CHAPTER III
PERFORMANCE REVIEWS

This chapter contains performance reviews on Implementation of Drugs and Cosmetics Act 1940 (3.1), Working of Public Works Department (3.2), Prevention and Control of Fire (3.3) and Integrated Watershed Development Programme (3.4).

Medical Education and Drugs Department

3.1 Implementation of Drugs and Cosmetics Act, 1940

Highlights

The Drugs and Cosmetics Act, 1940 is an important social legislation and is a very effective tool for safeguarding the consumers' interest. Provisions of Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules 1945 regulate the import, manufacture, distribution and sale of drugs and cosmetics in the country. Adulteration of drugs and production of spurious and substandard drugs causing serious threat to the health of the community are also sought to be prevented by application of the provisions of the Act. However, in Maharashtra, the Act has not been implemented effectively. The provisions of the Act regarding licensing and inspection of units, drawing/testing/reporting of samples, timely and effective actions against those manufacturing and selling substandard/spurious drugs were not implemented meticulously.

Licences in respect of 138 out of 1145 manufacturing units and 773 out of 4575 selling units that had expired on 31 December 2002 were not renewed up to March 2003 though renewal applications had been received.

(Paragraph 3.1.14)

Licences of 44 blood banks in Amravati, Mumbai and Nashik renewed by the respective Licensing Authorities, did not have the approval of the Drugs Controller General of India as the inspection of these units was pending.

(Paragraph 3.1.17)

Shortfall in samples drawn ranged from 19 to 39 *per cent* of the target during 2000-2003. Thus sampling, vital to ensure availability of quality drugs, was badly affected.

(Paragraph 3.1.19)

Norms for selecting units for inspections had not been fixed. The shortfall in these inspections ranged from 51 to 76 *per cent.* Moreover, a system of inspection of the records of Registered Medical Practitioners had not been introduced in the State.

(Paragraphs 3.1.20 and 3.1.21)

During the years 2001 and 2002 only 27 to 77 *per cent* samples were tested within the prescribed 90 days.

(Paragraph 3.1.25)

There was acute shortage of technical persons at all levels; 60 posts out of 223 remained vacant.

(Paragraph 3.1.34)

3.1.1 Introduction

The Food and Drugs Administration is responsible for implementation of the Drugs and Cosmetics Act, 1940 (Act) and the Drugs and Cosmetics Rules 1945, (Rules) in relation to allopathic, homeopathic, ayurvedic, *sidha* and *unani* drugs and also cosmetics. The provisions of the Act/Rules are enforced mainly through:

- Licencing and inspection of manufacturing and sales premises/units,
- Drawal of samples for testing, and
- Initiating prosecution against offenders.

To study and ascertain the effectiveness of the implementation of the Drugs and Cosmetics Act, 1940, the records of the Regulatory Authority viz Food and Drugs Administration, Maharashtra in the selected districts and those maintained by their eight divisions[*] along with eight[♦] districts out of 29 districts, for the years 1998-2003 were test checked from January to June 2003. Results of test check are shown in succeeding paragraphs.

3.1.2 Implementing Agencies

The Food and Drugs Administration (FDA) is under administrative control of Medical Education and Drugs Department of the State. The FDA is headed by the Commissioner who is assisted by 11 Joint Commissioners (Drugs), 53 Assistant Commissioners (Drugs) and 159 Drugs Inspectors. The Joint Commissioner of each division is the Licensing Authority for the manufacturing units and the Assistant Commissioner at the district place is the Licensing Authority for the selling units. The Joint Commissioner (Headquarters) in Mumbai also acts as Drugs Control Authority of the State. The Drug Control Laboratory (DCL) in Mumbai and a newly opened DCL at Aurangabad carry out the work of testing of drug samples. DCL, Aurangabad, however, analysed only the samples of ayurvedic drugs cosmetics for want of instruments and staff.

3.1.3 Standing of the Law

The Drugs and Cosmetics Act, 1940 is an important social legislation and is very effective tool for safeguarding the consumers interest. The objectives of the Act can be achieved only through proper implementation by the regulatory

[*] Amravati, Aurangabad, Mumbai (Hqrs), Mumbai Selling Units, Nagpur, Nashik, Pune and Thane.

[♦] Amravati, Beed, Mumbai, Nashik, Nagpur, Raigad, Satara and Wardha.

agencies and compliance of the provisions in totality by all persons engaged in manufacture, sale and distribution of the drugs and cosmetics.

3.1.4 Provisions contested--- Court rulings

The Authorities under the Act resort to administrative as well as legal action for violations of the Act. During the proceedings for administrative action based on the Government Analyst's report declaring a drug to be substandard, normally findings of the Government Analyst are contested. Under Section 25 (3) of the Act the Government Analyst's report can be contested by producing evidence in contraversion of the Government Analyst's report.

During legal proceedings, the procedure followed by the Drugs Inspector (DI) for carrying out search and seizure, procedure followed for drawing of sample and sending it to the Government Analyst and procedure followed by Government are also contested.

3.1.5 Inadequate provision for renewal

Under Rule 72 of the Rules a licence or a renewal certificate issued shall be valid for a period of five years from the date of issue. But once a renewal application is submitted either before the expiry of the original licence or within six months from the date of its expiry, the original licence shall continue to be in force until orders are passed on the application by the licensing authority. As such, in cases where the inspection of the premises is delayed for some reason and subsequently the licence is found unfit for renewal, the concerned unit can function with immunity during the interval. This is a lacuna to be corrected through appropriate amendments to Rule 72 by making a provision for filing of renewal application three or six months before the date of expiry of original licence and issue of renewal certificate on or before the date of expiry of original licence.

3.1.6 Non-differentiation of minor and major offences

There is no differentiation of minor and major offences in the Act/Rules. As such, decision on departmental action or prosecution is left to the discretion of the DC or DIs.

3.1.7 Lack of provision for free surrender of samples

According to existing provisions, drug samples are required to be collected by the DI only on payment of cost thereof. In view of financial stringency, the funds allotted for this purpose are generally inadequate. As such the provision in the Rules, acts as a hindrance in the collection of adequate number of samples for quality analysis.

3.1.8 Absence of provision for sale licence for ayurvedic drugs

Unlike in the case of allopathic drugs, no sale licence is required for ayurvedic drugs under the Act/Rules. The authorities find it difficult to keep track of the sale of spurious, adulterated or time expired ayurvedic drugs.

Prosecution cases

All offences under the Act are not treated as cognizable offences

3.1.9 In the State, all offences under the Act are not treated as cognisable. This is unlike provisions contained in Drugs and Magic Remedies Act 1954, which is also being implemented by the Administration. In terms of Section 27 of the Act, offences like manufacture and sale of adulterated or spurious drugs which when consumed would result in death or grievous hurt attract imprisonment of not less than five years extendable to life term and with fine. However offences of similar nature but of less intensity attract imprisonment for lesser period (ie ranging from one to three years). States like Uttar Pradesh and West Bengal have amended the Act, imposing life imprisonment for manufacture or sale of adulterated/spurious or misbranded drugs irrespective of their intensity. No such amendments have been proposed in the State so far (October 2003).

Government stated (October 2003) that offences where imprisonment of more than three years is prescribed like offences under Section 27(a), 27(b), 27(c), 27(Ai) etc are treated as cognisable offences. Government had made suggestions to the Dr Mashelkar Committee for making offences under the Act as cognisable and non-bailable.

3.1.10 Legal cell in Food and Drugs Administration

The FDA has a legal cell, headed by the Joint Commissioner (Law). Table below indicates the cases where prosecution was launched.

(In numbers)

Year	Opening Balance	Prosecution launched	Total	Cases decided	Convicted	Acquitted*	Discharged**
1998-99	1124	50	1174	48	7	18	23
1999-2000	1126	56	1182	25	11	06	08
2000-01	1157	123	1280	58	41	09	08
2001-02	1222	133	1355	61	26	14	21
2002-03	1294	122	1416	21	02	10	09
Total				**213**	**87**	**57**	**69**

In this regard, following deserve mention:

- Control register maintained at the Headquarters level was incomplete in many respects *viz* dates of filing of cases in court, present status of the cases etc were not noted.

3.1.11 There were 1395 pending cases as of 31 March 2003. The age wise details of pending prosecution cases were not, however, available with the FDA. The number of prosecution cases pending in the State increased from 1124 in 1998-99 to 1395 at the end of March 2003. It was stated to be due to pendency of cases in the court(s). Of the 213 cases decided during the period, only 87 cases led to conviction.

* Acquitted: Charges are framed against the accused, however, due to lack of evidence/documents the case is acquitted.

** Discharged: Charges could not be framed against the accused.

Lack of adequate evidence led to acquittal/discharge of the prosecuted cases

Analysis of 23 prosecution cases where acquittal/discharge was decided between April 1997 and March 2003 and made available to audit revealed that ten cases could not be established for want of adequate evidence, two cases were dismissed due to absence of the Drugs Inspectors, two cases were dismissed due to failure of the Administration to send the samples within the stipulated period of 28 days to the Central Drugs Laboratory, Kolkatta and remaining nine prosecution cases could also not be established due to other reasons like lack of complete address of accused, drugs in question found to be of standard quality subsequently by the Central Drugs Laboratory etc.

3.1.12 Analysis of 41 out of 87 cases of conviction revealed that in five cases the imprisonment given was more than one year but less than three years, in nine cases imprisonment awarded was for a period of less than one year, in 17 cases (40 *per cent*) it was for less than one month and 10 cases (25 *per cent*) were decided by imposing only fines.

Implementation of the Act - Survey and licensing procedure

3.1.13 According to Rules both manufacturing and selling units except those selling ayurvedic medicines and cosmetics have to obtain a licence. Prior to 24 August 2001 an original or a renewed licence was valid up to 31 December of the year following the year in which it was issued. With effect from 24 August 2001, however, the same is now issued for five years from the date of issue or its renewal except ayurvedic manufacturing licence for which the existing provision still continues.

According to Rule 79 of Drugs and Cosmetics Rules 1945, inspection of site is mandatory before grant or renewal of licence. The table below indicates the number of manufacturing and selling units, licence granted and renewed.

(In numbers)

Year	Units	Application pending at the beginning of the year		Application received during the year		Application disposed off during the year		Application pending at the end of the year	
		Fresh	Renewal	Fresh	Renewal	Fresh	Renewal	Fresh	Renewal
Manufacturing Units									
1999-2000	2832	175	1171	1349	1908	1376	2127	148	952
2000-01	2858	269	1010	1272	1496	1313	1599	228	907
2001-02	2976	204	1181	1474	2261	1604	2408	74	1034
2002-03*	3842	74	1034	1153	1921	1167	24	60	2931
Selling Units									
1999-2000	45522	642	4498	7396	17955	7371	16889	667	5564
2000-01	47021	830	4242	7665	16426	7513	15727	982	4941
2001-02	50278	519	4886	7458	18445	7518	14602	459	8729
2002-03*	52558	459	8729	6759	19107	6864	22940	354	4896

* Provisional Figures

It would be observed that there were several instances, where closing balance of outstanding applications in a year does not match with the opening balance in the succeeding year. Joint Commissioner (Headquarters) stated (November 2003) that the figures have been published in the Performance Budget of the

respective years and care will be taken in future to ensure that the closing balances of a year are correctly carried forward during the subsequent years.

It was observed that:

No master licence register was maintained

- No master licence register recording the name of the licensees, the licence number, date of issue/renewals due, etc was maintained in any of the test-checked divisions. Thus, the number of licences due for renewal at the end of a year could not be ascertained.

Government stated (October 2003) that all divisional offices had been instructed to maintain Master Licence Register. Further GOI has also provided a software for this purpose for which the work of data entry is going on.

138 manufacturing and 773 selling units whose licences had expired were not renewed upto March 2003

3.1.14 Of the 1145 manufacturing units and 4575 selling units in three divisions (Mumbai-Hqrs, Amravati and Nashik) whose licences had expired as on 31 December 2002, licence of 138 manufacturing and 773 selling units were not renewed up to March 2003 despite receipt of application for renewal. Information from other divisions was awaited (June 2003). Government stated (October 2003) that delays were due to receipt of large number of applications and time taken to carry out inspections etc.

No uniformity in the maintenance of records at division level

3.1.15 There was no uniformity in the maintenance of records among the divisions. Except Mumbai - Headquarters, no other division maintained index cards with information like date of grant of licence, date of inspection etc in respect of each manufacturing unit along with a file. Governemnt stated (October 2003) that program for Master Licence register has been prepared and is being taken up on computer network.

No provision in the Act for issue of licences to selling units of ayurvedic medicines and cosmetics

3.1.16 There is no provision to issue licences to selling units of ayurvedic medicines and cosmetics whereas such provision in the Act exists in respect of allopathic drugs. The provisions thus differentiate between selling units of allopathic drugs and ayurvedic medicines and cosmetics. Government stated (October 2003) that introduction of licence for the selling of ayurvedic medicines and cosmetics could be done only after amendment to the Act.

Renewal of licences in 44 blood banks of three divisions not approved by the Drugs Controller General of India

3.1.17 As per the provisions of the Act, the licensee holding a licence for operation of blood bank, manufacturing of blood products etc. shall apply for grant of licence before the expiry of the licence. The orders for grant or renewal passed by the State licensing authority alongwith licence and renewal certificate, is to be forwarded to the Central Approving Authority *viz*, Drugs Controller General of India (DCGI) for approval and he shall continue to operate the same till the orders on his application are communicated to him. In respect of renewal of 44 blood banks in Amravati, Mumbai and Nashik for the period 2000-2007, the necessary approval of DCGI was not accorded due to pending inspection of these units. These licensees could function until the decision of the approving authority was communicated. This meant that disapproval, if any, when communicated to them later, would mean operation without a valid licence during the intervening period. Procedure in this regard currently being followed needs to be reviewed by the Government of India.

Renewal of licenses without obtaining the compliances of inspection notes

3.1.18 In Nagpur division a manufacturing unit was inspected in April 1997 and another in October 1999 and January 2000. The licensing authority issued inspection notes to these units for giving compliance to the seven omissions detected by the DI. During audit it was observed that the licences of both units were renewed in routine fashion during next year even without obtaining the necessary compliance of those remarks.

Adequacy of Sampling and Inspections

3.1.19 Drawal of samples

Shortfall of 19 to 39 *per cent* in drawal of drug samples

Sampling is a post marketing surveillance activity of the regulatory authority. This is done to ensure circulation of quality drugs in the market. The DI collects samples of the drugs *ibid* for testing in the laboratory. According to norms each DI has to draw six samples in a month. Table below indicates the number of samples drawn by the DIs.

Year	Inspectors in position	Samples to be drawn	Samples drawn	Shortfall	Percentage of shortfall
	(In numbers)				
2000-01	131	9432	5728	3704	39.27
2001-02	123	8856	7131	1725	19.47
2002-03	127	9144	5759	3385	37.01

The shortfall in samples drawn by the DIs ranged from 19.47 to 39.27 *per cent* during 2000-2003. Government attributed (October 2003) the reasons to shortage of DIs and also due to the Commissioner's instructions (February 2001) to draw fewer samples to clear the pendency in the laboratory. Audit felt that issue of Commissioner's instructions to draw fewer samples to clear the pendancy is not the solution as non-drawal of samples may lead to non-detection of substandard drugs. Further, contention of the Government regarding shortage of DIs is not tenable as shortfall in samples was determined with reference to DIs working in the department. If shortfall is determined with reference to the number of manufacturing and selling units in the State on the premise that each unit should be covered atleast once in a year, it would increase to 75-90 *per cent*.

Inspection

3.1.20 All establishments licenced for the manufacture and sale of drugs are required to be inspected at least twice a year up to August 2001 and once a year thereafter to ensure that the conditions of the licence have not been violated. Besides, testing of samples, investigation of complaints, inspection of plant/process of manufacturing, methodology adopted for standardising and testing the drugs etc are also checked to maintain the standards of drugs. The table following indicates the shortfall in the inspections.

Year	Units	Inspection to be carried out	Inspection actually done	Shortfall	Percentage of shortfall
	(Numbers)				
1998-99	43751	87502	24797	62705	72
1999-2000	48354	96708	23018	73690	76
2000-01	49879	99758	28733	71025	71
2001-02	53254	53254	26336	26918	51
2002-03	56400	56400	26853	29547	52

It was noticed during the course of audit that:

331 selling units out of 745 units remained to be inspected for more than two years

- No norms have been fixed for selecting the units. As a result some units were inspected repeatedly while others remained uninspected for years together. In nine* districts, 331 selling units out of 745 units checked, remained uninspected for more than two years. Government stated (October 2003) that instructions were being issued to the licensing authorities to adopt a planned inspection programme of the units.

- The shortfall in inspections ranged from 51 to 76 *per cent* for both manufacturing and selling units due to shortage of DIs.

Drugs stored and supplied by the Registered Medical Practitioners and private hospitals not subject to inspection

3.1.21 Drugs supplied by Registered Medical Practitioners (RMPs) to patients are not covered under licensing rules. However, they have to purchase the drugs from licenced dealers/manufacturers only and maintain detailed records of such purchases, which are open to inspection by an Inspector appointed under the Act. But a system of inspection of RMP's records has not been introduced in Maharashtra (June 2003).

Government stated (October 2003) that though inspection of private hospitals and RMPs are not carried out periodically, but during special drive inspection of such dispensaries, nursing homes and hospitals are undertaken by FDA. Further, inspection of the RMPs on a regular basis would be undertaken according to Dr Mashelkar Committee report.

Working of Drugs Control Laboratories

3.1.22 Drugs Control Laboratory, Mumbai

Testing equipment costing Rs 1.2 crore not purchased due to paucity of fund.

The capacity of laboratory at Mumbai is to test 6000 samples in a year. To improve the testing facilities of the DCL, Mumbai, Government sanctioned (February 2000) Rs 1.2 crore for purchase of testing equipment. The DCL, Mumbai, invited (March 2000) tender for purchase of 31 equipments/ instruments of different types. The purchase of equipments however could not be made due to paucity of fund.

* Amravati, Aurangabad, Beed, Nashik, Pune, Raigad, Satara, Thane and Wardha

3.1.23 Drugs Control Laboratory, Aurangabad

Non-functioning of Drugs Control Laboratory, Aurangabad to its optimum capacity since October 2000 for want of staff and equipment

The newly opened DCL at Aurangabad was located in the premises hired in February 1997 on a monthly rent of Rs 22898. It however, started functioning from October 2000 but not utilised to the optimum capacity as only eight posts were filled in against the 48 posts sanctioned (June 2003). Thus, the expenditure of Rs 9.85 lakh paid as rent was unfruitful. An Ultra Voilet Spectro photometer valuing Rs 5.41 lakh purchased in March 2001 for testing allopathic drugs remained unutilised, as other related equipment for testing samples were not procured. Government stated (October 2003) that the laboratory could not start functioning due to ban on recruitment of staff, non-availability of funds to purchase the required instruments etc. Functioning of the laboratory would be streamlined in due course.

Testing of sample medicines and drugs- Time taken for reporting and the adverse impact on reporting delays

There were delays in testing and reporting results of tests of samples by the Drugs Control Laboratory

3.1.24 According to departmental instructions the samples were to be tested within 90 days. As per Section 23 of the Act, the person whose sample is to be drawn should get at least 28 days time for contradicting the report of the Government Analyst else the prosecution case against him would not stand. Table below indicates the samples tested and its results thereof.

(In numbers)

Period	Samples received	Samples reported	Samples found standard	Samples found substandard	No opinion	Samples reported in 90 days	Reported beyond 90 days.
January 2001 to December 2001	5612	3903	2988	563	352	1041	2862
January 2002 to December 2002	5826	4696	4075	433	188	3605	1091

Information for the earlier period was not available with the DCL.

3.1.25 There were inordinate delays in testing of samples by the DCL. During 2001 (Calendar year), only 27 *per cent* samples were tested within prescribed period of 90 days. Test-check of records of samples tested revealed that of the 164 samples found substandard, six samples took more than one year, 14 samples took more than six months and 82 samples took more than three months for testing. Thus by the time sample of substandard drugs were tested and action taken, bulk of such drugs would have been consumed.

3.1.26 Report of the 'substandard' drugs tested during February 1999 and January 2001 revealed that 34 samples were tested within 45 days of its expiry date, 36 substandard samples were tested within 28 daysof its expiry date and three such samples were tested after expiry date. Thus testing of samples not well before the expiry date in these cases would not be of any help to launch necessary prosecution.

The delay in testing the sample was stated (October 2003) to be due to shortage of chemical analysts, testing instruments and non-availability of testing formula/methods in respect of propriety drugs. Audit felt that

deficiencies in the DCL's testing facilities might result in circulation of substandard drugs in market, causing irreparable damage to the society. DCL thus failed to discharge their regulatory function.

3.1.27 Followup action on samples found substandard or spurious - Lack of co-ordination among States

Of the 570 reports of drugs declared as substandard relating to other States, action taken report in respect of 401 cases was not received

After sample of a drug is found to be "substandard", necessary action is taken against the licensee. If, however, the offender happens to be from another State and launching of prosecution under Section 27 of the Act is not warranted, necessary intimation is sent to the licensing authority of that State for taking necessary action against him.

Scrutiny of records revealed that of 570 reports sent to the Drugs Control Authorities (DCA) of other States during 2000-2002, action taken reports were received only in 169 cases. It was stated (June 2003) that States other than Gujarat and Karnataka did not give the details of action taken reports against the erring units in most of the cases even though reminders were issued to them. The matter needs to be brought to the notice of the Central Drugs Control Authorities for securing better coordination among the States.

Government stated (October 2003) that the job of sending of chemical analyst's report and the resultant follow up action to be taken in the case had been entrusted to the respective Divisional Officer since June 2003.

3.1.28 Incomplete action against licensees

On receipt of report of Government Analyst regarding sample of the drug tested as "substandard", the licensing authority, pending penal action informs the manufacturer immediately to withdraw the drug in question from the market and to keep the unconsumed quantity thereof for destroying.

Scrutiny of records revealed that of 57 licensees whose samples were tested substandard, 55 did not furnish any detail of the drugs consumed and remaining to be consumed. The licensing authority took no further action on such licensees. Government stated (October 2003) that the licensees had been asked to follow the departmental instructions in future.

3.1.29 Unutilised stock (3466 vials) of a "substandard" drug manufactured in September 1999 by a unit in Hyderabad was not lifted and remained in a Mumbai hospital without being destroyed for three years (June 2003).

Inadequate Administrative Action

Inadequate action against the licensees though the samples from different batches failed repeatedly in a short time span

3.1.30 According to recommendation of the Drugs Consultative Committee, FDA has categorised the offences in different categories viz A1, AII and B depending on the gravity of substandard drugs manufactured for the purpose of launching prosecution, while cases falling under category A1 lead to prosecutions, category AII and B lead to administrative action under Rule 85 like suspension/cancellation of licence and issue of warnings.

However, FDA in respect of selling units has prescribed no such categories of contravention of licensing conditions. Thus the penal action taken by the licensing authorities under Rule 66 differed substantially for similar type of contravention on the ground that each case was decided on its merit and the power granted to the licensing authorities was discretionary *eg* for an offence of selling smuggled drugs the licence of a selling unit had been cancelled in Pune whereas for the similar offence licence of a selling unit in Mumbai was suspended for a day only.

Government stated (October 2003) that the issue would be examined with a view to formulate broader guidelines and that proper training would be imparted to the licensing authorities for proper use of quasi-judicial powers vested in them.

3.1.31 Audit observed that in 48 out of about 50 cases appropriate penal action was taken and in two cases detailed below, the licensing authorities merely issued warnings instead of taking stringent penal action under Rule 85.

A manufacturer in Thane division manufactured eight batches of medicines between October and December 1999 valuing Rs 82.06 lakh. Medicine of Rs 68.60 lakh were sold and consumed. Samples of different batches drawn of the licensee failed more than twice in a short span. However, instead of cancelling or suspending the license for a specified period, the licensee was issued only warnings. In reply the Government stated (October 2003) that the Assistant Commissioner, Raigad had been instructed to carry out inspection of the licensee and also to draw samples of drug to find out whether there was any crystallisation or otherwise in it.

3.1.32 Samples drawn from three batches of a drug Antagit Gel manufactured by a manufacturing unit in Amravati division failed as the concentration of Simethecene was found to be in the range of 48.03 to 71.32 *per cent*. The licensing authority instead of taking stringent penal action issued only warnings to the unit in each case on the ground that reasons and extent of substandardness involved in each case was different.

Government stated (October 2003) that the licensing authority took into consideration the written reply furnished by the licensee that they had adduced evidence in contraversion of the Government Analyst's Report and therefore, having been satisifed only asked the licensee to follow Good Manufacturing Practice. The report of the Central Drugs Laboratory under which the evidence was adduced in contraversion of the earlier report of the Government Analyst was not made available to Audit. Further reply from the Government was awaited (November 2003).

3.1.33 Monitoring

The database, which is currently being used, was developed in respect of manufacturing and selling units and also Management Information Systems

and Monitoring Modules for drug control functions and the laboratory functions only for the Mumbai office and not for the State as a whole.

The meetings of the Licensing Authorities took place periodically to take stock of the various problems faced by the Administration. However no minutes were kept. Follow up action was taken by way of issue of circular only.

Manpower and Training

3.1.34 Manpower

Discharge of regulatory functions by the Food and Drugs Administration ineffective due to shortage of technical staff

The effective implementation of the Act is to be ensured mainly through the processes of inspections of the units and drawal of samples of the drugs by the DIs and also in taking action against the erring licensees by the Licensing and Drug Controlling Authorities. Scrutiny of records revealed that there was acute shortage of technical persons at all levels to carry out the above tasks as detailed below:

Category	Sanctioned	Men in position	Shortfall
Joint Commissioner	11	5	6
Assistant Commissioner	53	42	11
Drug Inspectors	159	116	43
Total	**223**	**163**	**60 (27 *per cent*)**

Further analysis revealed that DIs were holding additional charges of 11 Assistant Commissioners (licensing authority for the selling units) thereby affecting their vital functions of inspection and sampling. In three districts (Beed, Bhandara and Osmanabad) only a DI functioned both as Assistant Commissioner and DI for more than a year. The number of licensees in each district was in the range of 300 to 800.

Task force appointed by the Government of India in 1981 recommended appointment of one DI for every 25 manufacturing units and one DI for every 100 selling units. The post of DIs has not been sanctioned according to these norms.

Government stated (October 2003) that selection process for filling up the post of Joint Commissioner was completed recently. The proposal for filling up the vacant posts of DI and Assistant Commissioner was pending with the Government.

3.1.35 Training

The DI is appointed according to the provision of the Act under which he must be a Pharmacy Graduate. Records in respect of number of personnel imparted requisite training have not been maintained. Joint Commissioner (Headquarters) however, stated (November 2003) that the technical officers of the administration are being imparted training in technical matters very often in programmes conducted by various institutions such as Yashada[*], Indian

[*] Yashwantrao Chavan Academy of Development and Administration

Homeopathies, Pharmacopea Laboratory and Central Drugs Standard Control Organisation.

3.1.36 Interface with the Pharmaceuticals Industry/Trade

Database not utilised for detecting the pharmacists employed on more than one selling units

The FDA (Administration) has to remain in constant touch with pharmaceutical industry, trade, medical profession and Pharmacy Council of the State to collect information, data and exchange of views for strengthening the system. It was stated that Administration did have interface with the industry and other related institutions for exchange of views. To tackle the problem relating to manufacture and sale of spurious drugs, the Administration as a result of recommendation of a Committee nominated four nodal officers to interface with the Industry and Trade.

Scrutiny of records on penal action taken against the selling units revealed that in most of the cases sale of drugs was without a pharmacist, which contravened the conditions of the license. There has been a tendency of the sellers to apply for a new license or renewal thereof, in the name of a pharmacist who has been employed elsewhere. This menace required to be tackled by interface with the State Pharmacy Council. Joint Commissioner (Headquarters) stated (June 2003) that the database in this regard so kept by the Pharmacy Council was so far not utilised in the State.

3.1.37 Conclusion

Implementation of the Act is to be ensured through a system of licensing, inspection, sampling and testing of samples in the laboratory. It was noticed that there was shortfall in each of these regulatory functions of the Administration. Besides, delays in testing of samples, increasing number of court cases and also launching of prosecution cases with insufficient evidence did not serve the intended purpose of preventing manufacture and sale of substandard drugs and their consumption by the consumers.

3.1.38 Recommendations

- The Act needs to be amended to prescribe the time schedule for disposal of renewal applications by FDA.
- The Act 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 should be a provision for compounding of offences to minimise the number of litigants.
- Only offences attracting imprisonment of more than three years are treated as cognisable offences. There is need to amend the Act to make all the offences under it cognisable.
- Deterrent penalty should be imposed for manufacture or sale of adulterated/spurious or misbranded drugs irrespective of their intensity.