, nine tenements had been allotted (November 2013) by PSCB to beneficiaries who were evicted from the site identified for construction of a bye-pass road. Out of 72 tenements, 63 tenements were yet to be allotted (May 2016), as the UT Government had not identified the beneficiaries.

We observed from the scrutiny of records (March 2016) that SLNA had not finalised the list of beneficiaries before commencing construction and PSCB had so far allotted tenements only on rental basis and did not have any specific rules for allotment of tenements on non-rental basis. Thus, when PSCB forwarded (March 2012) beneficiary applications to Revenue Department for screening, the Collector requested (October 2012) SLNA to frame specific guidelines for selection of beneficiaries. The SLNA in turn, directed (January 2013) PSCB to propose draft amendments to the existing 'Rules'<sup>17</sup> for allotment of developed plots for slum dwellers and recovery of rent' and composition of the selection committee.

We further observed that the PSCB had already submitted a proposal to the UT Government during September 2012 itself, for forming an Advisory Committee<sup>18</sup> headed by Chairman, PSCB to consider and finalise the allotment of tenements. Based on some economic and caste criteria, the Advisory Committee was to select the slum dwellers, who were not having their own houses, either in their own names or their spouses or in the names of any other persons dependent on them.

It was further noticed that the PSCB had also clarified (December 2012) to the UT Government that no specific rules were framed by it for identification of beneficiaries for allotment of tenements and that it was only following the rules framed by the Town and Country Planning Department for allotment of tenements on rental basis. The PSCB had further submitted a proposal for amendment in the existing rules for allotment of tenements on non-rental basis and had sought UT Government's approval to form an Advisory Committee (October 2013) to identify eligible beneficiaries. A notification was issued in October 2015, constituting the Advisory Committee<sup>19</sup> with Secretary to Government (Housing) as Chairman, for selection of beneficiaries.

When we had called for (May 2016) the details of meetings convened by Advisory Committee for selection of eligible beneficiaries, the PSCB stated (May 2016) that meetings of Advisory Committee could not be conducted

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<sup>17</sup> Notified in August 1975

<sup>18</sup> The District Collector, Karaikal, Secretary to Government (Housing), Town Planner, Town and Country Planning Department, Karaikal and one non-official member, Karaikal would be the members and the Chief Executive Officer, PSCB would act as the Member Secretary

<sup>19</sup> The District Collector, Karaikal, Chief Engineer, PWD, Chief Town Planner, Town and Country Planning Department, Director, Social Welfare Department are members while the Chief Executive Officer, PSCB would act as the Member Secretary

due to enforcement of Model Code of Conduct on account of election for Legislative Assembly of Puducherry. We further observed that the Advisory Committee had not yet met for selection of eligible beneficiaries (July 2016).

The UT Government stated (September 2016) that the SLNA had put forth all the facts for favourable consideration by the UT Government for taking a decision in the matter and that the PSCB would be directed to allot the dwelling units without any further delay.

The reply was not acceptable, as SLNA should have finalised the beneficiaries before commencing the work and construction of tenements in absence of eligible beneficiaries indicated improper planning. Moreover, much time was lost in constituting the Advisory Committee and the amendments proposed for allotment of tenements on non-rental basis had not been approved by UT Government (July 2016).

Thus, the defective planning in commencing the construction of tenements without identifying the beneficiaries of the scheme in the absence of relevant rules for their identification coupled with delay in constituting Advisory Committee for making rules resulted in an idle expenditure of ₹ 3.72 crore<sup>20</sup> on construction of 63 tenements. Due to inaction and delays on the part of the UT Government in framing rules and identification of beneficiaries, the objective of the scheme to provide dwelling units to the slum dwellers could not be achieved even two years after the completion of the tenements.

## ***ADI-DRAVIDAR WELFARE DEPARTMENT***

### **3.4 Implementation of housing scheme for poor Scheduled Caste and Other Economically Backward Classes people in Union Territory of Puducherry**

#### **3.4.1 Introduction**

The UT Government of Puducherry (UT Government) estimated a demand of 12,000 housing units for 1.58 lakh SC population, which constituted 16.19 *per cent* of the total UT population. The UT Government, planned to fill the gap in a phased manner over a period of five years and as a first step in that direction, approved (February 2009) the construction of 3,000 Economically Weaker Section (EWS) houses for poor Scheduled Caste and Other Economically Backward Classes people in Puducherry.

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<sup>20</sup> ₹ 4.25 crore x 63/72 tenements

Out of 3,000 houses to be constructed at 34 locations, 1,660 were proposed to be constructed in urban areas (City Development Plan-CDP) at 17 locations under the Sub-Mission 'Basic Services for Urban Poor' (BSUP) of Jawaharlal Nehru National Urban Renewal Mission (JNNURM) at a cost of ₹ 92 crore<sup>21</sup>, to be shared between GOI (₹ 50.89 crore) and UT Government (₹ 41.11 crore). The remaining 1,340 houses were to be constructed at 17 locations under rural (non-CDP) areas by availing loan of ₹ 88.46 crore from Housing and Urban Development Corporation (HUDCO). The HUDCO was appointed (February 2009) as consultant for preparation of Detailed Project Report (DPR) and Puducherry Adi-Dravidar Development Corporation (PADCO) was nominated (December 2009) as Project Executing Agency. The cost of each housing unit to be constructed was ₹ 3.70 lakh and the selected beneficiaries were to be allotted houses free of cost as per the policy decision of the UT Government.

The construction of houses was taken up (October 2010) in a phased manner at 19 locations (two urban and 17 rural) and completed in January 2013. Out of 3,000 envisaged houses to be constructed, 1,496 (262 urban and 1,234 rural) houses were constructed, of which 1,303 (262 urban and 1,041 rural) houses were allotted<sup>22</sup> as of March 2016 (**Appendix 3.2**).

The audit of implementation of the Scheme was conducted during April-June 2016 with a view to assess whether:

- selection of beneficiaries was prudent and transparent,
- sufficient land was available for implementing the scheme and used for intended purpose and
- quality of the houses constructed under the scheme was satisfactory.

An Entry Conference with the Secretary to Government was held in May 2016 to discuss the audit objectives, criteria and scope of audit. Records were test-checked at Adi-Dravidar Welfare Department (ADWD), Town and Country Planning Department, Puducherry Adi-Dravidar Development Corporation Limited and Electricity Department. An Exit Conference was held with the Secretary to Government in November 2016, wherein the audit results were discussed.

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<sup>21</sup> ₹ 61.42 crore for 1,660 units at ₹ 3.70 lakh per unit and balance ₹ 30.58 crore for development works

<sup>22</sup> At 18 locations (two urban and 16 rural)

## Audit Findings

### 3.4.2 Planning

#### 3.4.2.1 *Ill-planning in identification of beneficiaries*

Identification of beneficiaries before commencing the scheme was a pre-requisite condition for release of grant and loan by GOI and HUDCO respectively. The ADWD, while submitting (July 2009) DPR for construction of houses in urban areas to GOI, had certified that beneficiaries were identified properly. Further, ADWD had agreed (March 2010) to provide list of beneficiaries to HUDCO, before release of loan for construction of houses in rural areas. Scrutiny of records revealed the following:

- ADWD had included the list of beneficiaries in the DPR submitted to the GOI. In respect of two urban locations (Ariyur and Pitchaveeranpet), where 262 houses were constructed and allotted, we verified the beneficiaries' list submitted to GOI with the allotment list, to ensure the reliability of the beneficiaries' list submitted to GOI. It was noticed that allotment list was containing 169 new beneficiaries (65 *per cent* variation), who were not mentioned in the list submitted to GOI, indicating that the beneficiaries' list submitted to GOI was not accurate. We, however, could not verify the basis of selection of beneficiaries in DPR, as the same was not furnished to us by the department.
- In respect of rural areas, a comparative exercise could not be undertaken by us, as the list provided by ADWD to HUDCO, for obtaining loan for construction of houses, was not available with the Department.

The above details indicated that ADWD did not have proper plan in place to identify the beneficiaries before commencing the scheme, which was a pre-requisite. As a result, the beneficiaries who were to be identified before commencement of the scheme could only be finalised by the Selection Committee in December 2015, nearly three years after completion of construction of houses in January 2013.

On being pointed out, the UT Government did not give any reply about the reasons for delay in the selection of beneficiaries.

#### 3.4.2.2 *Lapses in selection of beneficiaries*

Selection of beneficiaries was to be made as per Rule (3) of Pondicherry House sites / House Allotment Rules, 1981 (PHAR), which stipulated that applicant should be a citizen of India and native of Puducherry, belonging to Scheduled Caste, homeless person and none of the member of the

family<sup>23</sup> should own a house or house site and having an annual family income not exceeding ` two lakh.

As per PHAR, a village-wise register of applications for house and house sites was required to be maintained by ADWD, for monitoring details like receipt and forwarding the applications to the Revenue Department, caste, annual income, nativity, number of family members, date of placement before Selection Committee<sup>24</sup> and selection particulars, etc.

Rule (7) of PHAR further stipulated that the applications for allotment of houses should be placed before the Selection Committee, after conducting necessary enquiries by the Department. The Selection Committee after considering the applications and enquiry reports, should record its recommendation, which would be forwarded to the UT Government for approval. On approval, houses would be allotted to the beneficiaries.

On scrutiny of beneficiaries' selection process undertaken by ADWD for allotment of houses, we observed as under:

- UT Government's approval, as laid down in the Rules, was not obtained for the list of beneficiaries selected and ADWD had allotted houses based on the recommendations of the Selection Committee alone in all the cases.
- The village-wise register of applications for each location was not maintained by ADWD as laid down in the Rules and applications were diarised in Tapal (Dak) receipt register, in which, all official correspondences were recorded.
- The application for allotment of house was to be supported by a certificate from Deputy Tahsildar to the effect that the applicant did not own any house or house site. It was, however, noticed that in Puducherry region, Tahsildars had certified only about the nativity, caste and income of the applicants. The Welfare Inspectors of ADWD did not have access to revenue records and therefore, as such, they had certified house site or house ownership status of the applicant based on local enquiry.

While accepting the audit observations, the UT Government stated (October 2016) that these lapses would be avoided in future scrutiny of applications and UT Government's approval would be obtained in respect of the beneficiaries, as recommended by the Selection Committee. The reply confirmed the audit observations that deficiencies in procedure of

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<sup>23</sup> Family in relation to a person means such person, if married, the wife or husband as the case may be and the dependent children and grandchildren of such person

<sup>24</sup> Consisting of Member of Legislative Assembly, Member of Parliament (Lok Sabha), Member of Parliament (Rajya Sabha), Director of Adi-Dravidar Welfare Department, Deputy Director, Tahsildar and Welfare Inspector

selection of beneficiaries had contributed to selection of ineligible beneficiaries, as discussed in the succeeding paragraphs.

### 3.4.2.3 *Allotment of houses to ineligible beneficiaries*

One of the criteria for beneficiary selection was that selected person should be homeless and no member of the family should own a house or house site. A test-check of 778 out of 1,303 applications revealed that the houses were allotted to ineligible beneficiaries as detailed in **Table 3.1** below, despite the fact that the Welfare Inspectors had reported that the applicants or family members already owned houses or availed subsidy.

**Table 3.1 - Details of ineligible beneficiaries**

Number of ineligible beneficiaries	Remarks
10	Applicants already owned houses.
26	Applicants already availed subsidy under other housing schemes to construct houses in their plots.
13	Family members owned houses.
08	Houses allotted to more than one member in the family.
<b>57</b>	

The above deficiencies, on being pointed out, the UT Government accepted (October 2016) the audit observation and stated that a review committee had been constituted under the Head of a Deputy Director for resolving these discrepancies. The UT Government's reply confirmed the need to take action against the persons responsible for selection of ineligible persons for allotment of houses by ignoring the reports submitted by the Welfare Inspectors.

### 3.4.2.4 *Starting housing scheme without ensuring availability of adequate land*

Ensuring availability of land was a pre-requisite for release of grant by GOI for construction of houses in urban areas and UT Government submitted a certificate (July 2009) that requisite land was available for taking up construction of 1,660 houses in urban areas. GOI approved (September 2009) the scheme at a cost of ₹ 92 crore, to be shared between GOI (₹ 50.89 crore) and UT Government (₹ 41.11 crore) and released ₹ 12.72 crore as first installment, while UT Government released ₹ 1.24 crore as its share.

It was, however, noticed that against 1,660 houses envisaged in urban areas, UT Government constructed only 262 houses at a cost of ₹ 13.95 crore (June 2011) in two urban locations (Ariyur and Pitchaveeranpet). In respect of balance 1,398 houses, the same were not constructed on account of non-availability of land and due to paucity of funds despite availability of land, as mentioned in the following **Table 3.2**.

**Table 3.2 - Details of locations where houses were not constructed in urban areas**

Sl. No.	Location	Houses not constructed
<b>Locations where houses not constructed due to non-availability of land</b>		
1	Thiruvalluvar Nagar	51
2	Rajiv Gandhi Nagar	217
3	Uppalam	31
4	Ambedkar Nagar	136
5	Thondamanathampet-I	103
6	Thondamanathampet-II	55
7	Valluvanpet	57
8	Pitchaveeranpet (encroachment)	7
	<b>Total</b>	<b>657</b>
<b>Locations where houses not constructed due to paucity of funds despite land availability</b>		
1	Reddiyarpalayam	80
2	Odiyampet	87
3	Abhishekapakkam	157
4	T.N.Palayam- I	124
5	T.N.Palayam – II	50
6	T.N.Palayam –III	75
7	T.N.Palayam-IV	68
8	Athuvoikalpet	100
	<b>Total</b>	<b>741</b>
	<b>Grand total</b>	<b>1,398</b>

The UT Government approached (June 2014) GOI to curtail the project due to paucity of land. GOI had accepted (July 2014) the proposal and the project was curtailed. We observed that the request for curtailment of the project after commencing the scheme, due to non-availability of land, indicated poor planning by ADWD in conceiving and executing the project.

Scrutiny of the records revealed that out of 1,398 houses curtailed, ADWD had acquired lands for construction of 741 houses to an extent of 07-36-95 ha at a cost of ` 30.83 crore. However, those lands were not utilised due to paucity of funds. It was later decided by the UT Government (January 2016) to allot those lands as free house sites to beneficiaries, though the scheme was only meant for allotment of constructed houses. However, neither any action was taken to allot these house sites nor construction of houses was made on that land which remained idle without any meaningful utilisation till date (November 2016) thereby defeating the purpose for which it was acquired.

On being pointed out, the UT Government stated (October 2016) that construction work was not taken up immediately due to paucity of funds. It was further stated that a proposal for construction of 5,000 EWS houses had been submitted to GOI and as soon as the proposal was cleared by GOI, construction at those locations would be commenced. The reply was not acceptable as UT Government had earlier cited paucity of land to GOI



as reason for curtailing the project. However, this was not the case for the 741 houses discussed above, where houses could have been constructed in available land by availing balance GOI grant of ` 38.17 crore<sup>25</sup> and the benefit of the scheme could have been extended to eligible houseless Scheduled Caste and Other Economically Backward Classes beneficiaries.

### **3.4.3 Diversion of scheme fund for disbursement of education loan**

The loan agreement with HUDCO stipulated that the borrower should use the loan amount or any part thereof for implementation of the scheme alone. In the event of mis-utilisation, diversion, siphoning of loan amount by the borrower, HUDCO shall have the right to recall the entire loan amount together with interest, penal interest, cost and other charges.

Out of ` 86.05 crore released by HUDCO to PADCO towards construction of 1,340 houses in rural areas, ` 8.32 crore was sanctioned towards creation of infrastructure facilities like electricity, road and water supply.

Scrutiny of the records revealed that citing paucity of funds for disbursing education loan to SC students, PADCO diverted ` 2.68 crore (` 1.32 crore in 2013-14 and ` 1.36 crore in 2014-15) towards education loan out of ` 8.32 crore sanctioned for creation of infrastructure. While ` 1.13 crore was recouped (2015-16) by PADCO, ` 1.55 crore was yet to be recouped.

We further observed that the diversion of scheme funds for other purposes affected the execution of housing scheme adversely as necessary electrical infrastructure could not be created as the PADCO had failed to deposit ` 40 lakh to the Electricity Department, as discussed in detail in succeeding paragraph.

On being pointed out, the UT Government accepted (October 2016) and stated that PADCO had been directed to recoup the diverted fund and such lapses would be avoided in future. The reply was not acceptable, as on the one hand, UT Government cited paucity of funds for non-construction of houses and on the other, permitted diversion of funds for other schemes. There was, thus, a need to fix accountability for such a serious lapse.

### **3.4.4 Delay in provision of infrastructure facilities**

An amount of ` 8.32 crore was sanctioned for creation of infrastructure facilities in respect of houses constructed in 17 rural locations. The works relating to internal roads and drainage were proposed to be executed by PADCO and the provision of electrical infrastructure facilities was to be made by the Electricity Department. It was, however noticed that though construction of houses was completed in January 2013, PADCO submitted

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<sup>25</sup> ` 50.89 crore sanctioned by GOI *minus* ` 12.72 crore released as first installment by GOI

the estimate for providing infrastructure facilities only in November 2013 and UT Government released funds to provide infrastructure facilities in January 2014. This further delayed the allotment of constructed houses by more than two years, as discussed below:

- The work relating to provision of cement concrete pavement to the internal roads was taken up only in August 2014 and completed by June 2015, *i.e.*, more than two years after the completion of construction of houses.
- During a Joint field inspection by us along with departmental officials conducted in Manalipet (June 2016), it was noticed that transformers and LT and HT lines were yet to be installed (as shown in the pictures 1 and 2 given below), as the required amount of ` 40 lakh was not deposited with the Electricity Department by PADCO, due to diversion of fund towards disbursement of education loan as discussed in preceding paragraph. As a result, out of 35 houses allotted in Manalipet, 34 houses were not occupied by the beneficiaries for want of power connection due to non-installation of transformers and LT lines. Further, no street lights were provided in any of the 17 rural locations.



**Pictures 1 and 2 - Transformers and street lines yet to be installed – Manalipet Village**

Though internal wirings, switches and fuse board had been provided, the beneficiaries had not obtained power connections for their houses from Electricity Department except for three locations<sup>26</sup>. During field inspection, we observed that 180 beneficiaries in two locations<sup>27</sup> were tapping electricity illegally from lamp post and LT lines as shown in the following pictures 3 and 4.

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<sup>26</sup> Katterikuppam, Kudiyiruppupalayam and Pitchaveeranpet  
<sup>27</sup> Karikalampakkam and Koonichempet



**Pictures 3 and 4 - Power connection without meter box and illegal tapping of electricity from lamp post**

On being pointed out, the UT Government accepted (October 2016) the delay in creation of basic infrastructure like electricity, water and road facilities and stated that necessary arrangements would be made for provision of infrastructure facilities. As regards illegal tapping of power, it was replied (September 2016) that illegal tapping had since been disconnected at one location. However, action was yet to be taken in respect of the other location, which indicated continuous tapping of electricity illegally. This indicated lack of co-ordination between line departments in synchronising the infrastructure works, to ensure that houses could have been allotted to the beneficiaries without delay, upon their construction.

### 3.4.5 Houses handed over in damaged condition

Due to the delay in identification of beneficiaries and completion of infrastructure works as above, houses were allotted after a delay of more than three years after their completion. All the houses constructed were provided with two fans, two tube lights and two CFL bulbs each and the houses were to be handed over on completion of electrical fittings works. PADCO addressed (April 2012) ADWD that inordinate delay in finalisation of beneficiaries had resulted in damage of dwelling units by anti-social elements and theft of internal fittings and requested to protect the premises by providing security. However, no security was provided and the houses were handed over, as such, in damaged condition to the beneficiaries as discussed below:

- In respect of 142 houses completed in Ariyur, all the above electrical fittings were stolen and the houses were handed over (February 2016) to the beneficiaries without electrical fittings as shown in picture 5.



**Picture 5 - A house at Ariyur where door was damaged and fuse box, fans and internal wirings were stolen**

- During Joint inspection conducted (June 2016) at six locations<sup>28</sup> comprising 490 houses, it was noticed that there were instances such as theft of meter board, internal wirings, water pipes and outlets. Further, window panes and doors were found to be in damaged condition. However, the houses were handed over to the beneficiaries in the same damaged condition as shown in the pictures 6, 7, 8 and 9 given below.



**Picture 6 - House at Karayamputhur, where water line was stolen**



**Picture 7 - A house at Manalipet where door was damaged by miscreants**



**Picture 8 - Unallotted house at Rayanpalayam filled with debris and human waste**



**Picture 9 - House yet to be occupied in Kunichempet village**

- It was noticed that 35 units were unauthorisedly occupied by miscreants since July 2014 and ADWD had not taken any action to get those houses vacated.

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<sup>28</sup> Karayamputhur, Manalipet, Ariyur, Varichikudy (North), Varichikudy (South), and Koonichempet

On being pointed out, the Department stated (September 2016) that police complaints had been registered regarding stolen articles and coercive measures were being taken to evict the encroachers.

### **3.4.6 Conclusion**

ADWD failed to finalise the beneficiaries' list in time and the selection of beneficiaries was not handled in a professional manner, leading to allotment of houses to ineligible beneficiaries. Failure to ensure availability of land and non-implementation of scheme in the identified sites in urban areas resulted in denial of benefits to deserving beneficiaries. Consequent to delay in identification of beneficiaries and provision in infrastructure facilities, the houses were handed over to the beneficiaries in damaged condition. Accountability was not fixed for the various lapses noted, which needs to be critically reviewed by the UT Government and the system of beneficiary selection, ensuring site availability, timely construction and handing over of houses streamlined, to achieve the objective of the scheme for welfare of the poor Scheduled Caste and Other Economically Backward Classes people.

## ***DEPARTMENT OF DRUG CONTROL***

### **3.5 Implementation of Drugs and Cosmetics Act, 1940 in Union Territory of Puducherry**

#### **3.5.1 Introduction**

The GOI promulgated the Drugs and Cosmetics Act, 1940 (Act) and framed Drugs and Cosmetics Rules, 1945 (Rules) to regulate the import, manufacture, distribution and sale of drugs (including Indian Systems of Medicines<sup>29</sup> (ISM)) and Cosmetics. In UT, the Secretary to Government (Health) was the administrative head of the Department of Drugs Control (Department). The Department headed by the Drug Controller was responsible for issue and renewal of licences, monitoring, inspection and prosecution etc., in respect of the drug manufacturing and sale units situated in UT.

The audit of implementation of the Drugs and Cosmetics Act and Rules, was conducted from April 2016 to June 2016 to assess whether grant and renewal of licences, conduct of inspections, action initiated were in accordance with the provisions of the Act and Rules. An Entry Conference was held with the Secretary to Government in June 2016 to discuss the audit objectives, criteria and scope of audit. Records relating to the period

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<sup>29</sup> Ayurvedic, Unani, Siddha and Homeopathy

2013-16 were test checked at Health Department, Department of Drugs Control, Department of Food and Drug Testing and Laboratory for Indian System of Medicine.

A Performance Audit of 'Implementation of Drugs and Cosmetics Act, 1940' had appeared in the Audit Report for the year 2002-03. Replies of the UT Government to the recommendations of PAC given in its meeting held on 17 February 2009 were also examined along with further action taken and have been included in this report suitably wherever found necessary. An Exit Conference was held with the Secretary to Government in October 2016, wherein the results of audit were discussed and replies given have been incorporated in the Report.

## **Audit Findings**

### **3.5.2 Issue and renewal of Licences**

According to Section 18(C) of the Act, no person shall manufacture, stock, distribute, exhibit, offer for sale any drug or cosmetic, except in accordance with the conditions of a licence issued for such purpose. The licence was valid for a period of five years from the date on which it was granted or renewed (Rule 63). During 2013-16, the Department had issued 34 new licences to manufacturers of drugs and 228 licences to wholesalers and retailers in UT.

#### **3.5.2.1 *Delay in processing of applications for grant and renewal of licences***

The Drugs and Cosmetics Rules, 1945 Rules (Rules) did not specify any time limit for processing the application for grant and renewal of the licences, but specified that if the application for the renewal of a licence was submitted before its expiry or within six months of its expiry, after payment of the additional fees, the licence shall continue to be in force until orders were passed on the application.

The applications are received by the Licensing Authority (LA) in the Department of Drug Control (DDC), and after scrutiny of the documents submitted by the manufacturers, the applications are handed over to the Drug Inspector (DI) concerned for physical inspection of units. Based on DI's recommendations, the LA submits the application to the Secretary (Health) for approval and after receipt of the same, the LA issues the licence / grants renewal of licence.

A mention was made in paragraphs 3.1.18 and 3.1.19 of AR 2002-03 of C&AG of India regarding non-maintenance of basic records and failure to monitor the disposal of applications for renewal of licence and non-availability of pendency position at any point of time. The UT Government stated (December 2003) that the time schedule of 15 days was prescribed for renewal of licence. The Department stated in PAC meeting

that the system was fully computerised and the prescribed time schedule was strictly adhered to. Based on the reply, PAC had treated the issue as closed.

A test check of 27 applications<sup>30</sup> out of 104 applications received during 2013-16 for issue of new licences and renewal of licences revealed that though the applications for renewal were received within the validity period, the Department had taken time ranging from three months to more than a year for inspection, approval and issue of licences, as detailed in **Table 3.3**.

**Table 3.3 - Stage-wise application pending position**

Stage of applications	Within 15 days	Upto three months	More than three months upto one year	More than a year	Total
For inspection	--	3	15	9	27
For approval (on completion of inspection)	14	6	4	3	27
For issue (after approval)	12	6	6	3	27

Though the Department had committed in PAC meeting to complete the entire process in 15 days, but it had not even conducted inspection for any of the applications submitted within 15 days as evident from above details. Further, in one case, there was an inordinate delay of 68 months to issue licence and in respect of nine applications, the LA had taken more than three months' time even to issue licence after approval, indicating the failure of the Department to follow its own statement made in PAC meeting.

Thus, the prescribed time schedule of 15 days was not being followed by the department for issue / renewal of licences.

On being pointed out, the UT Government accepted (November 2016) audit observation and stated that Department was clearing the backlog and once the software was developed and additional posts created and filled up, the applications would be processed in time without delay.

### **3.5.2.2 Absence of database for renewal of licences**

The Department had stated in the PAC meeting that database was fully computerised, but we noticed that this database was not available for drug manufacturing firms and the Department continued to maintain only a manual register for issue / renewal of licences.

<sup>30</sup> Five new applications and 22 applications for renewal of licences

A check of all the 49 licences issued to manufacturing firms during the years 2009 (20) and 2010 (29), which had become due for renewal during 2014-16 on completion of the statutory period of five years, revealed that only eight firms had renewed their licences, while two firms had surrendered their licences and six firms had submitted applications for renewal of licences, which were under process.

We could not ascertain whether the remaining 33 firms were operational or not, as the Department stated (July 2016) that the files relating to those firms were not traceable. We further noticed that in absence of database, the DIs were conducting inspections only at the time of issue of new licences and renewal of licences and had not conducted inspection at least once in a year, as provided in Rule 52 (5) of the Drugs and Cosmetics Rules, 1945.

On being pointed out, the UT Government accepted (November 2016) audit observations and stated that suitable software was being developed for updating the data of manufacturing units. As such, the Department was neither aware of the fact that which firms were operating without valid licences nor it had invoked the penal provisions as per section 27 (b) (ii), which provided that the firms manufacturing drugs without a valid licence, were punishable with imprisonment and fine.

### **3.5.2.3            *Operation of Blood banks without valid licence***

Blood is treated as a drug. As per Rule 122 F of Drugs and Cosmetics Rules, 1945, application for grant / renewal of licence for the operation of a Blood bank / processing of human blood for components / manufacture of blood products shall be submitted before the LA appointed. The validity of licence for the operation of Blood bank and attached Blood storage unit<sup>31</sup> was five years and two years respectively from the date on which licence was granted / renewed. The LA would forward the application to Central Licence Approving Authority (CLAA) functioning under Central Drugs Standard Control Organisation (CDSCO) for arranging Joint inspection of the unit. If CDSCO was satisfied that conditions laid out in the Rules were fulfilled, it could grant / renew the licence of the unit.

The operation of Blood banks without valid licence was punishable with imprisonment and fine under Section 27 (b) (ii) and it should be the duty of the DI to inspect the Blood banks not less than once a year to satisfy that the conditions of licence were being observed (Rule 52).

A mention was made in paragraph 3.1.22 of Audit Report 2002-03 of C&AG of India about functioning of Blood banks after the expiry of their

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<sup>31</sup> Grant or renewal of licence of the Blood Storage Unit *i.e.*, Rajiv Gandhi Government Women and Children Hospital depends on the validity of licence of the mother Blood bank *i.e.*, Indira Gandhi Government General Hospital, Puducherry



respective licences. In the PAC meeting (February 2009), the Department had stated that the Blood banks, being Government Institutions, took time for making necessary alteration, which resulted in backlog and the Department was waiting for Joint inspection. The PAC had desired to know the latest position regarding renewal of licences to the Blood banks.

As of March 2016, 17 Blood banks and three Blood storage units were functioning in Puducherry. A review of licences issued and Joint inspection reports of CDSCO and DDC of Blood bank and Blood storage units revealed the following:

- Licences of three Blood banks<sup>32</sup> had expired during December 2000, December 2007 and March 2008, and they had applied for renewal of licences during December 2011, December 2012 and March 2013 respectively. Their applications for renewal had been kept pending by the LA for rectification of deficiencies noticed during joint inspection conducted<sup>33</sup> during 2012-13 and 2014-15 such as, absence of quality control test for kits and reagents, malfunctioning deep freezer, placing of screened and unscreened blood bags in same refrigerator, non-submission of compliance report, non-completion of Joint inspection for verification of compliance, etc.
- In respect of two Blood banks<sup>34</sup>, CDSCO after inspection had instructed (October 2014 and June 2015 respectively) to cancel their licences in the absence of tests for sterility of human blood and irregular antibodies, refrigerator for untested blood, emergency equipment like oxygen cylinder, etc. Instead of cancelling their licence, the Department, however, had issued (December 2014 and January 2016) only memorandums calling for compliance report after rectifying the defects noticed during Joint inspection.
- The Blood storage unit at Rajiv Gandhi Government Women and Children Hospital attached to Indira Gandhi Government General Hospital (mother Blood bank) had applied for licence in June 2011. However, after conducting inspection during July 2011, the Department had called for details such as list of equipment, technical staff, agreement with mother Blood bank, etc., only during December 2015, which was indicative of the fact that the Blood Storage Unit was functioning for four years without licence.

As such, all the above six Blood banks and storage units continued their operation without valid licences but the Department had not taken any effective follow-up action to ensure compliance or to cancel their licences.

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<sup>32</sup> GH (Karaikal), JIPMER and Indira Gandhi Government General Hospital (IGGGH)

<sup>33</sup> Conducted by CDSCO and DDC

<sup>34</sup> GH, Mahe and M/s Puducherry Private Hospitals Association

Thus, the above Blood banks had been functioning for more than eight years without valid licences which indicated that the quality of blood being distributed by these Blood banks could not be ensured thereby putting the lives of users of such blood at risk.

While accepting audit observation, the UT Government stated (November 2016) that Blood banks being Government institutions, the matter was pending for want of rectification and compliance report and assured that the deficiencies would be rectified before issue of licences to Blood banks.

### **3.5.3 Human resource issues**

#### **3.5.3.1 *Appointment of Licensing Authority without prescribed qualification***

Rule 162-A prescribes the qualifications for State Drug Licensing Authority for licensing Indian System of Medicine (ISM) drugs (*i.e.*) Ayurveda, Siddha and Unani drugs as B.Pharma (Ayurveda) of a recognised University and atleast five years experience in the manufacturing / testing of Ayurveda, Siddha and Unani drugs or teaching / research on clinical practice of Ayurveda, Siddha and Unani System. However, the UT Government had appointed (August 2013) LA, who did not possess the prescribed qualifications, for issue of licences to ISM drugs. It was noticed that during 2013-16, the LA had issued licences to five ISM manufacturing firms.

On being pointed out, the UT Government stated (November 2016) that the LA was officiating as a stop gap arrangement and licences for ISM units were issued after considering the recommendations of the Expert Committee formed for this purpose. The reply was not acceptable, as the LA continued to discharge the duties for more than three years without prescribed qualification, as specified in the Rule.

#### **3.5.3.2 *Vacancy in the post of Drug Inspectors***

As per Rule 51 and 52, DI is required to inspect not less than once a year all the establishments and premises licenced for sale / manufacture of drugs, to satisfy himself that the conditions of the licences are being observed, to take samples of the drugs manufactured on the premises and send them for test or analysis, to investigate any complaints and to institute prosecution in respect of breaches of the Act or Rules.

We observed that against the sanctioned strength of four posts in DDC, three DIs<sup>35</sup> were in position (June 2016). A mention was made in Audit Report 2002-03<sup>36</sup> of C&AG of India, that as per the recommendations of the Task Force (1982), there should be one DI for every 25 manufacturing

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<sup>35</sup> One post was vacant for more than five years

<sup>36</sup> Paragraph 3.1.5

premises or 100 sale units in order to have an effective control over manufacture and sale of drugs. The Department had informed PAC regarding manpower shortage and the PAC had directed the department to send a proposal to GOI for creation of eight more posts of DIs.

As the department had not maintained a database about the total number of firms operating in UT, we could not arrive at the actual number of DIs required as per the Task Force Committee recommendations. It was noticed that after the Department of Drugs Control was bifurcated (February 2011) from the Directorate of Family Welfare Services, Puducherry, a proposal for creation of 27 posts (including one Controller of drugs, four Assistant Controller of Drugs and four DIs) in various cadres was forwarded (March 2012) to GOI. The proposal was returned (April 2012) by GOI, with the instructions to examine the pay structure of the statutory posts of the DI and Assistant Drug Controller with other States and UT. The UT Government had sent (December 2012) a revised proposal, after considering the pay structure of the above posts. The GOI called for (October 2013) the number of sanctioned posts before bifurcation. The UT Government furnished (January 2014) the same to GOI but the approval of GOI was still awaited (October 2016).

On being pointed out, the UT Government stated (November 2016) that a reminder had been issued (October 2016) to GOI for early approval of the proposal.

As such, three DIs were available and Department had sent proposal to GOI for additional four posts, which was also pending. This impacted the implementation of Act and Rules in UT and led to shortcomings in discharging the duties of DIs, as discussed in the succeeding paragraph:

#### **3.5.4 Inspections by Drug Inspectors**

Scrutiny of the records relating to inspection activities of DIs in relation to the functions of DI as per Rules 51 and 52, revealed the following discrepancies:

- DIs inspected only those units which had applied for grant or renewal of licence and did not conduct periodical inspection of all units not less than once in a year as required in Rules 51 and 52. On being pointed out, the Department stated that no specific target was fixed for DIs and units were inspected only at the time of issue of new licences and renewal of licences. We observed that the reply of the Department was not correct as regular inspections were required as per rules, in the absence of which, the Department could not ensure whether the units were functioning with valid licence and conditions of licence were properly adhered to by the units.

- Though Sections 22 and 23 of the Act provide for drawing samples for test and analysis, Audit observed that no samples were drawn for testing in respect of ISM drugs.

Thus, in the absence of requisite inspection by DIs, the drug units were functioning without valid licences entailing risks of using untested drugs.

While accepting audit observations, the UT Government replied (November 2016) that after creation of additional DI posts, zone-wise jurisdiction would be assigned to them for conducting regular inspection and statutory functions of the Department would be implemented.

### **3.5.5 Drug testing laboratories**

#### **3.5.5.1 *Operation of Government Laboratory without sufficient staff***

The erstwhile Public Health laboratory functioning under the Directorate of Health and Family Welfare Services was converted (February 2011) into an independent Department of Food and Drug Testing (DFDT), with a view to set up a full-fledged and combined Food and Drug Laboratory for food and drug analysis. The DFDT was headed by Senior Public Analyst for Food and Government Analyst for Drug. The Government Analyst was responsible for testing samples of drugs and cosmetics sent to him by DIs or other persons under the provisions of Act and to furnish reports of the results of test.

For effective functioning, the laboratory was sanctioned (February 2011) with 39 technical and 13 non-technical posts. We observed that while all the non-technical posts were filled up, 22 out of the 39 technical posts were vacant. It was further noticed that against the sanctioned strength of five analysts, there was only one Analyst to conduct the tests. Though no time limit was prescribed for finalising the test reports, it was noticed that the laboratory had taken two to eight months' time to issue the test reports after receipt of samples, indicating poor performance of the laboratory.

On being pointed out, the UT Government accepted audit observation and stated (November 2016) that once the additional posts were created and filled up, the laboratory would be put into effective operation.

#### **3.5.5.2 *Non-establishment of Drug testing laboratory for ISM***

For strengthening of State Enforcement Mechanism under the Centrally Sponsored Scheme (CSS) of Quality Control of Ayurvedic, Siddha, Unani and Homeopathy Drugs, the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH), Ministry of Health and Family Welfare had released ` 31 lakh<sup>37</sup> during the year

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<sup>37</sup> ` 17 lakh (February 2008), ` 14 lakh (March 2009)

2007-09 to State Health Mission, UT of Puducherry. The UT Government had accorded approval (February 2014) to establish the Drug Testing Laboratory (laboratory) for AYUSH by Mother Theresa Post Graduate and Research Institute after a lapse of five years. The amount was utilised for purchase of equipment and furniture (June 2014). Subsequently, the Department had estimated an amount of ` 1.65 crore and sought ` 1.34 crore<sup>38</sup> (November 2014) from GOI for establishment of a full-fledged laboratory. No follow-up action was taken by the Department.

The GOI had, however, instructed (November 2014) the States to submit State Annual Action Plan (SAAP) for Grant-in-aid under another CSS for National AYUSH Mission. In the SAAP for the year 2015-16, the Department had sought (August 2015) ` 20 lakh under the component Quality Control of AYUSH drugs for purchasing equipment for laboratory. The GOI released ` 12.53 lakh (March 2016), which remained unutilised as of September 2016. As such, the laboratory was not established (September 2016) by UT despite receipt of ` 43.53 lakh from GOI.

Thus, we observed that the drug testing laboratory for ISM had not been established due to which the department was handicapped in ensuring quality of drugs and food.

On being pointed out, the UT Government stated (November 2016) that they had forwarded a proposal to GOI for additional funds for establishment of laboratory for ISM drugs.

### **3.5.6 Manufacturing of drugs without approval**

As per Rule 122 E, drugs falling under the category of a Fixed Dose Combination (FDC)<sup>39</sup> of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio or if the ratio for ingredients in an already marketed combination is proposed to be changed, with certain claims should be treated as New Drugs.

Any such FDCs falling under 'New Drug' had to be approved by Drugs Controller General of India (DCG (I)). In January 2013, DCG (I) instructed that in respect of FDCs, for which licences were issued before October 2012 without approval of DCG (I), the firms had to prove the safety and efficacy of the FDCs before DCG (I) within a period of 18 months, failing which such FDCs would be considered as prohibited for manufacture and marketing in the country.

We observed that 29 manufacturers had been issued licences for manufacturing FDC drugs in UT, prior to October 2012. But, out of 29 manufacturers, only 10 manufacturers had, submitted their applications to

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<sup>38</sup> ` 1.65 crore - ` 0.31crore (already received)

<sup>39</sup> FDC refers to drugs containing one or more active ingredients

the DCG (I), for getting approval for the manufacture and marketing FDC drugs.

On being asked, the department was silent about the status of the applications of remaining 19 manufacturers. In the absence of any reply in this regard, we could not ascertain whether these 19 manufacturers had submitted their applications to the DCG (I) for continued manufacturing of FDC drugs. Thus, the department failed to reply as to whether these 19 firms had ensured safety and efficacy of the FDCs before DCG (I).

We further noticed that four out of the 19 manufacturers continued manufacturing of the drugs and they were reported (January and September 2015) as non-standard quality drugs from other States as discussed in the succeeding paragraph, indicating lack of follow-up action by the Department.

On being pointed out, the UT Government also did not give any specific reply about the status of applications of 19 manufacturers submitted to DCG (I).

Thus, the manufacturers were manufacturing FDC drugs without any approval from the competent authority.

### **3.5.7 Failure to initiate action against Non-Standard Quality Drugs**

As per Section 27 (a) of the Act, whoever manufactures for sale or for distribution any drug deemed to be adulterated under Section 17-A or spurious under Section 17 B, when used by any person is likely to cause harm shall be punishable with imprisonment and fine. It was the duty of the DIs to investigate any complaint made and to institute prosecution in respect of breaches of the Act and Rules thereunder, as per Rules 51 and 52.

The Drug manufacturing firms located in UT, sold their drugs through various sale units outside UT. Instances of Non-Standard Quality (NSQ) Drugs manufactured in UT were identified based on the tests conducted in the drug testing laboratories situated in other States<sup>40</sup>. A total of 182 cases of NSQ drugs were reported to the Department for initiating necessary action, during the audit period.

A test check of 60 NSQ cases reported during 2013-16 revealed that the Department had taken action only in respect of 33 cases by suspending the licence for a specified period of one month to one year with a warning. However, in respect of the remaining 27 cases, only memorandums were issued to stop production and calling for explanation for violation of rules and no penal action was initiated.

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<sup>40</sup> Karnataka, Kerala, Chandigarh, Maharashtra and Tamil Nadu

Thus, the Department had not only failed to ensure the stoppage of manufacturing of NSQ drugs but also had failed to enforce penal action against the manufacturers for breach of Section 27 (a) of the Drugs and Cosmetics Act. The adulteration of drugs, being a serious offence, calls for taking immediate action after conducting necessary investigation in the matter.

While agreeing with audit observation, the UT Government stated (November 2016) that adequate strength of DIs was needed for enforcement of the provisions of the Act and Rules.

### **3.5.8 Failure to enforce provisions of Drugs (Price Control) Order, 1995**

As per Para 3 of Drugs (Price Control) Order, 1995 (DPCO), the Government may, with a view to regulate the equitable distribution of bulk drugs and making the same available at a fair price, fix a maximum sale price at which a drug shall be sold. In case of manufacturers charging higher price than fixed by Government, those manufacturers, importers or distributors were required to deposit the amount accrued due to charging of prices higher than those fixed, into the Drugs Prices Equalisation Account as provided in paragraph 13 of the DPCO. Any contravention of the provision of the DPCO, 1995 was punishable<sup>41</sup> in accordance with the provisions of the Essential Commodities Act, 1955.

We observed that the National Pharmaceutical Pricing Authority (NPPA) was entrusted with the task of fixation / revision of prices of pharmaceutical products (bulk drugs and formulations), enforcement of provisions of the DPCO and monitoring of the prices of controlled and decontrolled drugs in the country. The NPPA had issued (2013-15) Show Cause Notices to seven manufacturers, importers / distributors of drugs situated in UT to deposit ` 51.37 crore pertaining to the period 2008-15, as drugs were sold at higher prices than fixed. The Show Cause Notices were endorsed to the Department to take up the matter with the firms concerned for deposit of overcharged amount within the prescribed time limit.

We observed that despite specific direction by NPPA, the Department had not taken any action to recover the amount overcharged by the manufacturers, which resulted in non-remittance of ` 51.37 crore by the firms.

On being pointed out, the UT Government stated (November 2016) that due to acute shortage of DIs, they were not notified under DPCO to enforce the provisions of the Act and hence, could not take follow up action with the firms concerned for remittance of amount as communicated by NPPA. It was further stated that Department would be instructed to send a proposal

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<sup>41</sup> Section 7 of Essential Commodities Act, 1955

for notification of an existing DI under DPCO. The reply was not acceptable, as the shortage of DIs cannot be cited as a reason for not taking action against the defaulting manufacturers resulting in public being subjected to higher drug prices.

### **3.5.9 Conclusion**

The Department had not maintained any database for renewal of licences and was not aware of number of units existing at any given point of time. There were delays in issue of new licences and renewal of licences, despite the Department's commitment to PAC in February 2009 that the system was fully computerised and the prescribed time schedule was strictly adhered. Blood banks were allowed to function without valid licences for more than eight years. Periodical inspection of manufacturing and sale units was not conducted, as stipulated. Inspection was conducted only at the time of issue and renewal of licences. Samples were also not drawn from Indian System of Medicine manufacturing firms for testing. Strict action was not taken against firms charging higher prices for violation of Act, manufacturing drugs without approval and non-standard quality drugs, which might endanger the safety of the drug users. Thus, there was a critical need for UT Government to review and streamline these issues and ensure strict compliance to the provisions of Drugs and Cosmetics Act, 1940.