Medical and Health and Ayurved Departments

3.2 Implementation of Drugs and Cosmetics Act

Highlights

The Drugs and Cosmetics Act, 1940 (the Act) is a Central Act and is applicable to the whole of India. This Act and the rules made thereunder regulate the manufacture, sale, import, export and clinical research of drugs and cosmetics in India. While the parameters of control are devised by the Central Government, these are required to be actually implemented by the State Government. However, the Act and the Rules were not implemented effectively in the State as was noticed in test-check.

There was delay ranging between two and 34 months in granting/renewal of licences.

(Paragraph 3.2.4)

Shortfall in achievement of targets of drawal of samples and inspections ranged from six to 18 *per cent* and 39 to 74 *per cent* respectively. In Ayurved Department, there was shortfall in conducting inspections ranging between 38 and 63 *per cent.*

(Paragraphs 3.2.5 and 3.2.6)

The delay in sending samples for analysis to laboratories ranged upto 43 months. In 33 cases, test reports were received after expiry of drugs.

(Paragraph 3.2.7)

Sixty seven cases ordered by the Drugs Controller for being filed in the court of law were not filed for periods ranging from six months to more than five years. There was acquittal in 15 cases because of failure of the department.

(Paragraph 3.2.8)

3.2.1 Introduction

The Government of India (GOI) enacted the "Drugs and Cosmetics Act, 1940" (the Act) with a view to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The Drugs and Cosmetics Rules, 1945 (the Rules) were adopted in the State with effect from 16 July 1959. The Act also applies to patent or proprietary medicines, which relate to Ayurvedic and other systems of medicine and cosmetics.

3.2.2 Implementing Agencies

The Drugs Controller (DC) is the Regulatory Authority entrusted with the task

of enforcement of the Act and the Rules. DC is assisted by 11 Assistant Drug Controllers (ADCs) and 45 Drugs Control Officers[$] (DCOs). One Drugs Testing Laboratory (DTL) headed by the Government Analyst (GA) is working under the DC. The administrative control of the DC is vested with the Secretary, Medical and Health Department. For Ayurvedic (including *Siddha*) and Unani medicines, Director, Ayurved under the Secretary, Ayurved is the Regulatory Authority. The Director is assisted by one ADC (Ayurved).

3.2.3 Scope of audit

Implementation of the Act/the Rules for the period 1998-2003 was reviewed in audit (January 2003 to June 2003) in the offices of the DC, Rajasthan, Jaipur, 3 ADCs[@], DTL, Jaipur and Director, Ayurved, Rajasthan, Ajmer.

3.2.4 Survey and Licensing Procedure

There was delay in granting/ renewal of licence ranging between two and 34 months.

- As per directions (January 1999) of the Secretary, Medical and Health Department, Rajasthan, licences were to be granted within 15 days of the receipt of application. Applications for renewal were to be disposed off the same day. Test-check of records of three ADCs revealed that a time of two to 34 months was taken in granting/renewing licences. The ADCs, Kota and Ajmer attributed the reasons for delay in granting/renewing licences to shortage of staff and workload.

Two to 59 months period was taken for issue/renewal of licence.

- In respect of Ayurvedic medicines, Rules provide for issue of manufacturing licence within a period of three months from the date of receipt of application. However, two to 59 months were taken for issue/renewal of licence. The Director, Ayurved stated (April 2003) that delay was due to non-receipt of Inspection Reports from Drugs Inspectors (DIs), time taken by unit owners to comply with the deficiencies, closure of units, non-supply of information and workload in Licensing Authority (LA) office. The reply is not tenable as three months prescribed time is sufficient to meet the requirements essential for issue of licence.

- The manufacturing of Ayurvedic (including *Siddha*) or Unani drugs was to be carried out in such premises and under such hygienic conditions as specified[*] under Good Manufacturing Practices (GMP) (revised with effect from 23 June 2000). Existing licensee units were allowed two years buffer time to meet requirements as per revised schedule. However, as of March 2003, out of 447 manufacturing units, only two existing units had been granted certificate of GMP of Ayurved, which indicate that other units did not meet the requirements.

Blood Banks

As of 31 March 2003, there were 60 blood banks (Government sector: 43, Private sector: 17). Of these, 51 licences (Government sector: 42, Private

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$ Designation of 'Drugs Inspector' has been changed as 'Drugs Control Officer' by the State Government w.e.f. 5 April 2002 in respect of Allopathic medicines.

@ Ajmer, Chittorgarh and Kota.

* Schedule 'T' of the Drugs and Cosmetics Rules, 1945.

sector: 9) have not been renewed after expiry of their validity between 1998-2002.

No compliance report was furnished by any of the Government Blood Banks.

The licence for operating the blood banks at 43 Government Hospitals was granted (March 1993 to September 2002) with the condition to comply with the deficiencies pointed out in the Joint Inspection*. However, no compliance report was furnished as of June 2003 by any of the blood banks, even though, the licence was renewed up to 31 December 2002 in 31 cases. Thus, blood banks with deficiencies were working under a licence of Drugs Control Organisation, which may lead to health hazards.

Inadequacy of Sampling and Inspection

3.2.5 Sampling

During 1998-2003, 5079 samples were drawn, and 732 samples** (14 *per cent*) were declared as not of standard quality of which 54 samples were spurious. Following irregularities were noticed:

There was shortfall in achievement of targets in drawal of samples ranging between six and 18 *per cent.*

- The shortfall in achievement of targets in drawal of samples during 1998-2003 ranged between six and 18 *per cent*. Out of 38 to 42 Drugs Control Officers who worked during different periods five to 26 DCOs did not achieve their targets.

No samples of cosmetics and Homoeopathic medicines was drawn from rural as well as urban areas except two DCOs.

A comparison of samples drawn from urban and rural areas and of samples drawn from allopathic drugs, cosmetics, homoeopathic medicines and Government stores is given in the table below:

Year	Number of DCOs	Samples of Drug		Number of DCOs who did not take samples of			
		Rural	Urban	Allopathic drugs in rural areas	Cosmetics in urban and rural areas	Homoeopa-thic medicines in urban and rural areas	Governme-nt store in rural areas
		(Percentage in bracket)					
1998-1999	18	75 (16)	391 (84)	6	16	18	17
1999-2000	18	38 (10)	356 (90)	7	17	18	15
2000-01	19	58 (15)	317 (85)	7	19	19	17
2001-02	19	59 (14)	363 (86)	8	19	19	18
2002-03	19	45 (8)	496 (92)	11	19	19	16

There was a substantial urban bias in taking samples. Further, no samples of homoeopathic medicines were taken over the period 1998-2003 and no samples for cosmetics were taken over the period 2000-03. The DC stated (June 2003) that no targets were fixed for taking of samples, rural and urban area-wise, for proportionate collection of samples of Allopathic and Homoeopathic medicines and cosmetics. In respect of Government stores, target for taking one sample per month per DCO has now been fixed from January 2003.

* Representatives of Central Drugs Standard Control Organisation (North Zone), Ghaziabad, State Drugs Controller, Expert of Blood of the Blood Banks.

** Includes samples drawn before 1998-99 but test reports received during 1998-2003.

- Test reports of 23 samples (taken by DIs of other States) were challenged by concerned manufacturers after issue of show cause notices (September 1998 to July 2002). Thereupon the cases were referred to the concerned DCs. No further action was taken for the last one to four years.

- Transfusion of matching human blood may cause harm to the patients if transferred blood is infected or HIV positive. Not a single sample of human blood/ component/product was taken by any of the DCOs for testing during 1998-2003. On being pointed out in audit ADC, Jaipur stated that amendments have been made (April 2002) in the Rules inserting the name of National Institute of Biologicals, Noida as an additional centre for testing blood samples and action has been initiated at DC level to direct the DCOs for taking the blood samples. The reply was not tenable as the testing facility for blood was already available at three other institutes situated at Delhi, Pune and Vellore and no sample was drawn even after issue of amendments.

Only one sample was drawn even though facility of single component drug was available.

- Though the facility for testing of single component Ayurvedic drug was available, only one sample was drawn during 1998-2003. The Director, Ayurved asked (April 2003) the DIs to explain reasons for non-drawing samples during the last five years.

3.2.6 Inspection

There was shortfall in achievement of targets ranging from 39 to 74 *per cent.*

There was shortfall in achievement of targets of inspection of DCOs during 1999-2003, which ranged from 39 to 74 *per cent.*

In respect of manufacture of Ayurvedic (including *Siddha*) or Unani medicine, there was shortfall in conducting inspections ranging between 38 and 63 *per cent*. The Director, Ayurved while accepting the facts intimated (April 2003) that inspectors have now been directed to strictly follow the Rules.

3.2.7 Follow up action on samples found not of standard quality or spurious; effectiveness thereof

Test reports of 33 samples were received after expiry of drug.

- Test-check of records revealed that 81 samples were sent to laboratories with a delay from one to 43 months. Test-reports of 33 samples (11 declared as not of standard quality and one spurious) were received after expiry period of drugs and adverse test results were circulated to ADCs/DCOs of the State and DCs of other States with delay ranging from 10 days to four months. Consumption of drugs not of standard quality in the meantime may have led to health hazard to the consumers.

- As the drugs are sold through out the country, there should be proper coordination among the Drug Control Organisations of all the States for prompt communication. Such coordination was lacking which is indicative from the fact that during 1998-2003, information of adverse test results in 14 cases from other States was received in DC office with delays ranging from five to 36 months and in 25 cases test results were received one to 3½ months after the date of expiry of drug. The Rajasthan DC intimated adverse test results of 79 cases to other state Drug Control Organisations with a delay ranging from 10 days to 2½ months. Results of 35 cases declaring the drugs as

not of standard quality were intimated (April 2000 to April 2003) to all Drug Control Organisations after expiry date of the drug.

- Details like date of manufacture and expiry of drug, and reasons for declaring the drug as not of standard quality were not being given in the bulletin issued by the DC from time to time. Consequently, the concerned authorities were not in a position to assess time left, position of stock and gravity of the offence for taking prompt and suitable action.

- Reference to provisions of the Act and the Rules under which accused is to be prosecuted was not found mentioned in the sanctions issued by the DC (Controlling Authority).

- After the declaration of a sample as not of standard quality there was delay of six to 30 months in linking with the manufacturer in 15 cases where no stock was got retrieved from the suppliers/retailers resulting in consumption of drugs not of standard quality exposing the lives of patients to various hazards.

3.2.8 Prosecutions vis-a-vis cases filed

Out of 82 cases decided (1999-2003) by various courts there was acquittal/discharge in 48 (59 *per cent*) cases and out of 23 test checked cases, in 15 cases (65 *per cent*) the acquittal/discharge was due to various departmental failures such as deprival of right of re-examination of sample because of expiry of drug, not issuing proper prosecution sanction, delay in analysis/reporting, drawal of samples by official not notified etc. In 67 cases where the DC had issued orders for filing the case in the court of law, cases were not filed for periods ranging from six months to five years and more. In 34 cases (out of 180 cases) there was departmental delay of more than 12 months in filing the challan in court of law against the offenders. The main reasons for delay were linking of firms and non-receipt of their constitution.

3.2.9 Working of Drugs Testing Laboratories

Following major deficiencies were noticed in the working of DTL functioning in the State since 1961:

- The sanctioned strength of DTL during 1998-2003 was 24 for technical (13) and administrative (11) work. Of these, six technical posts and one post of Deputy Director were lying vacant since 1998.

Pharmacology lab, Micro-Biological lab and computer room were lying unutilised.

- Pharmacology, Micro-Biological Laboratory and Computer room constructed at a cost of Rs 35 lakh and handed over between October 1997 and November 2001 were lying unutilised.

- DTL was having testing facilities for 11 major categories of drugs. Out of 2728 samples received for testing during 1998-2003, 291 samples (11 *per cent*) were returned without analysis mainly due to non-availability of testing facility, testing equipment being out of order or the samples were not sealed properly. While most of the samples received for test related to

analgesic/antipyretics/anti-inflammatory (30 to 74 *per cent*) and surgical dressing (four to 36 *per cent*) categories, representation of samples of other categories like vitamins, anti-tubercular, anti-malarial, raw material and cosmetics was negligible. In 114 cases test checked, during 1998-2003 time taken in analysis of samples ranged from two to 24 months. In 31 cases samples were declared as not of standard quality which may have resulted in consumption of these drugs in field during such delay.

3.2.10 Manpower

- The State Government sent (November 1998) requirement of 55 additional posts to GOI under capacity building project for strengthening drug enforcement machinery with World Bank assistance. The DC also sent (February 2002) proposals for creation of 55 posts of DCOs based on recommendations of task force committee to the Director for submission to State Government. No decision on the proposals was taken (April 2003).

- No time limit has been laid down for issue of gazette notification for appointment as Drugs Inspector. During 1993-2001, the notifications for appointment of five DCOs were issued with abnormal delay of 86 to 190 days after their joining duty. In absence of notification they were not authorised to perform duties entrusted by the Act.

3.2.11 Inadequacy of financial and administrative powers of Drugs Control Authorities

Though the DC is head of the Drugs Control Organisation and independent for enforcement of the Act and the Rules, he has no financial/administrative powers in respect of transfer and posting of staff essential for effective control over the performance of organisation as a whole.

3.2.12 Training

No training facility existed nor any training programme was conducted.

- No training facility existed nor any training programme was conducted for developing/upgrading the skills of DCOs of Drugs Control Organisation/DIs of Ayurved Department during 1998-2003 to make them efficient in discharging the specialized functions envisaged in the Act and the Rules.

- The Rules envisaged that licensee of a blood bank was responsible to ensure through maintenance of records and other latest techniques used in blood banking system that the personnel involved in blood banking activities for collection, storage, testing and distribution are adequately trained in the current Good Manufacturing Practices/Standard Operating Procedures for the tasks undertaken by each personnel. No such training was found to have been conducted by any blood banks.

3.2.13 Monitoring

There was lack of coordination with other States as is seen by the fact that reports of drugs of not of standard were received or dispatched to the

respective Drug Controllers after considerable lapse of time.

3.2.14 Conclusion

In Rajasthan, the Act has not been implemented effectively. The provisions of the Act regarding inspection of units, drawing/testing/reporting of sample, speedy and effective action against defaulters were not implemented strictly. There was shortfall in conducting inspections of units and action against drug offenders was inadequate. There was no proper coordination among the Drug Control Organisations of various States. There was serious risk, therefore, of fake/spurious/not of standard quality drugs being supplied to consumers in the State. There was delay in sending of samples to laboratories for analysis, delayed reports of analysis even after expiry of drugs, full consumption of stock of "not of standard quality" drugs, and shortfall in sampling of all categories of drugs.

3.2.15 Recommendations

In view of the above shortcomings Audit recommends that:

- The drawal and testing procedures of samples need to be rationalised.

- Drugs Testing Laboratories should be fully equipped with testing equipment and technical staff, for strengthening and ensuring effective enforcement of the Act.

- Time limit for testing of samples should be specified.

- Proper coordination among the Drug Control Organisations of various states should be ensured.

These points were referred to the Government in July 2003; reply had not been received (November 2003).