MEDICAL DEPARTMENT

3.3 Implementation of Drugs and Cosmetics Act, 1940

Highlights

The Drugs and Cosmetics Act, 1940 was enacted to combat production and marketing of spurious / not of standard quality(NSQ) drugs and cosmetics causing serious health hazards and even death of consumers. Due to various inadequacies in implementation of the provisions of the Act in the State such as acute shortage of Drug Inspectors, faulty system of licensing, shortfalls in inspections of manufacturing/selling units and collection of samples, inefficient Government Laboratories and non-appointment of the Government Analyst for Homeopathic medicines etc. the consumers were prone to risk of health hazards. Monitoring and evaluation of the implementation of the provisions of the Act was, by and large, non-existent.

- ***There was no Regulatory Authority to co-ordinate the efforts of the authorities responsible for the implementation of the provisions of the Act/ rules for all the three systems of medicines.***

[Paragraph 3.3.5]

- ***Inspections of manufacturing facilities/Sale points of Allopathic medicines ranged between 4 per cent and 49 per cent.***
- ***Sampling of Allopathic medicines from Sellers ranged between one per cent and four per cent and from manufacturers between 22 per cent and 57 per cent.***

[Paragraph 3.3.6]

- ***Delay in testing samples ranging from 1 to 5 years rendered the working of the Government Analyst ineffective. Further, Rs. 65 lakh for the Government Analyst's Lab was not utilized.***

[Paragraph 3.3.7]

- ***Working of the intelligence branch(IB) established to intercept the manufacture and sale of sub-standard Allopathic medicines was inefficient and in respect of Homeopathic and Ayurvedic & Unani medicines, no IB was established.***

[Paragraph 3.3.8]

- ***Rs.1.24 crore out of Rs.1.55 crore released (March 2002) by Government of India for the strengthening of labs of Government Pharmacies remained unutilised.***

[Paragraph 3.3.11]

- ***No system, for monitoring and evaluating the working of Drugs Controller's Organization and Directors, Homeopathic and Ayurvedic & Unani Medicines in respect of the implementation of the Act and Rules, was in place in the State.***

[Paragraph 3.3.12]

3.3.1 Introduction

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 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; and The Drugs (Prices Control) Order 1995 (Under the Essential Commodities Act). However, 'The Drugs and Cosmetics Act, 1940' (D & C Act) continues to be the main Act.

Main features of the Act

- Regulatory measures to ensure standards of Drugs and Cosmetics, Diagnostics and Devices.
- Monitoring of quality of drugs and medicines imported, manufactured, distributed and sold to consumers.
- Punitive measures for dereliction of provisions of the Act.
- Regulate clinical research and publication of Indian Pharmacopoeia.

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/sales units and drug testing laboratories, (b) approval of formulations of drug for manufacture, (c) investigation and prosecution in respect of violation of provisions of the Act, (d) regulation of standards of drugs, (e) inspection and (f) recall of sub-standard drugs.

3.3.2 Implementing Agencies: implementation arrangement

Drugs Controller (DC) was the Licensing and Controlling Authority for the manufacturers of allopathic and homeopathic medicines and cosmetics. The powers of the Licensing Authority for sale of allopathic and homeopathic medicines were exercised by the Chief Medical Officers (CMOs) up to March

2001. Thereafter five Pathologists[&] and one CMO were notified (August 2001) as the Drug Licensing Authority for sale of allopathic medicines and Director Homeopathy for sale of homeopathic medicines. The Director, Ayurvedic and Unani Services functioned as the Controlling and Licensing Authority for manufacturers and sellers of Ayurvedic and Unani medicines.

Drugs Inspectors (DIs) for allopathic medicines were responsible for collection of samples from the premises of manufacturers/whole sellers/retailers of allopathic medicines. The District Homeopathic Medical Officers were designated DIs for homeopathic medicines, and the powers of DIs in respect of Ayurvedic and Unani medicines were exercised by the Regional Ayurvedic and Unani Medical Officers and the Principals of the Ayurvedic and Unani Medical Colleges. Government Analysts were there to test/analyse the samples of Allopathic and Ayurvedic and Unani drugs and medicines.

3.3.3 Audit Coverage

Implementation of the Drugs and Cosmetics Act for the period 1998-2003 was reviewed in Audit between March and November 2003 through test check of records of the offices of the Director General of Medical and Health, DC of the State, Directors of Homeopathic and Ayurvedic and Unani Medicines**,** Government Analysts (GAs) of Allopathic and Ayurvedic and Unani Medicines, DIs, and Inspectors of Homeopathic and Ayurvedic and Unani Medicines in 16[⊃] districts.

3.3.4 Infirmities in the Act

There were many infirmities in the Act itself due to inadequate provisions in respect of licensing, absence of time frame for prosecution etc.

Inadequate provision for renewal

Under the Rules a licence or a renewal certificate issued shall be valid for a period of 5 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. No time frame has however, been prescribed in the Act for renewal of licences. 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.

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. As such they are amenable to outside pulls and pressures.

Lack of provision for free surrender of samples

[&] The number of pathologists was raised to 13 from December 2001.

[⊃] Allahabad, Kanpur Nagar, Varanasi, Gonda, Lucknow, Moradabad, Ghaziabad, Bareilly, Bulandshahar, Muzaffar Nagar, Meerut, Agra, Saharanpur, Gorakhpur,Shahjahanpur and Gautam Budh Nagar.

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.

No time frame for drug analysis

No time frame has been prescribed to analyse the drugs samples due to which substandard/ spurious drugs continue to be sold in the market. Rule 46 envisages that after analysis, the test-report is to be sent 'forthwith'. But there is no specific mention about the time limit for testing/sending test reports resulting in consumption of untested drugs before availability of the report leading even to death. Standing of the Law.

Testing of samples was delayed upto six years

Scrutiny of records of the GAs of Allopathic and Ayurvedic and Unani medicines for the period 1998-2002 revealed that only 14 *per cent* of samples were tested within the year of their receipts. The delay in testing of the remaining samples ranged between 1 and 6 years in case of allopathic medicines and between 1 and 4 years in case of Ayurvedic and Unani medicines as discussed in paragraph 3.3.5. Delay in testing the samples hampered the effectiveness of the quality control. Delay in testing also meant that the drugs, to be retested under section 25(4) of the Act, in case of appeal by manufacturers would not be feasible due to prescribed expiry period of medicines.

Absence of time frame for prosecution

No time frame has been prescribed in the Act to file the complaint by the department in the court of law with the result that action against the offenders gets delayed.

3.3.5 Deficiencies in administrative structure

A unified regulator for all the systems of medicine was not created in State

No unified regulator for all system of medicines, viz. Allopathic, Homeopathy and Indian System of Medicines was available. Thus, unlike Maharashtra a central authority to monitor the effectiveness of implementation of the provisions of the Act was not operational in the State. Government, however, stated (March 2004) that a decision had been taken to setup a unified Drugs and Food Authority in the State.

Chain of command in Drugs Controllers Organisation was not well defined

Further, DC, who was responsible for implementation of the Act, did not have an independent set up under him. He was subordinate to the Director General/ Medical & Health, while Assistant DCs and the DIs, instead of being under his administrative control, were working under the control of Additional Director/ Medical and Health and Chief Medical Officers respectively. Thus, the DC had no administrative control over the DIs. This resulted in uneven distribution of available strength of the DIs and transfers without taking into consideration of the progress of investigations in hand as pointed out in succeeding paragraphs.

3.3.6 Delay in grant of renewal of licenses for manufacturing

Rules provide that a license for manufacturer of medicines and cosmetics was valid if the application for renewal of the license was made before its expiry or

within six months of its expiry. Rules, however, do not specify any time limit allowed, to the Licensing Authority, for completing the renewal process.

Scrutiny of renewal cases revealed that out of 62 renewal cases pending as of September 2003, 17 were delayed by two to five years, 16 by six to ten years and five cases by more than 10 years. This included a case where the license was valid up to 31 December, 1973 and had not been renewed nor refused till date (September 2003). In another case license for 19 drugs, valid up to 31 December 1999, was renewed on 15 December 2002 for the period from January 2000 to December 2001 only. Further, renewal was for 14 drugs only. Thus, manufacture of five drugs for which license was not renewed, continued during January 2000 to December 2002. There was no record on evidence that the manufacture of these five drugs was ever stopped.

The Drugs Controller stated (September 2003) that delay in renewal of the licenses was caused due to non posting of the DIs in some of the districts, non-availability of inspections reports or incomplete inspection reports, non co-operation by the concerned units and higher number of licensed sellers and manufacturers. Records, however, revealed that in the test-checked districts, available manpower was deployed for inspections of the premises of new applicants only and not for those seeking renewal of licenses. Thus, better management of the available resources could have avoided these cases of delays.

Delays in renewal of licenses of Blood Banks

The DC of the State was the Licensing Authority to issue to licenses to the Blood Banks with the prior approval of the Drugs Controller of India. It was noticed that as against 121 licensed blood banks in the state, renewal of 107 licenses was pending as of May 2003.

The DC attributed the pendency to the delay in joint inspections with the team of the Drugs Controller of India and delays in compliance of the earlier observations of the DIs. Such delays in renewal of licenses of blood banks tantamount to lack of quality control.

Licenses renewed without inspections

Licenses were renewed without proper inspection

A license for selling of medicines is renewed after inspections of the premises to ensure that the conditions requisite for granting the license have been fulfilled. Scrutiny of records of the Drugs Controller Organization revealed that licenses of 700 Whole Sellers of allopathic medicines in Allahabad district were renewed during 2002-03 without receiving the inspection reports of the concerned DI.

Inadequate collection of sampling and inspections

Inspections and samplings were much below the required numbers

Drugs and Cosmetics Rules, 1945 provide that an Inspector shall inspect not less than twice a year (reduced to once a year w.e.f. September 2001), all establishments licensed for the manufacture and sale of drugs.

Scrutiny of records in test-checked districts revealed that in respect of all systems of medicines, neither inspection of the premises of manufacturers /sellers nor collection of samples therefrom were according to the prescribed

norms. Details of inspections and sample collection during the period from 1998-2002 were as follows:

Systems of Medicines	Number of inspections carried out as a percentage of the inspections due			Number of samples collected as a percentage of samples due		
	Manufac-turer	Whole Sellers	Retailers	Manufact-urer	Whole Sellers	Retailers
Allopathy	17 to 49	4 to 12	5 to 16	22 to 57	2 to 4	1 to 2
Ayurvedic and Unani	50 to 54	Nil	Nil	1 to 8	Nil	Nil
Homeopathy	23 to59	10 to 13	9 to 13	Nil	Nil	Nil

Government attributed (March 2004) the shortfall to shortage of manpower and lack of supporting facilities.

During the period 1998-2002, only 11 samples of cosmetics were collected out of which five were tested and two were found sub-standard**.** It was, thus, evident that the requisite number of inspections and samplings were not being carried out. This diluted the regulatory impact of the Act.

The manufacturers and wholesalers were the source from where medicines were available for retail sale to the consumer. A comparison of inspections of sampling from the manufacturers/ wholesalers and retailers carried out during 1998-2002 revealed as follows:

Year	Number of samples pertaining to Manufacturers/ Wholesalers		Number of samples pertaining to Retailers		Number of samples found to be adulterated/ substandard	
	Collected	Tested	Collected	Tested	Out of Col. 3	Out of Col. 5
1	**2**	**3**	**4**	**5**	**6**	**7**
1998	444	164	169	67	4	1
1999	454	188	214	72	49	1
2000	310	67	194	55	11	3
2001	341	85	153	39	14	4
2002	664	92	231	38	32	5
Total	**2213**	**596**	**961**	**271**	**110**	**14**

It was thus evident from the above that the percentage of adulteration in the samples collected from the manufacturers and wholesalers was higher (18.45 *per cent*) as compared to those collected from the retailers (5.16 *per cent*) indicating ineffectiveness of the inspections carried out at the premises of the manufacturers and wholesalers.

3.3.7 Working of Drug Testing Laboratories

Inadequate testing capacity in the laboratory

Testing laboratories did not have adequate capacity to test samples

As provided under the Rules 45 and 46 of the Drugs and Cosmetics Rules, 1945 the Government Analyst (GA) for allopathic medicines and cosmetics was responsible for testing or analyzing of samples of medicines and cosmetics and furnishing results of such testing to the DC. Inordinate delays were noticed in testing of the samples at the level of the GA as detailed below:

Year	Opening Balance	Samples received during the year	Tested/analyzed			Returned untested			Closing Balance	Samples found NSQ/ spurious
			Relating to Current year	Relating to previous years	Total	Current year	Previous years	Total		
1	2	3	4	5	6	7	8	9	10	11
1998	4974	2889	705(24%)	560	1265	67	672	739	5859	127
1999	5859	2853	475(17%)	454	929	118	860	978	6805	108
2000	6805	2772	345(12%)	375	720	55	3960	4015	4842	113
2001	4842	2889	129(4%)	383	512	60	1560	1620	5599	67
2002	5599	3216	388(12%)	721	1109	34	1011	1045	6661	203
Total		**14619**	**2042 (14%)[β]**	**2493**	**4535**	**334**	**8063 (29%)[χ]**	**8397**		**618 (14%)**

It was observed that

- The percentage of testing of samples, out of current year samples, went down from 24 *per cent* in the year 1998 to 12 *per cent* in the year 2002;
- During 1998-2002, 4,535 samples were tested, out of which 2493 (i.e. 53 *per cent*) samples related to preceding years;
- The GA returned 8,397 samples untested due to lack of capacity.

In reply the GA of allopathic medicines stated that testing was delayed as the Laboratory had a capacity to test only 600 samples per year. Thus, the capacity of the laboratory was grossly inadequate as it could test only 600 samples in a year whereas more than 2800 samples were being collected each year.

The Government stated (March 2004) that strengthening of the laboratory was under process.

Similarly during 1998-2002, the GA of Ayurvedic and Unani Medicines received 820 samples for testing in addition to opening balance of 222 samples available at the beginning of the period. Out of these, only 419 samples were tested during the year of their receipt, 459 within next one to three years and

[β] Percentage of samples tested, out of samples collected during current year as shown in col.3
[χ] Percentage of samples returned, out of opening balances of the years as shown in the col. 2.

eight samples were tested after three years, leaving a balance of 156 samples un-tested at the close of 2002.

The GA of Ayurvedic and Unani medicines stated that the laboratory had the capacity to test only 100 samples per year and that for determination of *putties* in the *Bhasm*, and the components in the medicines containing more than eight ingredients could not be identified for want of instruments and non fixation of standards for raw drugs of mineral and animal origins, and for composition of medicines. The reply was not tenable as a sum of Rs.65 lakh received from Government of India in March 2001 for strengthening the laboratory remained unutilised in a current account of State Bank of India, Lucknow as of June 2003. No effort was taken to utilize the funds for strengthening the laboratory.

There was no GA for homeopathic medicines

Further, there was no Government Analyst for testing or analyzing samples of homeopathic medicines and cosmetics.

Follow up action on samples found sub-standard or spurious

No legal action could be taken against deficiencies in case of Ayurvedic and Unani medicines

To deter the defaulters it was necessary that deterrent actions as provided in the Act should be taken. It was noticed that out of 886 samples tested by the Government Analyst (GA) of Ayurvedic and Unani medicines during 1998-2002, 309 samples were found adulterated, spurious and misbranded. None of these cases were however, found fit for prosecution by the Director, Ayurvedic and Unani Services.

In reply the Director, Ayurvedic and Unani Services stated (September 2003) that as pharmacopoeia standards for single and compound drugs were not available, the prosecutions would not have stood the test of court of law. As such, show-cause notices were issued to the defaulting firms and further administrative action decided keeping in view their reply.

3.3.8 Intelligence Branch

No Intelligence Branch, to intercept the manufacture and sale of adulterated, sub-standard, spurious or misbranded Homeopathic and Ayurvedic & Unani medicines existed in the State.

Intelligence branch remained un operational

In respect of allopathic medicines, State Government established (March 1987) an Intelligence Branch (IB) in the Drugs Controller Organization and created one post of Assistant Drugs Controller and five posts of Drug Inspectors. No records, relating to the working of IB during 1998-2002 were maintained at the headquarters level.

Further it was seen that the IB was not in touch with any other similar organization such as Central Economic Intelligence Units, Income Tax department and IBs of other States to exchange information. No special training was given to the ADC and the DIs for intelligence work. No secret fund was created to induce the informers. Creation and operation of IB in the Drugs Controller Organization were also not advertised to make the people aware of their existence and to invite public participation. The services of the ADC and DIs meant for IB were being utilized in different districts in other routine activities of the department. Thus, IB was totally non-functional.

The Government while accepting (March 2004) the audit observations attributed the non-functioning to lack of manpower, mobility and other strategic support facilities.

3.3.9 Improper system of initiation of prosecutions

Prosecution was not initiated in large number of cases

The records in the office of the DC revealed that out of 618 samples found sub-standard, adulterated and spurious during 1998-2002 by the GA of Allopathic medicine, DC approved only 151 cases for prosecution. The prosecutions could however, be launched only in 93 cases by the concerned DIs as detailed below:

Year	Number of Cases	
	Approved for prosecution	Cases filled
1998-99	9	2
1999-2000	30	8
2000-01	73	12
2001-02	4	48*
2002-03	35	23
Total	**151**	**93**

The DC stated (September 2003) that initiation of legal proceedings got delayed due to consumption of more time in investigations and also due to transfers of the Investigating Officers midway. The reply is not tenable, as the department should have developed a suitable system to ensure expeditious investigations of cases to avoid delays in filing of prosecutions since delays in remedial/ legal action diluted the deterrent effect of the Act and Rules.

3.3.10 Lack of Human Resource

Due to shortages of Drugs Inspectors, 30 districts remained uncovered

To implement the provisions of the Drugs and Cosmetics Act in the state, in respect of Ayurvedic & Unani medicines, there was only one regular DI at Directorate level to examine the issue of licenses to the manufacturers. At district level, all Regional Ayurvedic and Unani Medical Officers, Ayurvedic and Unani Medical Officers and Principal, Ayurvedic and Unani Colleges were assigned additional duties of the DIs.

In respect of manufacturers and sellers of allopathic medicines only 47 DIs were available. These DIs were so deployed as to cover only 40 districts out of 70 districts of the State (five DIs earmarked for Intelligence Branch). Thus, 30 districts were virtually without DIs.

The shortage of regular DIs affected adversely the quantum of inspections and collection of samples of the manufacturers and sellers as discussed earlier.

Government stated (March 2004) that the strengthening of the Drugs Control Department was under process.

* includes cases approved during earlier years.

3.3.11 Other Points of interest

Blocking of funds.

Rs. 124.16 lakh sanctioned by GOI in March 2001 remained unspent

The Government of India, Ministry of Family Welfare sanctioned[⊕] Rs. 170 lakhs (Rs. 50 lakhs for buildings and Rs. 120 lakhs for equipments) and released Rs. 155 lakhs for strengthening the laboratories of the Government Pharmacy at Lucknow and Pilibhit. Out of Rs. 155 lakhs received, Rs. 27.30 lakhs only was spent on constructions of building by the Government Pharmacy Lucknow, Rs. 3.54 lakh on equipments by Government Pharmacy Pilibhit and the remaining amount of Rs. 124.16 lakh remained unspent (May 2003).

No quality control of raw materials

Quality of raw material was not checked

Government Ayurvedic Pharmacy, Lucknow is manufacturing Ayurvedic and Unani Medicines to supply all the Government Ayurvedic and Unani Hospitals & dispensaries of the State but its Laboratory for testing raw materials and finished medicines was closed for the last 10 years.

Non-communication of test results.

Test results not communicated to GA

GA of Ayurvedic and Unani Medicines tested 251 samples of medicines manufactured by the Government Pharmacy and found 107 samples sub-standard. However, the Pharmacy did not receive any information regarding sub-standard medicines, though both the Government Analyst and Government Pharmacy functioned under the administrative control of the Director, Ayurvedic & Unani Services, Lucknow.

3.3.12 Monitoring and Evaluation

A system of Monitoring and Evaluation developed

No reports/returns were prescribed for Licensing Authority, Government Analyst, Asstt. Drugs Controllers, Senior Drugs Inspectors and Drugs Inspectors for submission to DC to monitor the progress of grant and renewal of licenses, test/analysis of samples, inspections and collections of samples. Thus, there existed no system to maintain the data in respect of granting and renewal of licenses to sellers and manufactures of allopathic medicines, their inspections and sampling and testing the samples and to monitor and evaluate the performance of the authorities responsible for implementing the provisions of the Act/Rules.

In the Directorate of Homeopathy, a system to ensure sufficient number of inspections and sampling by District Homeopathic Officers (DHO) as Drug Inspector was not in place as required in Rule 51 and 52 of the Drugs and Cosmetics Rules, 1945. Submission to audit by the DHOs of Varanasi, Allahabad, Lucknow, Bareilly, Ghaziabad and Moradabad districts revealed that there existed no whole sellers and retailers of homeopathic medicines in their districts except Moradabad where there was only one retailer in the years 2001-02. These facts, at face value, did not appear reliable. As such there was

[⊕] Sanctioned and released: Government Pharmacy, Lucknow sanctioned in March 2001 (Rs. 30Lakh for building and Rs. 50 lakh for equipments) and released Rs. 70 lakh. Government Pharmacy, Pilibhit sanctioned in March 2002 Rs. 90 lakh (Rs. 20 lakh for buildings and Rs. 70 lakh for equipments) and released Rs. 85 lakh.

no monitoring and evaluation at the Director of Homeopathy level to implement the provisions of the Act and Rules.

There was no prescribed format/register to maintain the records relating to Manufacturers/Sellers of Ayurvedic and Unani medicines and cosmetics at district level as well as at Controlling Authority level. No system was developed to submit returns to the Director, Ayurvedic and Unani Services in respect of inspections and collection of samples by Drug Inspectors i.e. Regional Ayurvedic and Unani Officers and their evaluation at Director level, which was also evident from the fact that Regional Ayurvedic and Unani Officer, Varanasi did not furnish information in respect of inspection and sampling for the period 1998-2001.

Government stated (March 2004) that the monitoring and evaluation of the Drugs Control Organisation was being improved and a Management Information System (MIS) was under process of development.

3.3.13 Conclusions

The machinery responsible for implementation of provisions of Drugs & Cosmetics Act, 1940 was ineffective due to lack of a clear chain of command. The numbers of inspection of/sampling from the premises of manufacturers and traders were inadequate. Lack of capacity for testing of drugs resulted in delay in reporting test results, which led to weakening of the prosecution proceedings against the defaulters.

3.3.14 Recommendations

- A Regulatory Authority to monitor the implementation of the Act common for all the systems of medicines may be set up.
- The Drugs Testing Laboratories may be strengthened so that all the samples received are tested/ analyzed without delay.
- A timeframe for disposal of the cases of renewal of licenses may have to be prescribed to arrest manufacture/sale of drugs without valid license.
- Shortage of Drug Inspectors needed attention.
- Computerized databank of the licensed manufacturers and sellers and those of banned substandard drugs may be maintained.