# CHAPTER III
# PERFORMANCE REVIEWS

This chapter contains performance reviews on 'Implementation of Drugs and Cosmetics Act, 1940', 'Prevention and control of fire', 'National AIDS Control Programme', 'Functioning of Agriculture Department', 'Alimineti Madhava Reddy Project' and 'Information Technology Audit of computerisation in Forest Department'.

## HEALTH, MEDICAL AND FAMILY WELFARE DEPARTMENT

### 3.1 Implementation of Drugs and Cosmetics Act, 1940

**Highlights**[·]

***The Drugs and Cosmetics Act 1940 (Act) is a Central Act to be implemented by all the States. The Act along with the other associated Acts and the rules made thereunder regulate the import, manufacture, distribution, sale and clinical research of drugs and cosmetics. In Andhra Pradesh the Drugs Control Administration (DCA) was functioning with only 55 Drugs Inspectors (DIs) for the last 10 years against the requirement of 240. Huge shortage of DIs adversely affected the functioning of the DCA and menace of spurious drugs continued to prevail. No follow-up action was taken to withdraw the drugs (from the market) declared as not of standard quality. The licensing system was ineffective and the DCA did not maintain proper record. Monitoring at State level was poor. Thus the objective of prevention of the menace of spurious drugs to eliminate the danger to human life had not been achieved.***

- **Eighty per cent (578) of the prosecution cases were pending trial in courts due to lack of administrative will.**

  ***[Paragraph 3.1.3 (i)]***

- **The shortfall in inspections of manufacture and sale units ranged from 15 to 67 per cent due to huge shortage (77 per cent) of Drugs Inspectors. There was no increase in the number of DIs during last 10 years.**

  ***[Paragraphs 3.1.4 II (i) and (iii)]***

- **Approval of Government on proposals of strengthening of Drugs Control Administration with the World Bank assistance submitted in 1997 was awaited.**

  ***[Paragraph 3.1.4 III]***

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[·] The abbreviations used in this review are listed alphabetically in glossary vide Appendix XLIX (page 211)

- **Due to lack of funds for payment of cost of samples, the targets fixed for analysis of drugs samples were not achieved; shortfall ranged from 4 to 21 per cent.**

***[Paragraphs 3.1.4 II (ii) and IV (i)]***

- **Out of 18493 samples analysed there were delays of over three months in 1588 samples. Analysis of 1807 samples was not completed, of which life of 57 samples had expired.**

***[Paragraph 3.1.4 IV (ii)]***

- **Though 832 samples were declared as not of standard quality (NSQ), no follow-up action was taken by the Drugs Inspectors/ DCA to ensure withdrawal of these drugs from the market.**

***[Paragraph 3.1.4 V]***

- **The Legal-cum-Intelligence Cell and Anti-spurious drugs squads were not established.**

***[Paragraph 3.1.4 VII]***

- **Information, Education and Communication (IEC) activities were not undertaken. The DCA had not developed any database of manufacturers/sale concerns/ licences/ management information system and monitoring system modules for drug control functions.**

***[Paragraphs 3.1.4 VIII and 3.1.7]***

- **Inspection of Indian Medicine units had not been conducted except at the time of sanction of fresh licences. Shortfall in respect of Homoeopathic units was between 92 and 98 per cent.**

***[Paragraph 3.1.5 (i)]***

- **Training of DIs and other staff was altogether neglected and no training programmes were organised by the ADG, DCA.**

***[Paragraph 3.1.6]***

- **There was no proper monitoring at State level on the implementation of the Act and Rules in the State.**

***[Paragraph 3.1.7]***

### 3.1.1 Introduction

***i) Background:*** At the beginning of the twentieth century, pharmaceuticals were being imported from abroad. After the First World War, manufacturing concerns, both Indian and Foreign, sprang up to produce pharmaceuticals at cheaper rates to compete with imported products. Some of these products were of inferior quality and harmful. Government, therefore, decided to introduce legislation to control the manufacture, distribution and sale of drugs and medicines. A Select Committee appointed by the Central Legislative Assembly in 1937 recommended various measures, providing for the uniform control of manufacture and distribution of

drugs as well as of import and finally the Drugs Act[1] was enacted on 10 April 1940.

At present, the Acts and Rules, apart from the Drugs and Cosmetics Act, 1940, which govern the manufacture, sale, import, export and clinical research of drugs and cosmetics in India are : The Pharmacy Act, 1948; The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954; The Narcotics Drugs and Psychotropic Substances Act, 1985; The Medicinal and Toilet Preparations (Excise Duties) Act, 1956; The Drugs (Prices Control) Order 1995 (Under the Essential Commodities Act). However, 'The Drugs and Cosmetics Act, 1940' continues to be the main Act.

### *ii) Main features of the Act*

- To ensure standards of Drugs and Cosmetics, Diagnostics and Devices.
- To monitor quality of drugs and medicines imported, manufactured, distributed and sold.
- To take punitive measures for violation of provisions of the Act.
- To regulate clinical research and publication of Indian Pharmacopoeia.

***iii) Statutory functions:*** This is a Central Act and is applicable to all the States. Central Government lays down the regulatory measures and the standards of drugs, cosmetics and diagnostics, and makes amendments to Acts and Rules. It regulates market authorisation of new drugs and standards of imported drugs. It is the Central Licence Approving Authority for Blood Banks, Large Volume Parenterals and Vaccines and Sera. Drugs Technical Advisory Board (DTAB), Drugs Consultative Committee (DCC) and Central Drugs Laboratories are under the control of the Central Government.

The main functions of the State Government are (a) licensing of drug manufacturing and sales units, (b) licensing of drug testing laboratories, (c) approval of drug formulations for manufacture, (d) monitoring of quality of Drugs and Cosmetics manufactured, (e) investigation and prosecution in respect of contravention of legal provisions, (f) regulation of the standards of imported drugs, (g) inspection and (h) recall of sub-standard drugs.

A review on the implementation of Drugs and Cosmetics Act 1940 and other related Acts and Rules thereunder was conducted by test-check of the records for the period 1998-2003 at the office of the Additional Director General, Drugs and Copyright, Drugs Control Administration (ADG, DCA), six Assistant Directors (ADs),

[1] Drugs Act, 1940 was amended in December 1961 to provide for regulation of the manufacture of cosmetics and prohibition of import and sale of sub-standard and misbranded cosmetics

15 Drugs Inspectors (DIs), two Drugs Control Laboratories (DCLs) and the Commissioner of Indian Medicine and Homoeopathy covering nine districts and a population of 3.38 crore (44.6 per cent). The results of the review are mentioned in the succeeding paragraphs.

### 3.1.2 Implementation arrangements

The Principal Secretary to Government, Health, Medical and Family Welfare Department is responsible for implementation of the Act and the Rules at Government level. The ADG, DCA is the regulatory authority for allopathic drugs and cosmetics and is assisted by a Director, supported by two Joint Directors and other enforcement staff. The Organisational chart is given in *Appendix XXV*.

In regard to Ayurveda and other systems of medicines, the Commissioner of Indian Medicine and Homoeopathy is the head of the department and is assisted by three[2] Additional Directors[3] and six[4] Medical Officers posted as DIs.

Budget provision vis-à-vis the expenditure of the DCA during 1998-2003 was as follows.

(Rupees in crore)

| Year | Budget estimates projected by DCA | Budget provision | Expenditure | Expenditure on salaries (percentage) | Expenditure on Travelling Allowances (percentage) |
|---|---|---|---|---|---|
| 1998-99 | 2.82 | 2.61 | 2.80 | 2.39 (85) | 0.06 (2) |
| 1999-2000 | 3.08 | 3.18 | 3.29 | 2.94 (89) | 0.06 (2) |
| 2000-01 | 4.25 | 3.68 | 4.26 | 3.42 (80) | 0.11(2) |
| 2001-02 | 4.17 | 4.00 | 4.09 | 3.48 (85) | 0.12 (3) |
| 2002-03 | 4.91 | 4.56 | 4.13 | 3.57 (86) | 0.08 (2) |
| **Total** | | **18.03** | **18.57** | **15.80 (85)** | **0.43 (2)** |

**Incidence on TA was meagre 2 per cent**

Though the main activity of the department requires enforcement staff to travel across the State to inspect the drugs manufacturing and sale units, meagre expenditure on travelling allowance was indicative of inadequate and ineffective coverage of inspections.

### 3.1.3 Enforcement

***i) Standing of the Law – violation of provisions of Act/Poor progress in prosecution cases:*** Drugs and Cosmetics Act envisages that no person shall himself or by any other person on his behalf manufacture for sale or for distribution or sell or exhibit or offer for sale or distribute, any drug or cosmetic which is not of standard quality or is misbranded, adulterated or spurious.

[2] one for each system of medicine (Ayurveda, Unani & Homoeopathy)
[3] not exclusively for implementation of the Act
[4] 3 Ayurveda, 2 Unani, 1 Homoeopathy

**578 prosecution cases (80 per cent) were pending trial in courts**

During 1998-2003, out of 19017 violations reported, 492 charge sheets (three per cent) were filed in the Courts. Of these, 182 cases were filed in Vijayawada region during 2002-03, which included 55 cases of seizures of ayurvedic drug containing 'Sildanafil Citrate' (Para 3.1.4 VI (ii) refers). Out of the total 721 prosecution cases as of March 2003 (including 229 cases prior to 1998-99) 578 cases (80 per cent) were pending trial in courts for various reasons viz., (i) non-serving of summons (eight) by the Drug Inspectors and non-bailable warrants (23) of the offenders through police, (ii) absence of parties involved in the court at the time of hearing, etc. Of 143 cases decided in the courts during the period 115 were convicted. In 28 cases, the accused were acquitted mainly due to (i) failure to prove that the drugs seized were stocked for sale purpose; (ii) failure to produce two independent local mediators/witnesses; (iii) non-furnishing of drugs samples and analysis profile to the accused; (iv) delay in filing the complaint in the court; (v) contradictory evidence by the officials of enforcing authority in securing panch witnesses; and (vi) failure to prove the basic fact of inspection of place of detection of violation. Out of 38 conviction cases decided during 2002-03, fines of Rs 1000 and Rs 5000 was imposed in two cases and in other cases (36) both imprisonment (one month to five years) and fines (Rs 500 to Rs 20000) were awarded by courts.

Thus, lack of administrative will on the part of the enforcing authority and non-adherence of mandatory provisions of the Act led to the failure of prosecutions, despite the recommendations of Public Accounts Committee (March 2001) to take effective steps to launch the prosecutions without loss of time and to avoid lapses in prosecution to ensure that the offenders get due punishment.

**Of 861 cases of violation during 1995-2003, 417 cases (48 per cent) were still under investigation with DCA**

***ii) Drugs (Price control) Order, 1995 and Drugs and Magic Remedies (Objectionable Advertisements) Act 1954:*** **(a)** As per the Drugs (Price Control) Order 1995, no person shall sell a bulk drug/formulation at a price exceeding the maximum sale price fixed by National Pharmaceutical Pricing Authority (NPPA), a body authorised by GOI. Under the Act, 861 cases of violation[5] were detected during 1995-2003 (up to March 2003). Of these, the ADG, DCA filed charge sheets only in 85 cases (10 per cent), 156 cases (18 per cent) being sub-judice were kept in abeyance and 417 cases (48 per cent) were under investigation as of September 2003. It was noticed that particulars of violation cases (802) detected during 1995-2002 were sent to NPPA only in September 2002 due to delay in receipt of GOI orders on the representation of Drug Manufacturers Association.

**56 out of 140 cases of violations (40 per cent) were still under investigations with DCA**

**(b)** As per the provisions of Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954, no person shall take part

[5] 1995 : 8, 1996 : 481, 1997 : 134, 1998 : 37, 1999 : 9, 2000 : 32, 2001 : 101, 2002 : 59

in advertising any matter which (i) directly or indirectly gives a false impression regarding the true character of drug (ii) make false claim of the drug or (iii) misleading in any material particular. During 1993-2003, 140[6] cases of violations of the Act were detected. Of these, complaints were filed in the courts in 66 cases (47 per cent) and conviction orders were issued only in 28 cases; 56 cases were under investigation with the DCA as of September 2003.

The delay in investigation of the cases could only result in the drugs continuing to be sold at higher rates/illegal sale of drugs.

### 3.1.4 Implementation of the Act - Allopathic medicines and Cosmetics

#### I Survey and licensing functions

**No surveys of spurious drugs manufacture/ distribution were conducted by DCA**

Surveys were to be conducted at regular intervals to have the full information on the manufacture and sale of drugs in the market. Watchers/decoy customers were to be engaged for purchasing samples of drugs and to keep watch over the movement of suspected drugs especially at sensitive market places which were suspected to have manufacturers/distributors of spurious or doubtful quality of drugs by providing secret funds for such activity. DCA had not undertaken any such activity for want of such funds. As such, the manufacture and sale of spurious drugs continued to prevail in the market as evident from the NSQ drugs detected during 2002-03.

**No record maintained to verify the current status of the grant of renewal of licence**

***i) Non-maintenance of licensing records:*** As per the Act the licences granted/renewed up to August 2001 was valid up to the end of the following calendar year in which the licence/renewal was granted. Since September 2001 the validity period was five years from the date of issue of licence/renewal.

The ADG, DCA however, did not maintain the records showing the total number of manufacture/sale units, the number of units applied for renewal, renewals sanctioned and units not applied for renewals. Separate records for fresh licences and renewals were maintained but no cross-linking of these records was done. In the absence of such data, the current status of the units and those not applied for renewals could not be established.

Scrutiny of the records of licensing pertaining to the year 1998 revealed that, out of 244 manufacturing units for which fresh licences were issued, subsequent renewals were made only in respect of 88 units, and 156 units (64 per cent) had not renewed their licences. No records were available with ADG, DCA to ensure that the enforcing authorities (DIs) have inspected such units after expiry

[6] 10 cases pertained to the period 1993-98

of licence, to curb the any possible illegal manufacturing activity/manufacture of spurious drugs.

**No mechanism to ensure compliance of stop production orders**

Based on NSQ reports, Director, DCA ordered to stop production in 370 units and cancelled the licences of 198 units during 1998-2003. The DCA could not furnish the information with regard to the mechanism to ensure compliance of their orders.

**Loss of revenues of Rs 5.72 lakh towards fees for fresh licences and renewals**

***ii) Short payment of licence fee:*** **(a)** The licence fee for both fresh licences and renewals in respect of manufacturing units was revised with effect from 24 August 2001. For each additional product Rs 300 was to be paid by the manufacturer. It was, however, noticed that the licence fee for additional products (i.e., in excess of 10 products) was not paid by 31 manufacturing units which applied for renewal during 2001 and 2002 resulting in a short payment of Rs 2.94 lakh.

**(b)** With effect from 24 August 2001 licence fee for distribution/ sale of drugs and cosmetics was raised to Rs 3000 for a period of five years from Rs 80 for two calendar years. It was however noticed that the ADs, Cuddapah, Warangal, Vijayawada and Rajahmundry collected the licence fee at the old rate of Rs 80 from 235 applicants who applied for renewals between 24 August 2001 and 31 October 2001. This resulted in short realisation of Rs 2.78 lakh for two years. The ADs stated that Government notification was not communicated by ADG, DCA till November 2001.

The total loss of revenue in these cases amounted to Rs 5.72 lakh.

## II Adequacy of sampling and inspection

**Shortfalls in inspections ranged from 15 to 67 per cent**

***i) Shortfall in inspections:*** **(a)** As per the provisions of the Act and Rules, Drugs Inspectors (DIs) were required to inspect the manufacturing and sale units of drugs and cosmetics twice in a year up to 25 April 2001 and once in a year from 26 April 2001 to ensure compliance of conditions of licence, etc. and also to draw drug samples for quality test. There were shortfalls in inspection ranging from 15 to 67 per cent as detailed below:

| Year | Number of Licensed units | | Number of inspections | | Shortfall in inspections (percentage) |
|---|---|---|---|---|---|
| | Manufacturing | Sale | to be conducted | Conducted | |
| 1998-99 | 1993 | 32265 | 68516 | 23399 | 45117 (66) |
| 1999-2000 | 2204 | 34815 | 74038 | 24569 | 49469 (67) |
| 2000-01 | 1612 | 28319 | 59862 | 24729 | 35133 (59) |
| 2001-02 | 1854 | 31348 | 33202 | 23367 | 9835 (30) |
| 2002-03 | 1977 | 30726 | 32703 | 27836 | 4867 (15) |

The shortfall led to inadequate check on the Good Manufacturing Practices to be followed by the manufacturers. The ADG, DCA did

not maintain any record to ensure inspections of all the manufacturing/sale units over a specified period.

The Director attributed (January 2003) the shortfall in inspections to shortage of DIs. Thus, due to short-coverage of inspection the menace of spurious drugs could not be arrested as discussed in succeeding paragraphs.

**Shortfall in inspections was more than 50 per cent in Cuddapah, Vijayawada and Rajahmundry regions**

**(b)** Shortfall in inspection in 21 DIs (test-checked 15 DIs and six DIs attached to ADs) ranged from 22 per cent (Nizamabad) to 72 per cent (Kakinada) in 1999-2000 and 2000-01 (*Appendix XXVI* refers). The shortfall in Cuddapah, Vijayawada and Rajahmundry regions was more than 50 per cent in all the years up to 2000-01. Further, there were large variations between the figures of units/inspections conducted as furnished by the six ADs and those furnished by the Directorate (*Appendix XXVII* refers). The reasons for variations were not explained by the Director.

***ii) Shortfall in lifting of drugs samples:*** In order to ensure the quality of drugs manufactured and sold, the DIs are required to draw samples from manufacturing, distribution and sale units including hospitals for sending them to DCL for analysis. No methodology was evolved by the Department to ensure coverage of all the manufacturing and distribution units in a year. As per the targets[7] fixed by the Department each DI was to collect at least six samples per month (eight from April 2002).

Scrutiny of the records of DIs revealed that two to four drugs samples were collected from a single unit to achieve the targets by covering less number of units. Nevertheless, the targets were not achieved by the DIs during 1998-2003, as shown below.

| Year | Number of samples | | Shortfall (percentage) |
|---|---|---|---|
| | to be drawn | Drawn | |
| 1998-99 | 3960 | 3377 | 583 (15) |
| 1999-2000 | 3960 | 3467 | 493 (12) |
| 2000-01 | 3960 | 3976 | -- |
| 2001-02 | 3960 | 3900 | 60 (2) |
| 2002-03 | 5280 | 4706 | 574 (11) |

**No criteria adopted in regard to lifting of samples for analysis and drugs samples of general in nature concentrated/other samples ignored**

The Director attributed (March 2003) the shortfall to vacancies in the cadre of DIs as also the inadequacy of budget provision for payment of cost of samples drawn. No criteria was adopted by the Department in regard to lifting of samples for analysis of various categories/types of drugs such as bulk drugs, formulations[8]. Thus, priority was not given to lifting samples of life saving drugs, antibiotics and other essential drugs, required for treatment of diseases like Cancer, TB, Cardio-Vascular, Renal etc. This led to

[7] no basis for fixation of these targets

[8] parenterals, ointments, syrups, tablets, surgical dressings, etc.

concentration on lifting drug samples, such as Paracetomol, Ibuprofen, B.Complex, Diclofenac Sodium etc. which were general in nature repeatedly while other essential drugs were ignored due to non-availability of sufficient funds for procurement of costly drugs.

**Only 55 DIs were in place against 240 required. No increase in staff for the last 10 years**

***iii) Non-observance of staffing pattern:*** As per the recommendations of Hathi Committee (1975) and House Committee (1991), there should be one DI for every 25 manufacturing units and for every 200 sale units. The pattern of enforcement staff and analytical staff should be in the ratio of 1:1. There were 1977 manufacturing and 30726 sales units in the State as of March 2003, and to inspect these units 240 DIs and equal number of Junior Analysts were required for efficient functioning of the department. Against these, only 55 DIs (three vacant) and 25 Junior Analysts (seven vacant) were available; shortage being 77 per cent and 90 per cent respectively. There was no increase in number of staff for the last 10 years. Despite the PAC (2000-01) recommendation[9] to place the enforcement staff to the required strength, no action was taken by Government to improve the position.

Though the ADG attributed the shortfall in inspections, lifting of samples and their analysis and other statutory functions mainly to the shortage of DIs, the ADG did not effectively pursue[10] this key aspect with the Government. This adversely affected the prevention of spurious drug activity in the State endangering the health of public at large.

## III Working of Drugs Testing Laboratories

**Proposal of strengthening of Drugs Control Administration awaiting Government's approval**

A proposal for strengthening of Enforcement Staff and augmentation of analytical testing facilities under World Bank assisted capacity building project (100 per cent Central assistance) were submitted by ADG, DCA to Government in March 1997. The proposal included augmentation of drug testing facilities, strengthening of Drugs Inspectors, construction/expansion of DCL buildings, purchase of vehicles and Laboratory equipment, etc. at an estimated cost of Rs 6.83 crore. Approval of the Government was not accorded as of September 2003. As a result, there was no improvement in all statutory functions of the Department.

## IV Testing of drugs samples

**Targets for testing of drugs samples not achieved**

***i) Shortfall in analysis of drugs samples:*** Analysis of drugs samples play an important role in determination of standards prescribed, prevention of consumption of sub-standard, adulterated

[9] in its VI Report of XI Legislative Assembly

[10] ADG submitted proposal in May 1997, but reminded Government only in April 2001, November 2002 and February 2003

and spurious drugs. GOI fixed annual target of 5000 drugs samples for analysis in the State. As against this, the Department fixed (1996-97) a target of 15 samples per month for analysis for each Junior Analyst i.e., 4500 samples per year. It was, however, observed that even the available samples were not analysed during 1998-2000 though these were less than targets fixed and these targets were not achieved during 2001-03 as detailed below.

**Shortfall in analysis of samples was 4 to 21 per cent**

| Year | Number of samples | | | | Shortfall (percentage) |
|---|---|---|---|---|---|
| | Opening balance | Received | Total | Analysed | |
| 1998-99 | 874 | 3377 | 4251 | 4088 | 163 ( 4) |
| 1999-2000 | 163 | 3467 | 3630 | 3275 | 355 (10) |
| 2000-01 | 355 | 3976 | 4331 | 3588 | 743 (17) |
| 2001-02 | 743 | 3900 | 4643 | 3566 | 934 (21) |
| 2002-03 | 1077 | 4706 | 5783 | 3976 | 524 (12) |

Note: Number of samples to be analysed during each year is 4500

**Delays in testing of samples ranged up to three months**

***ii) Delay in testing of samples:*** No time limit was prescribed in the Act/Rules for analysis of drugs samples. However, as per the recommendations of the House Committee of the State (1991), the drugs samples should be analysed within two months. It was however, noticed that out of 18493 samples analysed during the period 1998-2003 there were delays of over one to three months in respect of 2980 cases (16 per cent) and over three months in 1588 cases (nine per cent). Analysis of 1807 samples (10 per cent) received during 1997-2003 was not completed as of March 2003, of which life of 57 samples had expired. The delay in analysing the drugs samples defeated the very purpose of prevention of sub-standard drugs sold in the market. The ADG, DCA attributed (December 2002) the delay to inadequate staff and testing facilities.

## V Lack of adequate follow-up action on substandard drugs

**Follow-up action not taken to ensure withdrawal of sub-standard drugs from market**

Out of the 18493 samples analysed in the Laboratories at Hyderabad (15560) and Vijayawada (2933), 832 samples[11] were declared as not of standard quality (NSQ). No follow-up action was taken by the DIs/DCA, to ensure withdrawal of sub-standard drugs from the market.

## VI Searches and Seizures

**48 per cent cases of NSQ drugs were under investigation of DCA since 1998**

***i) Delay in finalisation/investigation of cases:*** As per the Act, no person shall manufacture for sale/distribution/stock/exhibit/offer for sale, any drug which is sub-standard quality/mis-branded/ spurious, except in accordance with the conditions[12] of licence

[11] Hyderabad (759), Vijayawada (73)

[12] such as to manufacture under the supervision of competent technical staff, to follow and comply with the schedule 'M' and should contain therapeutic justification for ingredients, etc.

granted. During 1998-2003, ADG carried out 225 seizures[13] suspected to be spurious/mis-branded, and detected 832 cases[14] (Para 3.1.4 (V) also refers) of NSQ drugs. Of these, 399 cases (48 per cent) were under investigation as of March 2003; 87 cases were more than three years old. This indicated slackness of the DCA in completion of investigation and filing the complaints in the court; attributable to non-provision of any time limit in the Act/Rules.

**55 out of 62 samples analysed contained Sildanafil Citrate**

***ii) Seizure of Ayurvedic drug containing Sildanafil Citrate:*** Based on a press news, the DIs conducted (September 2002) surprise check on a manufacturing firm[15] and distribution/sale units and lifted 62 samples of Ozomen and Ozomen forte (Ayurvedic drugs) suspected to be containing "Sildanafil citrate" an allopathic drug. The firm had no licence for mixing 'Sildanafil Citrate' with the Ayurvedic drug. The samples were sent (September 2002) to DCL for analysis and the stock available (value : Rs 63.33 lakh) was also seized. Out of 62 samples analysed 55 samples contained Sildanafil citrate (Para 3.1.3 (i) refers). The case was still under investigation by the ADG, DCA (September 2003).

**Gauze cloth, Roller Bandages were never lifted for analysis**

***iii) Manufacture of gauze cloth, roller bandages by un-licensed manufacturers:*** As per the provisions of Act, guaze cloth, roller bandages, bandage cloth are termed as drugs. Though the DIs lifted the drug samples from Government Hospitals and Institutions these items were never lifted for analysis evidently as no criteria was laid down for lifting of samples of drugs of different categories for analysis (Para 3.1.4 II (ii) refers). The materials were not seized though the labels of materials did not contain the particulars of licence granted for its manufacture. During the investigation, Anti Corruption Bureau (ACB), noticed (March 2001) that out of 58 firms who manufactured and supplied these items to Medical and Health Department during 1998-2000, 44 firms did not possess the drug licence. Government blacklisted (December 2001) 55 firms involved in manufacture of surgical dressing items such as gauze cloth, bandage cloth, roller bandages etc., under the provisions of the Act. The aggrieved firms approached the Hon'ble High Court and the Court issued interim orders (April 2002) suspending the Government Orders.

***iv) Seizure of Viagra and Bethanecol drugs:*** In September 2002 DI, Uppal[16] conducted surprise check at the premises of a firm whose licence was not renewed after December 1999. Certain drugs such as Sildnafil citrate caps, Viagra, Bethanecol tablets, Cifro floxicin, Acezoxforte and other material worth Rs 50 lakh, were

[13] 1998-99 : 47, 1999-2000 : 34, 2000-01 : 46, 2001-02 : 39, 2002-03 : 59
[14] 1998-99 : 191, 1999-2000 : 162, 2000-01 : 179, 2001-02 : 151, 2002-03 : 149
[15] Fizikem Laboratories, Vijayawada
[16] RangaReddy District

seized as these were suspected to be spurious and misbranded. The case was still under investigation by ADG, DCA and charge sheet not filed as of September 2003.

### VII Non-establishment of Intelligence-cum-Legal branch/ Task Force Cells

**Legal-cum-Intelligence Cell not formed/Anti-spurious drugs squads not established**

The Legal-cum-Intelligence cell was not formed (September 2003) though recommended by the Hathi Committee (1975), and the police help was not taken during the departmental raids and also in tackling the spurious drug cases.

The Department had not also established any anti-spurious drugs squads, except formation of a task force cell in January 2003 with the existing staff under the supervision of a Joint Director who was entrusted with the co-ordination, conduct of seizures and searches and detection of violation of the Act. In the absence of independent task force cell the spurious drugs activity continued to prevail.

### VIII Information, Education and Communication (IEC) activities not undertaken

**IEC activity altogether neglected**

Though active participation of enforcement agencies, pharma industry, trade and consumers and common public, etc. was necessary to combat the menace of spurious and sub-standard drugs activity, the ADG, DCA had not undertaken any IEC activities during 1998-2003 statedly due to budget constraints. This was not tenable as no proposals were sent by him for budget allotment under IEC.

**Communication network not established either within the State or with other States**

The DCA had not created any communication network within the State, with other States and with other departments for dissemination and sharing of information on movement of spurious drugs and persons involved in such activity.

### 3.1.5 Ayurvedic and other systems of medicines

No separate budget provision was made for implementation of the Act by Indian Medicine and Homoeopathy Department. Expenditure of Rs 19 lakh to Rs 23 lakh, was incurred every year during 1998-2003. The following points were noticed in audit.

**DIs had not conducted any inspection of Ayurvedic and Unani units**

***i) Non-conducting of inspections of Manufacturing units:*** **(a)** As per the Act the DIs (Ayurvedic and Unani) were required to inspect the premises licensed for manufacture of Ayurvedic and Unani drugs twice a year.

Scrutiny revealed that the DIs had not conducted any inspection during 1998-2003, except at the time of sanction of fresh licence to the units (ranging from 484 to 656), statedly due to shortage of staff.

**Heavy shortfall (92 to 98 per cent) in inspections of units of Homoeopathic drugs**

**(b)** Shortfall in inspection of the manufacturing and sale units of Homoeopathic drugs were as follows:

| Year | Number of | | Number of inspections | | Shortfall (percentage) |
|---|---|---|---|---|---|
| | Manufacturing units | sale units | to be conducted | conducted | |
| 1998-99 | 35 | 325 | 720 | 11 | 709 (98) |
| 1999-2000 | 39 | 307 | 692 | 35 | 657 (95) |
| 2000-01 | 40 | 231 | 542 | 15 | 527 (97) |
| 2001-02 | 38 | 170 | 208 | 17 | 191 (92) |
| 2002-03 | 39 | 175 | 214 | 14 | 200 (93) |

The Commissioner attributed (December 2002) the shortfalls to shortage of staff and funds. Due to huge shortfall in inspection, possibility of spurious drug activities could not be ruled out.

***ii) Short collection/Delay in analysis of drug samples:*** As per the Act, the DIs were required to inspect the manufacturing units and collect the drugs samples for quality test. The department has not fixed any targets for lifting samples of Ayurvedic and Unani drugs for analysis. During 1998-2002, only 19 samples of Ayurvedic drugs were collected. In 2002-03, out of 47 samples collected 11 were not analysed. During 1998-2003, only 11 samples of Unani drugs were collected, of which nine samples collected during 1999-2001 were not analysed. Reasons for poor lifting of samples were not explained by the Commissioner. Though non-analysis of samples was attributed (December 2002) to non-availability of chemicals, ingredients and methods of testing in the Drug Testing Laboratory for want of funds; separate budget provision was not sought for the laboratory needs by the Commissioner.

***iii) Drug Testing Laboratory not strengthened:*** The Drug Testing Laboratory (DTL), Katedan, Hyderabad conducts analysis of raw material and finished Ayurvedic Medicines of Government Indian Medicine Pharmacy (Ayurveda), Katedan. Samples of Ayurveda and Unani drugs were also taken up for analysis depending upon the feasibility at the laboratory, as the samples were of patent in nature and did not have proven method of analysis as there is no prescribed pharmacopoeia[17] for ayurvedic drugs.

**Drugs Testing Laboratory (Ayurvedic) not strengthened despite the availability of Central assistance**

For strengthening the DTL, GOI released Rs 55 lakh[18] in March 2001, of which Rs 15 lakh was spent (March 2002) for construction of additional buildings and Rs 26.61 lakh paid (March 2002) to Hospital Services Consultancy Corporation, New Delhi (HSCC) for purchase of machinery and equipment. The balance Rs 13.39 lakh was retained by the Department. The machinery and equipment had

[17] indicating percentage/quantity of ingredients of a particular drug

[18] Construction of additional buildings (Rs 15 lakh), Purchase of machinery and equipment (Rs 30 lakh) and for contractual manpower (Rs 10 lakh)

not been received[19] as of September 2003 except for two items valued Rs 0.39 lakh.

Thus, the objective of strengthening the DTL had not been achieved even after a lapse of two years.

### 3.1.6 Training

**No training programmes conducted for DIs and other staff**

Licensing, inspections and investigations are important regulatory functions[20] through which the Act is implemented and these functions require knowledgeable and trained Officers/Staff. However, the DCA had not conducted any training programmes to DIs and other officials, except imparting training to three Junior Analysts during 1998-2003. The ADG, DCA, stated (April 2003) that no proposals were submitted for conducting training programmes without however, indicating the reasons.

Inaction of the ADG in organising training programmes to DIs, etc could have adversely affected efficient and effective functioning of the DCA.

### 3.1.7 Monitoring

**Monitoring at State level was very poor**

Though the State Government was going ahead with the computerisation in all the departments the DCA had not developed any database of manufacturers/sale concerns/licensees/management information system, monitoring system modules for drug control functions, laboratory functions and licensing functions; except holding the quarterly periodical meetings with the field staff. This indicated the ineffective handling of the affairs of the DCA by the ADG.

The State Drugs Advisory Committee met only once in January 2002. Thus there was no proper monitoring on the implementation of the Act and Rules in the State.

### 3.1.8 Conclusions

Implementation of the Drugs and Cosmetics Act has been ineffective in the State mainly due to shortage of enforcement staff and insufficient budget provision. The system of licensing and renewal thereof was not fool-proof. There were huge shortfalls in inspection of units. No norms were fixed for sampling of the drugs. Even drugs which were found to be spurious and "not of standard quality" were dealt with in routine fashion leading to pendency of high

[19] due to some constraints in payment of Customs Duty on imported equipment viz., High Performance Thin Layer Chromatography system, Gas Liquid Chromatography, Moisture Balance, Electronic balance and Micro balance

[20] involving intelligence, detection, investigation, preparing and filing of complaints, etc. updation of technical matters and court procedures

number of prosecution cases in courts for years. No communication network was in place for dissemination and sharing of information on movement of spurious drugs and persons involved in such activity.

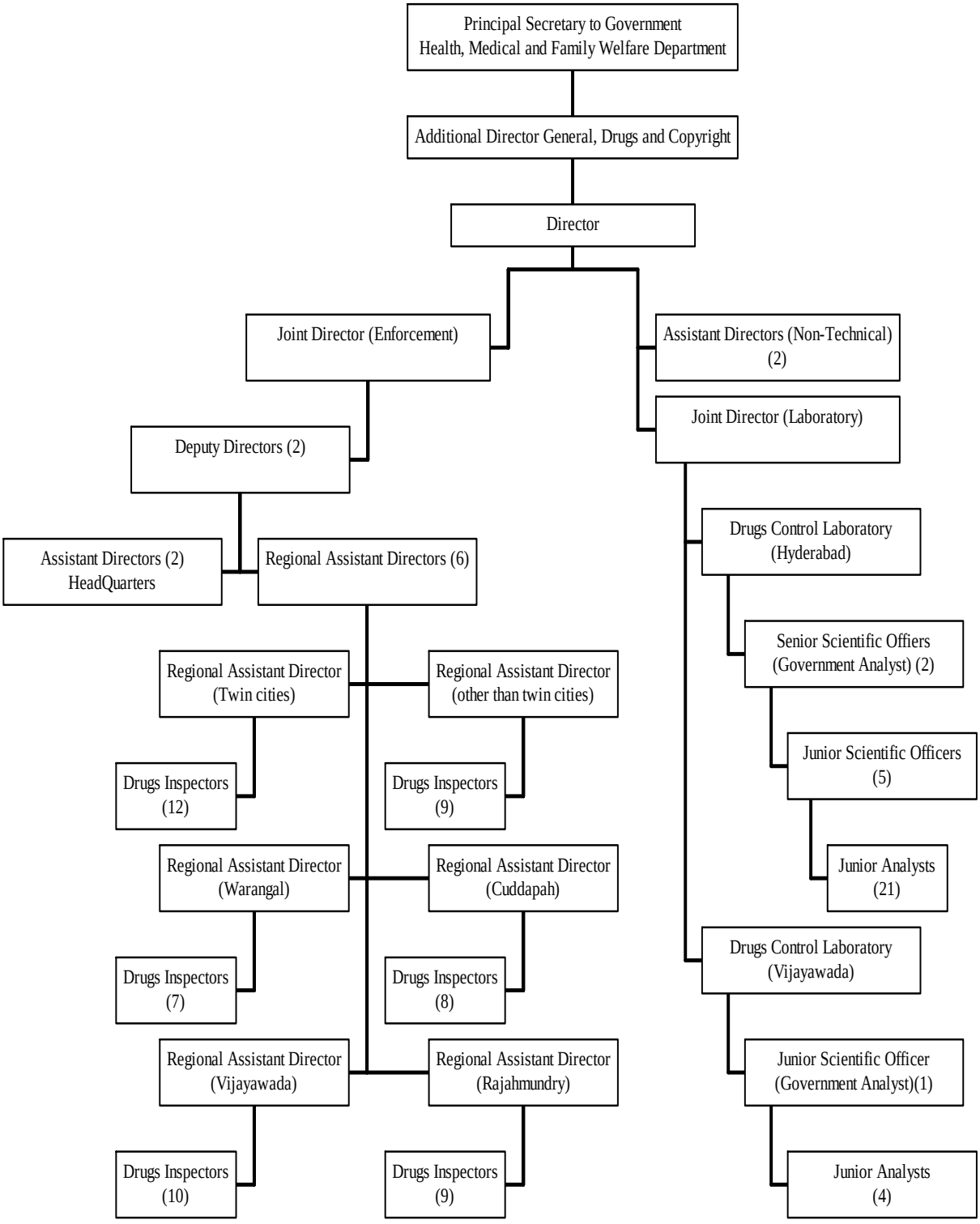
### 3.1.9 Recommendations

- The Act needs to be amended to prescribe the time schedule for disposal of renewal applications by the DCA.
- The Act also needs to be amended to bring the selling units of Ayurvedic medicines and Cosmetics also under the purview of the Drugs and Cosmetics Act, 1940 to ensure quality.
- There is a need to amend the Act to make all the offences under it as cognizable.
- Each manufacturing/selling unit should be inspected at least twice a year to have proper control.
- Special courts should be established for speedy disposal of cases.
- More enforcement and analytical staff are needed to be acquainted with the latest techniques and legal matters.
- Deterrent penalty should be imposed for manufacture or sale of adulterated/spurious or mis-branded drugs.
- DTL should be strengthened so as to cope up with the requirement of the large number of testing of samples.

The above points were referred to Government in June 2003; reply had not been received (November 2003).

**Appendix XXV**
**(Reference to paragraph 3.1.2 page 36)**

**Organisation set up of Drugs Control Administration**



## Appendix XXVI
## (Reference to paragraph 3.1.4 II (i) (b) page 40)

### A. Shortfalls in inspections by Drugs Inspectors

| S.No. | Name of the office | Number of units | Inspections to be conducted | Inspections Conducted | Shortfall | Percentage |
|---|---|---|---|---|---|---|
| **1998-99** | | | | | | |
| 1. | Amalapuram | 480 | 960 | 513 | 447 | 47 |
| 2. | Anakapalli | 428 | 856 | 513 | 343 | 40 |
| 3. | Chittoor | 529 | 1058 | 451 | 607 | 57 |
| 4. | Cuddapah | 325 | 650 | 412 | 238 | 37 |
| 5. | Guntur | 580 | 1160 | 526 | 634 | 55 |
| 6. | Jagityal | 424 | 848 | 603 | 245 | 29 |
| 7. | Kakinada | 849 | 1698 | 548 | 1150 | 68 |
| 8. | Karimnagar | 472 | 944 | 456 | 488 | 52 |
| 9. | Machilipatnam | 606 | 1212 | 595 | 617 | 51 |
| 10. | Mahaboobnagar | 478 | 956 | 393 | 563 | 59 |
| 11. | Narasaraopeta | 385 | 770 | 557 | 213 | 28 |
| 12. | Nizamabad | 286 | 572 | 492 | 80 | 14 |
| 13. | Proddatur | 283 | 566 | 383 | 183 | 32 |
| 14. | Rajahmundry | 438 | 876 | 553 | 323 | 37 |
| 15. | Tenali | 488 | 976 | 517 | 459 | 47 |
| 16. | Tirupati | 449 | 898 | 391 | 507 | 56 |
| 17. | Vijayawada-I | 624 | 1248 | 561 | 687 | 55 |
| 18. | Vijayawada-II | 519 | 1038 | 472 | 566 | 55 |
| 19. | Visakhapatnam | 453 | 906 | 492 | 414 | 46 |
| 20. | Warangal (R) | 288 | 576 | 551 | 25 | 4 |
| 21. | Warangal (U) | 379 | 758 | 548 | 210 | 28 |
| **1999-2000** | | | | | | |
| 1. | Amalapuram | 482 | 964 | 523 | 441 | 46 |
| 2. | Anakapalli | 475 | 950 | 599 | 351 | 37 |
| 3. | Chittoor | 561 | 1122 | 534 | 588 | 52 |
| 4. | Cuddapah | 354 | 708 | 398 | 310 | 44 |
| 5. | Guntur | 682 | 1364 | 608 | 756 | 55 |
| 6. | Jagityal | 461 | 922 | 603 | 319 | 35 |
| 7. | Kakinada | 969 | 1938 | 552 | 1386 | 72 |
| 8. | Karimnagar | 504 | 1008 | 348 | 660 | 65 |
| 9. | Machilipatnam | 649 | 1298 | 615 | 683 | 53 |
| 10. | Mahaboobnagar | 533 | 1066 | 373 | 693 | 65 |
| 11. | Narasaraopeta | 455 | 910 | 625 | 285 | 31 |
| 12. | Nizamabad | 322 | 644 | 501 | 143 | 22 |
| 13. | Proddatur | 316 | 632 | 419 | 213 | 34 |
| 14. | Rajahmundry | 523 | 1046 | 616 | 430 | 38 |
| 15. | Tenali | 533 | 1066 | 575 | 491 | 46 |
| 16. | Tirupati | 511 | 1022 | 447 | 575 | 56 |
| 17. | Vijayawada-I | 650 | 1300 | 644 | 656 | 50 |
| 18. | Vijayawada-II | 572 | 1144 | 379 | 765 | 67 |
| 19. | Visakhapatnam | 480 | 960 | 521 | 439 | 46 |
| 20. | Warangal (R) | 332 | 664 | 511 | 153 | 23 |
| 21. | Warangal (U) | 477 | 954 | 415 | 539 | 56 |
| **2000-01** | | | | | | |
| 1. | Amalapuram | 545 | 1090 | 594 | 496 | 45 |
| 2. | Anakapalli | 568 | 1136 | 635 | 501 | 44 |
| 3. | Chittoor | 601 | 1202 | 470 | 732 | 61 |
| 4. | Cuddapah | 395 | 790 | 313 | 477 | 60 |
| 5. | Guntur | 772 | 1544 | 549 | 995 | 64 |
| 6. | Jagityal | 524 | 1048 | 647 | 401 | 38 |
| 7. | Kakinada | 1054 | 2108 | 584 | 1524 | 72 |
| 8. | Karimnagar | 573 | 1146 | 460 | 686 | 60 |
| 9. | Machilipatnam | 688 | 1376 | 597 | 779 | 57 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 10. | Mahaboobnagar | 592 | 1184 | 400 | 784 | 66 |
| 11. | Narasaraopeta | 546 | 1092 | 554 | 538 | 49 |
| 12. | Nizamabad | 376 | 752 | 509 | 243 | 32 |
| 13. | Proddatur | 349 | 698 | 410 | 285 | 41 |
| 14. | Rajahmundry | 599 | 1198 | 697 | 501 | 42 |
| 15. | Tenali | 571 | 1142 | 476 | 666 | 58 |
| 16. | Tirupati | 600 | 1200 | 543 | 657 | 55 |
| 17. | Vijayawada-I | 705 | 1410 | 576 | 834 | 59 |
| 18. | Vijayawada-II | 648 | 1296 | 725 | 571 | 44 |
| 19. | Visakhapatnam | 518 | 1036 | 550 | 486 | 47 |
| 20. | Warangal (R) | 377 | 754 | 631 | 123 | 16 |
| 21. | Warangal (U) | 527 | 1054 | 566 | 488 | 46 |
| **2001-02** | | | | | | |
| 1. | Amalapuram | 552 | 552 | 577 | -- | -- |
| 2. | Anakapalli | 659 | 659 | 496 | 163 | 25 |
| 3. | Chittoor | 630 | 630 | 490 | 140 | 22 |
| 4. | Cuddapah | 422 | 422 | 381 | 41 | 10 |
| 5. | Guntur | 883 | 883 | 490 | 393 | 44 |
| 6. | Jagityal | 619 | 619 | 521 | 98 | 16 |
| 7. | Kakinada | 1214 | 1214 | 642 | 572 | 47 |
| 8. | Karimnagar | 649 | 649 | 387 | 262 | 40 |
| 9. | Machilipatnam | 722 | 722 | 517 | 205 | 28 |
| 10. | Mahaboobnagar | 679 | 679 | 469 | 21 | 3 |
| 11. | Narasaraopeta | 629 | 629 | 462 | 167 | 26 |
| 12. | Nizamabad | 445 | 445 | 495 | -- | -- |
| 13. | Proddatur | 385 | 385 | 420 | -- | -- |
| 14. | Rajahmundry | 688 | 688 | 544 | 144 | 21 |
| 15. | Tenali | 598 | 598 | 436 | 162 | 27 |
| 16. | Tirupati | 635 | 635 | 520 | 115 | 18 |
| 17. | Vijayawada-I | 717 | 717 | 561 | 156 | 22 |
| 18. | Vijayawada-II | 759 | 759 | 530 | 229 | 30 |
| 19. | Visakhapatnam | 562 | 562 | 427 | 135 | 24 |
| 20. | Warangal (R) | 391 | 391 | 406 | -- | -- |
| 21. | Warangal (U) | 602 | 602 | 587 | 15 | 2 |
| **2002-03** | | | | | | |
| 1. | Amalapuram | 577 | 577 | 587 | -- | -- |
| 2. | Anakapalli | 695 | 695 | 638 | 57 | 8 |
| 3. | Chittoor | 643 | 643 | 520 | 123 | 19 |
| 4. | Cuddapah | 473 | 473 | 428 | 45 | 9 |
| 5. | Guntur | 981 | 981 | 590 | 391 | 40 |
| 6. | Jagityal | 670 | 670 | 613 | 57 | 8 |
| 7. | Kakinada | 1289 | 1289 | 610 | 679 | 53 |
| 8. | Karimnagar | 683 | 683 | 492 | 191 | 28 |
| 9. | Machilipatnam | 778 | 778 | 610 | 168 | 22 |
| 10. | Mahaboobnagar | 725 | 725 | 571 | 154 | 21 |
| 11. | Narasaraopeta | 665 | 665 | 532 | 133 | 20 |
| 12. | Nizamabad | 523 | 523 | 501 | 22 | 4 |
| 13. | Proddatur | 413 | 413 | 360 | 53 | 13 |
| 14. | Rajahmundry | 745 | 775 | 578 | 197 | 25 |
| 15. | Tenali | 628 | 628 | 437 | 191 | 30 |
| 16. | Tirupati | 687 | 687 | 527 | 160 | 23 |
| 17. | Vijayawada-I | 749 | 749 | 600 | 149 | 20 |
| 18. | Vijayawada-II | 850 | 850 | 558 | 292 | 24 |
| 19. | Visakhapatnam | 609 | 609 | 535 | 74 | 12 |
| 20. | Warangal (R) | 351 | 351 | 544 | -- | -- |
| 21. | Warangal (U) | 644 | 644 | 621 | 23 | 3 |

**B. Shortfalls in inspections – Regional Offices**

| Office of the Regional Assistant Director | Number of Inspections | | | Shortfall (Percentage) |
|---|---|---|---|---|
| | Units | To be conducted | Conducted | |
| **1998-99** | | | | |
| Warangal | 2685 | 5370 | 3431 | 1939 (36) |
| Cuddapah | 3337 | 6674 | 3185 | 3489 (52) |
| Vijayawada | 3740 | 7480 | 2827 | 4653 (62) |
| Rajahmundry | 6404 | 12808 | 4726 | 8082 (63) |
| Hyderabad (OTC) | 2696 | 5392 | 4264 | 1128 (21) |
| Hyderabad (TC) | 2161 | 4322 | 2289 | 2033 (47) |
| **1999-2000** | | | | |
| Warangal | 3102 | 6204 | 3189 | 3015 (49) |
| Cuddapah | 3600 | 7200 | 3352 | 3848 (53) |
| Vijayawada | 5127 | 10254 | 2614 | 7640 (74) |
| Rajahmundry | 6417 | 12834 | 5078 | 7756 (60) |
| Hyderabad (OTC) | 3229 | 6458 | 4410 | 2048 (32) |
| Hyderabad (TC) | 2714 | 5428 | 2786 | 2642 (49) |
| **2000-01** | | | | |
| Warangal | 3233 | 6466 | 3539 | 2927 (45) |
| Cuddapah | 3855 | 7710 | 3250 | 4460 (58) |
| Vijayawada | 5908 | 11816 | 2455 | 9361 (79) |
| Rajahmundry | 7002 | 14004 | 5258 | 8746 (62) |
| Hyderabad (OTC) | 3672 | 7344 | 4630 | 2714 (37) |
| Hyderabad (TC) | 3199 | 6398 | 2429 | 3969 (62) |
| **2001-02** | | | | |
| Warangal | 3678 | 3678 | 3084 | 594 (16) |
| Cuddapah | 4123 | 4123 | 3685 | 438 (11) |
| Vijayawada | 6984 | 6984 | 2850 | 4134 (59) |
| Rajahmundry | 7768 | 7768 | 4958 | 2810 (36) |
| Hyderabad (OTC) | 4117 | 4117 | 4446 | -- |
| Hyderabad (TC) | 3721 | 3721 | 2235 | 1486 (40) |
| **2002-03** | | | | |
| Warangal* | 3891 | 3891 | 3640 | 251 (6) |
| Cuddapah* | 4351 | 4351 | 3121 | 1230 (28) |
| Vijayawada* | 7592 | 7592 | 2302 | 5290 (70) |
| Rajahmundry$ | 8354 | 8354 | 4178 | 4176 (50) |
| Hyderabad $ (OTC) | 4691 | 4691 | 5203 | -- |
| Hyderabad (TC) upto March 2003 | 4027 | 4027 | 2984 | 1043 (26) |

* Upto December 2002

$ Upto February 2003

**Appendix XXVII**
**(Reference to paragraph 3.1.4 II (i) (b) page 40)**

**Statement showing the variations between figures furnished by Additional Director General, Drugs Control Administration (ADG, DCA) and Regional Assistant Directors**

| Year | Number of licenced units | | | Number of Inspections conducted | | |
|---|---|---|---|---|---|---|
| | ADG, DCA | Regional Assistant Directors | Variation | ADG, DCA | Regional Assistant Directors | Variation |
| 1998-99 | 34258 | 21023 | 13235 | 23399 | 20722 | 2677 |
| 1999-2000 | 37019 | 24189 | 12830 | 24569 | 21429 | 3140 |
| 2000-01 | 29931 | 26869 | 3062 | 24729 | 21561 | 3168 |
| 2001-02 | 33202 | 30391 | 2811 | 23367 | 21258 | 2109 |
| 2002-03 | 32703 | 32906 | (-) 203 | 27836 | 21428* | 6408 |

* Figures as on December 2002 (3 regions), February 2003 (2 regions) and March 2003 (one region)

**Implementation of Drugs and Cosmetics Act, 1940**

| | | |
|---|---|---|
| ACB | : | Anti Corruption Bureau |
| ADG, DCA | : | Additional Director General, Drugs & Copyright, Drugs Control Administration |
| ADs | : | Regional Assistant Directors |
| D&C Rules | : | Drugs and Cosmetics Rules, 1945 |
| DCA | : | Drugs Control Administration |
| DCLs | : | Drugs Control Laboratories |
| DIs | : | Drugs Inspectors |
| DTL | : | Drugs Testing Laboratory |
| HSCC | : | Hospital Services Consultancy Corporation |
| IEC | : | Information, Education and Communication |
| NPPA | : | National Pharmaceutical Pricing Authority |
| NSQ | : | Not of Standard Quality |
| PAC | : | Public Accounts Committee |
| R&D | : | Research and Development |
| TA | : | Travelling Allowance |
| TB | : | Tuberculosis |

**Prevention and control of fire**

| | | |
|---|---|---|
| ADFO | : | Assistant Divisional Fire Officer |
| APGENCO | : | Generation Corporation of Andhra Pradesh Limited |
| APPHC | : | AP Police Housing Corporation |
| APSRTC | : | AP State Road Transport Corporation |
| DFO | : | Divisional Fire Officer |
| DGFS | : | Director General of Fire Services |
| DO | : | Driver Operator |
| EFC | : | Eleventh Finance Commission |
| GOI | : | Government of India |
| HUDA | : | Hyderabad Urban Development Authority |
| LF | : | Leading Firemen |
| MCH | : | Municipal Corporation of Hyderabad |
| MSBs | : | Multi Storied Buildings |
| NOC | : | No Objection Certificate |