3.2. Implementation of the Drugs and Cosmetics Act, 1940

Highlights

HEALTH AND FAMILY WELFARE DEPARTMENT

The Drugs and Cosmetics Act, 1940 (Act) is a Central Act and is applicable to the whole of India. This Act alongwith the other associated Acts 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. Dereliction occurs in the implementation of regulatory parameters especially in the areas of licensing, approval, monitoring, prosecution, inspection and recall of substandard/spurious drugs. In Punjab, the Act has not been implemented effectively. The provisions of the Act regarding inspection of units, drawing/testing/reporting of samples, speedy and effective action against those manufacturing and marketing sub-standard/spurious drugs were not implemented strictly and meticulously. There was shortfall in conducting inspections of manufacturing units and action against drug offenders was inadequate. There was no co-ordination with other States/State Vigilance Authorities for tracking down the activities of drug offenders.

- ***Shortfall in drawing of samples for testing of allopathic drugs ranged between 10 and 35 per cent during 1998-2003. No samples of Ayurvedic and Unani drugs were drawn for testing.***

  (Paragraphs 3.2.15. & 3.2.16.)
- ***Ten Blood Banks and 11 drug manufacturers continued to function without renewal of licences. Applications for renewal of 7,932 licences of wholesalers and retailers relating to the period 1998-2002 were still pending for renewal as of February 2003/May 2003.***

  (Paragraphs 3.2.9., 3.2.11. & 3.2.12.)
- ***Against 74,459 inspections of drug manufacturing and selling units required to be conducted by the Drug Inspectors during 1998-2003, only 10,489 inspections were conducted.***

  (Paragraph 3.2.17.)
- ***Samples of drugs awaiting analysis in the Drug Testing Laboratories increased from 615 in March 1999 to 1,679 in March 2003. Delay of one to 23 months in analysing 369 samples resulted in continued sale of sub-standard and spurious drugs.***

  (Paragraphs 3.2.18. & 3.2.19.)
- ***Action against 486 drug offenders was not finalised despite the fact that samples of their drugs were declared substandard, spurious, etc. during 1998-2002.***

  (Paragraph 3.2.20.)

Introduction

Background

3.2.1. At the beginning of the twentieth century, the Drug Industry was practically non-existent in India and pharmaceuticals were being imported from abroad. The First World War changed the scene and not only were the cheaper drugs imported in increasing volume, the demand for indigenous products also started growing. With the call for Swadeshi, manufacturing concerns, both Indian and Foreign, sprang up to produce pharmaceuticals at cheaper rates to compete with imported products. Some of these were of inferior quality and harmful. The Government was, therefore, called upon to take note of the situation and consider the matter of introducing 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. The outbreak of the Second World War in 1939 delayed the introduction of legislation and finally the Drugs Act[*] was passed on 10 April 1940.

At present, the following Acts and Rules made thereunder apart from the Drugs and Cosmetics Act, 1940 govern the manufacture, sale, import, export and clinical research of drugs and cosmetics in India : The Pharmacy Act, 1948; The Drugs and Magic Remedies (Objectionable Advertisement) 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 Essentials Commodities Act). But the main Act continues to be the 'The Drugs and Cosmetics Act, 1940.'

3.2.2. Main features of the Drugs and Cosmetics Act, 1940

- 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 public.
- Punitive measures for dereliction of provisions of the Act.
- Regulate clinical research and publication of Indian Pharmacopoeia.

Scope of Statutory Functions

3.2.3. This is a Central Act and is applicable to the whole of India. The main functions of Central Government are (a) laying down standards of drugs, cosmetics, diagnostics and devices (b) laying down regulatory measures, amendments to Acts and Rules (c) to regulate market authorisation

[*] Drugs Act, 1940 was amended to provide for regulation of the manufacture of cosmetics and prohibition of import and sale of sub-standard and misbranded cosmetics vide Government of India Gazette notification dated 4th December 1961.

of new drugs, clinical research in India, and standards of imported drugs (d) to approve licences to manufacture certain categories of drugs as Central Licence Approving Authority i.e. for Blood Banks, Large Volume Parenterals and Vaccines & Sera (e) work relating to the Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC) (f) testing of drugs by Central Drugs Laboratories (g) publication of Indian Pharmacopoeia, etc.

The main functions of the State Government are (a) licensing of drug manufacturing and sales establishments (b) licensing of drug testing laboratories (c) approval of drug formulations for manufacture (d) monitoring of quality of Drugs & Cosmetics manufactured by respective state units and those marketed in the state (e) investigation and prosecution in respect of contravention of legal provisions (f) administrative actions to regulate the standards of imported drugs (g) pre– and post– licensing inspection and (h) recall of sub-standard drugs.

Scope of Audit

3.2.4. It would be seen from the scope of responsibility that while parameters of control are devised by the Central Government, these are required to be actually implemented by the State Government, excepting areas of standard setting for imported drugs, regulations of clinical research and market authorisation of new drugs. It is in the implementation of the regulatory parameters that derelictions occur particularly in the areas of licensing, approval, monitoring, prosecution, inspection and recall of sub standard/spurious drugs.

Audit examination of the implementation of the Drugs and Cosmetics Act, 1940 adopts these areas of possible dereliction as critical indicators for the level of implementation.

The implementation of Act for the period 1998-2003 was reviewed during November 2002 to March 2003, based on the test check of records of State Drugs Controller, Punjab in the office of the Director, Health and Family Welfare, Punjab (Director), State Drugs Laboratory at Chandigarh and records of Drug Inspectors in six[16] districts keeping in view the critical indicators.

Implementation arrangement

3.2.5. The State Drugs Control Organisation is functioning under the administrative control of the Director who is assisted by three Assistant Drugs Controller at Headquarters and 15 Drug Inspectors at field level working under the administrative control of respective Civil Surgeon. State Drugs Laboratory, Punjab, Chandigarh is under the charge of Government Analyst who is assisted by six Analysts. In respect of Ayurveda, the Director of Ayurveda is the licensing authority who is assisted by a Deputy Director at Headquarters and 14 District Ayurvedic and Unani Officers at field level who have been notified as Drug Inspectors. No separate budget allotment is made as the State Drugs Controller and State Drugs Laboratory work under the overall control of Director.

[16] Amritsar, Ferozepur, Jalandhar, Ludhiana, Patiala and Ropar.

The position of staff sanctioned and in position for the implementation of the Act during 1998-2003 is as under:

Sanctioned strength						In Position					Shortage
Year	Asstt Drugs Controller	Drugs Inspector	Government Analyst	Analyst	Total	Asstt Drugs Controller	Drugs Inspector	Government Analyst	Analyst	Total	
1998-99	3	15	1	6	25	3	6	1	5	15	10
1999-2k	3	15	1	6	25	3	12	1	5	21	4
2000-01	3	15	1	6	25	3	12	--	6	21	4
2001-02	3	15	1	6	25	3	11	1	4	19	6
2002-03	3	15	1	6	25	3	9	1	3	16	9

It would be seen that shortage in the cadre of Drug Inspectors, which are the main constituent of the organisation for implementing the provisions of the Act, ranged between 20 and 60 *per cent* during 1998-2003. No efforts were made to provide sufficient staff for proper implementation of the Act.

Enforcement

Infirmities in the Act/Rules

3.2.6. The following infirmities were noticed during test check of records for which no subordinate legislation were passed by the Government.

- Under Rule 63 of the Rules, if an application for renewal of licence in force is made before its expiry, the licence shall continue to be in force until orders are passed on the application. No time frame has, however, been prescribed in the Act for renewal of licences.
- No time limit has been prescribed in the Act to file the complaint by the department in the court of law with the result action against the offenders get delayed.
- No time limit has been prescribed to analyse drug samples due to which substandard/spurious drugs continue to be sold in the market.

3.2.7. In the test checked districts, 24 cases were decided by the Courts in respect of samples of drugs declared substandard/spurious during 1998-2003; in 14 cases only, the offenders were convicted and in the remaining 10 cases the offenders were acquitted.

Deficiencies in the Licensing procedure

3.2.8. Licences are required for manufacture of drugs and cosmetics for sale, stock or exhibit for sale, distribution, etc. The licence is required to be renewed after two years (five years with effect from 24th August 2001). No survey was conducted for identification of such units as no surveillance unit was established by the State Drugs Controller.

Non-renewal of manufacturing licences

Non-renewal of licences resulted in continued manufacture of drugs after the expiry of their licences

3.2.9. Test check of records revealed that licences of 11 drug manufacturers were not renewed upto May 2003 though their licences were due for renewal in January 2000 and January 2001. In five cases, neither the manufacturers applied for renewals nor department initiated any action against

them. Although the remaining six firms applied for renewal in time, the Drug Inspectors had not inspected the units as of May 2003. There was nothing on record to indicate whether the firms continued to manufacture drugs.

The department contended (January 2003) that inspection for renewal of licences could not be conducted due to shortage of staff.

Delay in renewal of licences

Renewal of licences after expiry of the period upto which licences were applied for

3.2.10. Test check of records revealed that 38 dealers applied in time for renewal of their licences for sale of drugs for the period January 1999 to December 2000 (six cases) and January 2000 to December 2001 (32 cases). The department, however, renewed licences of 37 dealers with delays ranging between four and 23 months after the expiry of the period upto which these were applied for. In one case, licence had not been renewed so far (June 2003).

The department pleaded (January 2003) that licence of a unit who has applied for renewal in time, is treated as valid till its renewal but due to shortage of staff, licences could not be renewed in time. Evidently, these units were not even inspected during the validity period of licences to ensure that conditions for renewal of licence under the Act were fulfilled.

Licences pending renewal

3.2.11. A licence is required to be renewed before its expiry. Out of 19,087 applications received for renewal of wholesale/retail licences by the Drug Inspectors of test checked districts during January 1998 to December 2002, 7,932 licences (42 *per cent*) had not been renewed (February 2003) as detailed below:

7,932 licences awaiting renewal though applications were received during January 1998 to December 2002

Year	Number of applications received	Number of licences renewed	Pending
1998	3610	3390	220
1999	3778	3588	190
2000	3675	3121	554
2001	3998	1021	2977
2002	4026	35	3991
Total	**19087**	**11155**	**7932**

The department stated (February 2003) that licences were pending for renewals for want of some documents from the licencees. The plea was not tenable because it was responsibility of the department to either renew or cancel the licences before the expiry period.

Non-renewal of licences to operate Blood Banks

Ten Blood Banks continued to operate for three to four years without renewal of licences

3.2.12. In eight cases, the licences to operate Blood Banks expired on 31 December 1999 and in two cases on 31 December 2000. Although seven Blood Banks applied for renewal of licences, their licences were not renewed (May 2003). While State Drugs Controller directed (November 2002) one Blood Bank to apply for renewal of licence, no action was initiated against the

remaining two Blood Banks. Thus, ten Blood Banks continued to operate for the last three to four years without a valid licence.

The department admitted (January 2003) the facts and stated that due to shortage of staff, inspections for grant/renewal of licences could not be carried out.

Improper maintenance of licence registers

3.2.13. Licence register is an important record to monitor the number of licences issued/renewed or cancelled pertaining to manufacturers, wholesalers and retail dealers of drugs and cosmetics. The register should normally contain name and address of licencees, number and period of licence granted, particulars of competent person/technical staff, date of renewal/cancellation and licence fee paid.

Licence Registers not maintained properly

It was noticed that registers contained details only about the number of licences issued and the period for which issued but did not contain information regarding date of renewal/cancellation of licences, receipt of licence fees, etc. Thus, due to improper maintenance of licence register, at no time was the department aware of the existing number of units, licences due for renewal/ renewed or cancelled and change of constitution of the firms, if any. The department, thus, failed to monitor licencees operating unauthorisedly after expiry of their licences.

Non-maintenance of receipt records

3.2.14. Licence fee is directly deposited into treasury by the licencees through challans and one copy of the same is attached with the application. These challans were neither entered in any register to verify the correctness of the amount deposited nor reconciled with the treasury. Thus, due to non-maintenance of receipt records, correctness of amounts deposited by various licencees could not be ascertained.

Reconciliation of receipts with the treasuries was not done to verify the correctness of amount deposited

Inadequacy of Samples drawn

Shortfall in drawing of samples

3.2.15. As per Drugs and Cosmetics Rules, 1945 (Rules), a Drugs Inspector was empowered (i) to take samples of any drug and cosmetics, (ii) to send such samples for analysis to Government Analyst and (iii) to launch prosecutions in the court of law against the offenders with the prior approval of the Director. The department has prescribed 15 samples per month to be taken by each Drugs Inspector for big districts, 10 for small districts and seven for the Drugs Inspector holding additional charge of a district.

Shortfall in samples drawn ranged between 10 and 35 *per cent*

Based on these norms, the position of samples in six test checked districts during the period 1998-2003 (upto February 2003) was as follows:

Year	Samples to be taken	Samples actually taken	Shortfall (*Per cent)*
1998-99	1068	691	377 (35%)
1999-2000	1068	693	375 (35%)
2000-2001	1140	971	169 (15%)
2001-2002	1140	1024	116 (10%)
2002-2003 (Upto February 2003)	908	786	122 (13%)
Total	**5324**	**4165**	**1159**

Thus, against 5,324 samples to be taken, 4,165 samples were taken resulting in shortfall of 1,159 samples ranging between 10 and 35 *per cent* during 1998-2003.

The Drug Inspectors attributed (February 2003) the shortfall in taking samples to shortage of staff. The reply is not tenable because targets were fixed by the department keeping in view the availability of Drug Inspectors in the respective districts.

Non-taking of samples of Ayurvedic and Unani Drugs

No sample drawn/tested for Ayurveda and Unani Drugs

3.2.16. No samples of Ayurvedic and Unani Drugs were drawn/got tested by the Director of Ayurveda, Punjab, Chandigarh. The department stated (December 2002) that sample of drugs were not drawn as there was no laboratory for testing of samples of Ayurvedic drugs in the State. This indicated the low priority attached to testing of Ayurvedic and Unani Drugs.

Shortfall in inspection of Units

Against 74,459 inspections required to be conducted, only 10,489 inspections were conducted resulting in shortfall of 63,970 inspections

3.2.17. As per Rules, a Drugs Inspector was required to inspect drug manufacturing and selling units at least twice a year (once a year with effect from 28th September 2001) within the area assigned to him.

In six test-checked districts, against 73,179 inspections required to be conducted by the Drug Inspectors, 10,009 inspections were conducted during 1998–2003 which resulted in shortfall of 63,170 inspections (86 *per cent*).

Similarly, in four districts (Ferozepur, Jalandhar, Ludhiana and Ropar), against 1,280 inspections required to be conducted by the District Ayurvedic and Unani Officers, 480 were conducted resulting in shortfall of 800 inspections (63 *per cent*).

The Drug Inspectors attributed (February 2003) the shortfall to shortage of staff and non-availability of vehicles. The plea is not acceptable because percentage of shortfall of inspections were not commensurate with the shortage in the posts of Drug Inspectors.

Working of Drug Testing Laboratory

3.2.18. Test check of records of Government Analyst, Punjab, Chandigarh revealed that 1,281 samples of drugs received during 1996-97 (291) and 1997-98 (990) were pending for testing in the laboratory as of March 1998. Further, of 9,619 samples received for testing/examination in the laboratory

1,679 samples were still awaiting testing

during 1998-2003, 9,221 samples were analysed and 1,679 samples received during 2001-02 (167) and 2002-03 (1,512) were pending for testing as on March 2003. The number of samples pending for testing increased from 615 as on March 1999 to 1,679 in March 2003 which could result in production of sub-standard and spurious drugs by manufacturing units. No separate laboratory was set-up to accelerate the analysing of drug samples.

The department attributed (March 2003) the delay in testing of samples to non-availability of various chemicals, latest equipment and shortage of staff. It was, however, seen that 50 *per cent* funds remained unutilised during the period 1998-2003.

Testing of samples of drugs

3.2.19. Testing of drug samples in time plays an important role in preventing the manufacture/sale of substandard and spurious drugs.

Continued sale of substandard and spurious drugs due to delay of one month to 23 months in analysing 369 drug samples

Out of 492 drug samples declared sub-standard, spurious etc. during 1998-2003 in the test checked districts, 369 drug samples were analysed late with delays ranging between one month and 23 months (after one month of receipt of samples for analysis in the laboratory).

The department stated (January 2003) that there was no time limit prescribed in the Act for analysing a drug sample and all samples were analysed before their expiry. The reply is not acceptable because delay in analysing and declaring a drug substandard, spurious, etc., results in continued sale of these drugs. Besides, in the absence of any time limit for analysis of a sample in the Act, the objective of preventing the manufacture/sale of sub-standard, spurious drugs till declaration of result, remained unachieved.

Follow up action on samples found sub-standard or spurious

Action against 486 cases of samples of drugs declared sub standard, spurious etc. during 1998-2002 not finalised so far

3.2.20. Of 886 samples of drugs declared substandard (698), spurious (46) and misbranded (142) during April 1998 to March 2003 in the State, 54 samples were of life saving drugs, 182 of antibiotics and 650 of other drugs. Out of 492 drug samples declared sub-standard, spurious and mis-branded (as detailed below in the test checked districts) action against only six cases was taken by issuing simple warnings (four cases) and suspension of permission for manufacturing drugs for 15 days (two cases).

Year	No. of cases			Total	Cases not finalised	Cases finalised	First action delayed
	Substandard Drugs	Spurious Drugs	Misbranded Drugs				
1998	48	-	32	80	79	1	16
1999	79	7	5	91	88	3	30
2000	81	8	20	109	108	1	11
2001	88	6	18	112	112	-	27
2002	86	2	12	100	99	1	6
Total	382	23	87	492	486	6	90

Action against 486 cases, including 23 cases of spurious drugs (life saving 2, antibiotic 8 and others 13) have not been finalised so far despite delay ranging between one and five years. In 90 cases, even the first action to intimate the

licencees of the failure of their sample was taken after a delay ranging between one and 24 months.

Reasons for delay in initiating/finalising action against the defaulters were not furnished.

Seizures and Searches

No records of seizures/raids conducted and results thereof produced to Audit

3.2.21. Seizures and searches in the premises of various manufactures/ sellers of drugs are to be carried out by the Drugs Inspector/Assistant Drugs Controller under Section 22-I (c) with a view to ensuring that the units were not manufacturing/ selling sub-standard/spurious drugs. In response to an audit querry, the department stated that most of the complaints on the basis of which raids are conducted remain in the custody of concerned Drugs Inspector. However, no records regarding receipt of complaints from various quarters and seizures and searchers was produced to Audit. In the absence of relevant records, number of seizures/ raids conducted and results thereof could not be ascertained/ reviewed in audit.

Establishment of Intelligence-cum-Legal cell

3.2.22. In view of the apprehension of availability of sub-standard and spurious drugs in the market, setting up of Intelligence–cum–Legal Cell under the State Drugs Authority is essential to collect information and to keep a check on the quality/standard of drugs. However, no such unit has been set up. Further, no liaison was established with other States/State Vigilance Authorities for monitoring the activities of manufacturers, wholesalers and retailers of spurious drugs.

Training

3.2.23. In order to upgrade the skills of Drug Inspectors, the State Drugs Controller should organise various training programmes. It was, however, noticed (January 2003) that no training programmes were arranged by the department during 1998-2003.

Monitoring

No monitoring for implementation of the provision of the Act done in the State

3.2.24. The various regulatory functions require close monitoring to ensure that the objectives envisaged in the Drugs and Cosmetics Act are achieved. However, no database of manufactures/licences issued, drug control functions and laboratory functions has been developed by the State Drugs Controller, Punjab for use by the department, as part of management information system.

The State Drugs Controller, Punjab stated in (November 2002) that monitoring system has not been established by the department due to shortage of staff.

Conclusion

3.2.25. In Punjab, the Drugs and Cosmetics Act was not implemented effectively. The provisions of the Act regarding inspection of units, drawing/testing/ reporting of samples, speedy and effective action against those manufacturing and marketing sub standard/spurious drugs were not implemented strictly and meticulously. No independent laboratory was set up by the Government for speedy analysis of samples. There was no co-ordination with other States/ State Vigilance Authorities for tracking down the activities of drug offenders.

The matter was referred to Government in April 2003. Reply is awaited (August 2003).

3.3 ACCELERATED IRRIGATION BENEFIT PROGRAMME

IRRIGATION AND POWER DEPARTMENT

Introduction

3.3.1. To accelerate the completion of on-going projects over the next four working seasons (i.e. in two years time), Central Loan Assistance (CLA) was provided to the State Governments by the Government of India (GOI), Ministry of Water Resources (MOWR) from October 1996 under Accelerated Irrigation Benefit Programme (AIBP). Initially, the multipurpose projects, major and medium irrigation projects costing more than Rs 1,000 crore which were in an advanced stage of completion were included. From March 1997, projects costing Rs 500 crore or more were also included. The CLA was to be given in the form of loan on matching basis and was to be released quarterly. From March 1997, the CLA was to be released in two equal instalments and second instalment was to be released only after the State Government had released the matching contribution against the first instalment. From March 1999, the funds were to be provided in ratio of 2:1 (Centre **:** State).

In Punjab State, following five projects were covered under AIBP:

- Ranjit Sagar Dam Project (RSDP)
- Shahpur Kandi Dam Project (SKDP)
- Remodelling of Upper Bari Doab Canal (UBDC) System
- Irrigation to Himachal Pradesh area below Talwara
- Kandi Canal Project–Stage II