3.2 Implementation of Drugs and Cosmetics Act, 1940

Highlights

The Drugs and Cosmetics Act 1940 (Act) is a Central Act to be implemented by all the States. The Act along with the other associated Acts and the rules made thereunder regulate the import, manufacture, distribution, sale and clinical research of drugs and cosmetics.

The Act was not implemented effectively in the State. The Drug Controller's office did not have master control registers indicating the numbers of manufacturing/selling units, the validity period of licenses, the dates of inspections, dates of collection of samples, the reports of testing laboratory etc. Licenses to manufacturing and selling units were not renewed periodically. There was huge shortfall in the survey and inspection of sick and manufacturing units. Inordinate delay was observed in the testing of drugs and consequential action against the manufacturers/sellers of sub-standard drugs. There was lack of adequate infrastructure facilities for quality testing of samples collected. Price control mechanism was not in vogue. The possibility of manufacture and sale of sub-standard drugs and cosmetics could not be ruled out and the intended objective of making available essential life saving drugs at fair prices to masses was not realised.

The Controller of Drugs did not have a master control register which would indicate the actual status of manufacturing/selling units of the State and licenses to manufacturing/selling units were not periodically renewed, though required.

(Paragraph 3.2.5)

Targets for inspection of selling/manufacturing units in the State fell short by 59 to 68 per cent during 1998-2003. In 25 districts, inspections carried out by 34 Drug Inspectors fell short by 79 to 86 per cent.

(Paragraph 3.2.6)

Samples collected fell short of targets by 96 to 97 per cent. Only 75 per cent of samples of drugs collected during 1998-2003 by the State Drug Control Laboratory, Patna were tested. Government Analyst attributed the shortfall to inadequate infrastructure such as chemical, power supply, testing equipment and manpower.

(Paragraph 3.2.7)

The Controller of Drugs did not initiate punitive and deterrent action in respect of 122 cases of sub-standard drugs reported by five Regional Licensing Authorities during 1998-2003.

(Paragraph 3.2.8)

Interface of State Drug Regulatory Authority with pharmaceutical industry/trade, consumers and medical professionals was non-existent. This adversely affected dissemination of information and feed back on the functioning of enforcement authorities.

(Paragraph 3.2.9)

No intelligence branch was set up for keeping a watch on illegal manufacture of drugs and its trade activities. No training was imparted to Drug Inspectors to tone up enforcement of the Act.

(Paragraph 3.2.10)

Controller of Drugs stated that there was no price control mechanism in vogue in the State.

(Paragraph 3.2.11)

There was lack of monitoring and evaluation mechanism to ensure effective implementation of the provisions of the Drugs and Cosmetics Act, 1940.

(Paragraph 3.2.13)

3.2.1 Introduction

At the beginning of the twentieth century, pharmaceuticals were being imported from abroad. After the First World War manufacturing concerns, both Indian and Foreign, sprang up to produce pharmaceuticals at cheaper rates to compete with imported products. Some of these products were of inferior quality and harmful. Government, therefore, decided to introduce legislation to control the manufacture, distribution and sale of drugs and medicines. A Select Committee appointed by the Central Legislative Assembly in 1937 recommended various measures, providing for the uniform control of manufacture and distribution of drugs as well as of import and finally the Drugs Act[1] was enacted on 10 April 1940.

At present, the Acts and Rules, apart from the Drugs and Cosmetics Act, 1940, which govern the manufacture, sale, import, export and clinical research of drugs and cosmetics in India are : The Pharmacy Act, 1948; The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954; The Narcotics Drugs and Psychotropic Substances Act, 1985; The Medicinal and Toilet Preparations (Excise Duties) Act, 1956; The Drugs (Prices Control) Order 1995 (Under the Essential Commodities Act). The Drugs (Prices) Control Order 1995 introduced by Government of India under the Essential Commodities Act, 1955 aimed at making available essential life saving drugs at fair and affordable prices to the masses. There was no separate legislation of the State in this regard. However, 'The Drugs and Cosmetics Act, 1940' continues to be the main Act.

Main features of the Act

- To ensure standards of Drugs and Cosmetics, Diagnostics and Devices.
- To monitor the quality of drugs and medicines imported, manufactured, distributed and sold.

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

- ❖ To take punitive measures for violations of provisions of the Act.
- ❖ To 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 and selling units, (b) licensing of drug testing laboratories, (c) approval of drug formulations for manufacture, (d) monitoring of quality of Drugs and Cosmetics manufactured, through periodical inspection of manufacturing and selling units and collection of samples for independent testing (e) investigation and prosecution in respect of contravention of legal provisions, (f) regulation of the standards of imported drugs and (g) recall of sub-standard drugs.

The Drugs and Cosmetics Act, 1940 formulated by Government of India supplemented the Dangerous Drugs Act, 1930 followed by Drugs and Cosmetics Rules, 1945. The Act aimed at preventing manufacture and supply of sub-standard drugs and cosmetics.

3.2.2 Implementing Agencies : Implementation arrangement

Commissioner–cum–Secretary to Government, Health, Medical Education and Family Welfare Department has the overall responsibility of regulating manufacture, sale and distribution of drugs in Bihar. He is assisted by the Controller of Drugs (DC) and his subordinate officers viz. a Deputy Drug Controller and an Assistant Drug Controller. The Controller of Drugs is the Chief Licensing Authority for grant and renewal of licenses for manufacture of drugs for sale. Drug Inspectors (DI) have been appointed (since July 1994) as Regional Licensing Authority at divisional level to grant licenses for sale, stock and distribution. At the district level, Drug Inspectors are responsible for inspecting manufacturing and selling units, collecting samples for test and reporting to the regional and State headquarters.

Implementation of the Drugs and Cosmetics Act, 1940 and rules framed there under in the State during 1998-2003 was reviewed in audit between January and May 2003 through a test-check of the records of the Controller of Drugs (Chief Licensing Authority), Patna, eight Regional Licensing Authorities[2] and Drug Control Laboratory, Patna.

[2] *Bhagalpur, Chapra, Darbhanga, Gaya, Muzaffarpur, Patna, Purnea and Saharsa*

3.2.3 Provision of funds

Of Rs 16.47 crore provided during 1998-2003 for administration of Drug and Cosmetic Act and Rules, Rs 6.63 crore (40 per cent) remained unutilised as shown in the table below :

40 per cent of funds remained unutilised

Year	Budget Provision	Expenditure	Excess (+)/ Savings(-)
	(Rupees in lakh)		
1998-99	310.91	228.44	(-) 82.47
1999-00	659.69	299.92	(-) 359.77
2000-01	251.54	194.11	(-) 57.43
2001-02	234.28	152.46	(-) 81.82
2002-03	190.21	108.31	(-) 81.90
Total	**1646.63**	**983.30**	**(-) 663.39**

It was noticed that savings occurred against both the plan and non-plan items under the head 2210- Public Health Drug Control. No reason for huge savings year after year was on record. The DC did not obtain information of receipt and expenditure from any regional field offices and the Government Analyst (GA).

3.2.4 Inadequacies in the Act

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. 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 Rules by making a provision for filing of renewal application three months 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.

No time frame for testing of the samples

The Act does not provide any time frame for testing of the samples of the drugs/cosmetics collected during inspections of the manufacturing/selling units. As a result, 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.

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. No time frame has also 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 get delayed.

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.

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.

3.2.5 Licenses

Master control register non- existent

The DC did not have a master control register, indicating the number of operational and functioning manufacturing and selling units of the State, the number of units which have been inspected by the Drug Inspectors and number of units, where inspections are due etc. It would therefore appear that the internal control system in the department was deficient.

In the absence of data at the State level, audit collected information of manufacturing and selling units from the Regional and District Offices. The licenses were valid for two calendar years and they were to be renewed every two years. From August 2001, the tenure of licenses was fixed for five years from the date of issue.

The number of manufacturing units of drugs, their licenses due for renewal and licenses renewed during 1999-2003 was as under :

(In number)

Year	Issuance of licenses			Renewal of licenses		
	OB units	Licenses issued during the year	Total units at the end of the year	License due for renewal	Licenses renewed	Shortfall
1999-2000	604	96	700	308	300	8
2000-2001	700	83	783	331	300	31
2001-2002	783	39	822	396	239	157
2002-2003	822	29	851	282	261	21

Of the total 851 manufacturing units as of March 2003, licenses of 21 manufacturing units were not renewed. As there was no report on closure of 21 units whose licenses were not renewed during 1999-2003, operation of these units without license and possibility of manufacture of spurious/fake/adulterated drugs by those units could not be ruled out.

DIs in the regions were functioning as licensing authority for selling units

Prior to July 1994 the authority for issuing licenses for sale, stock and distribution of drugs was vested in the Civil Surgeons-cum-Chief Medical Officers of the districts concerned. From July 1994 this power was vested in the Regional Licensing Authorities. However, there was no post of Regional Licensing Authority as of March 2003. As a result the DIs in the regions and the districts had to function as licensing authority of selling units.

Inadequate renewal of licenses of selling units

The number of selling units of drugs, their licenses due for renewal and licenses renewed during 1998-2003 was as under :

(In number)

Year	Issuance of license			Renewal of license		
	OB units	License issued during the year	Total units at the end of the year	Licenses due for renewal	Licenses renewed	Shortfall
1998-1999	21972	2429	24401	11655	10079	1576
1999-2000	24401	2768	27169	11893	9534	2359
2000-2001	27169	1283	28452	12508	10737	1771
2001-2002	28452	2572	31024	12302	9144	3158
2002-2003	31024	388	31412	10916	4839	6077

Of 31412 selling units as of March 2003, licenses of 6077 selling units were not renewed. The continuance of these units without renewal of licenses could not be ruled out as no verification is done in respect of those units, which do not submit application for renewal.

3.2.6 Survey and inspections

The target of inspections fell short by 59 to 68 per cent of the norm prescribed in the State

The Drugs and Cosmetics Rules, 1945 provide that inspection of each selling/manufacturing unit should be conducted at least once a year. Scrutiny revealed that the Government fixed a target of 20 inspections per month for each DI though they were fully aware that with this target, the provision of the Act in respect annual inspection of each manufacturing / selling units would not be fulfilled. Accordingly 43 DIs in the State had a target of 10,320 inspections in a year against the requirement of 25000 to 32000 inspections annually during 1998-2003. Thus, the target fixed during 1998-2003 fell short by 59 to 68 per cent of the manufacturing and selling units in the State as indicated below:

Year	Selling units due for inspection	Manufacturing units due for inspection	Total units due for inspection	Target of inspection fixed by the State	Shortfall	Per cent
1998-1999	24401	604	25005	10320	14685	59
1999-2000	27169	700	27869	10320	17549	63
2000-2001	28452	783	29235	10320	18915	65
2001-2002	31024	822	31846	10320	21526	68
2002-2003	31412	851	32263	10320	21943	68

During 2000-2003 performance of 34 DIs in 25 districts test-checked was as under:

Year	Total units due for inspection in 25 districts	Number of inspections conducted	Shortfall	Per cent
2000	22036	3028	19008	86
2001	23116	4805	18311	79
2002	25180	5402	19778	79
	70332	**13235**	**57097**	**81**

81 per cent shortfall in conducting inspections in 25 districts test-checked

Thus, against 70332 units due for inspections in 2000-02, number of inspections conducted by 34 DIs was 13235 only. As a result, there was a shortfall of 81 per cent in inspection of the manufacturing/selling units in 25 districts. As such, nearly four-fifth (80 per cent) manufacturing/selling units were allowed to carry on operations without any inspections. No reason for shortfall in conducting inspections was available.

Records of inspections prescribed not maintained

As per rules, the inspection books in prescribed form obtained from the licensing authority were to be kept by the manufacturer and sellers of the drugs. The observations of the DIs were to be recorded in the prescribed format in triplicate. The original copy was to be retained in the inspection book. The duplicate copy was to be sent to licensing authority, while the triplicate copy was to be taken as record by the DI. However, the DIs did not record inspection notes in the prescribed format. Though the inspection notes otherwise recorded were available with the DIs, copies thereof were neither available with the manufacturers/sellers nor with the licensing authorities i.e. the Controller of Drugs in all the cases of records of 34 DIs test-checked. As a result reliability of inspections carried out was doubtful.

3.2.7 Collection of samples and testing of drugs

Collection of samples and their analysis by 34 DIs in 25 districts test-checked were as under :

Year	Total units due for sample collection *	Number of samples collected	Shortfall	Analysis
2000	22036	589	21447(97)	389 (66)
2001	23116	845	22271(96)	599 (71)
2002	25180	1125	24055(96)	318 (28)
	70332	**2559**	**67793(96)**	**1306 (51)**

* @ one sample per inspection of each unit (Figures in brackets indicate per cent)

Collection of samples fell short of targets and samples collected only partially analysed

Samples collected fell short by 96 per cent and only 51 per cent of the samples collected were analysed. It would therefore appear that even one sample of nearly 95 per cent manufacturing and selling units were not tested by the DIs in the districts. Hence there was virtually no enforcement of the Act in the state. Poor collection of sample was attributed by the DIs concerned to lack of funds for payment of cost of samples to the selling units. The reasons advanced were not tenable as huge funds remained unutilised every year during 1998-03. Poor analysis of samples collected was attributed by the Government analyst to lack of chemicals and erratic power supply.

Samples not collected from hospitals and blood banks

The Act provided that samples of drugs were to be collected by the DIs from government hospitals, institutions, blood banks etc. for quality testing. However, no sample was collected by them during 1998-2003. Thus, in a state with a large population of eight crore, not a single blood sample was tested in five years. As a result, the quality of the blood being supplied by the blood banks in the state could not be verified.

Quality of drugs/cosmetics manufactured not assured

As required under Rule 150 B of the Drugs and Cosmetics Rule, 1945 every manufacturing unit was to test quality, purity and strength of drugs or cosmetics or the raw materials used in their manufacture by its own agency or any outside agency with the approval of the Drug Controller. However, none of the manufacturing units in the State sought approval of the DC during 1998-2003 for quality testing of drugs and cosmetics manufactured. Thus, quality of drugs and cosmetics manufactured by the units could not be assured.

Information of samples tested by Laboratories at Kolkata and Ghaziabad not available

Samples of drugs and cosmetics collected and received were to be analysed/tested at State Drug Control Laboratory, Patna, Central Drug Control Laboratory, Kolkata and Central Institute of Pharmacopial Laboratory, Ghaziabad. Samples for testing and reporting from Kolkata and Ghaziabad were paid for by the DC. The information regarding number of samples tested by the laboratories of Kolkata and Gaziabad and fee paid to them was not furnished.

Only 75 percent of samples of drugs collected were tested by State Drug Control Laboratory, Patna

Scrutiny revealed that only 75 per cent (3247) of samples collected (4352) during 1998-2003 were tested by the State Drug Control Laboratory, Patna, while eleven per cent of the samples of drugs tested were declared sub-standard.

Year	Total Manufacturing/ Selling units	Previous balance of samples	Samples received for analysis	Samples analysed	Samples not analysed	Drugs declared sub standard
1997-98	NA*	Nil	408	269	139	50
1998-99	25005	139	581	476	244	79
1999-00	27869	244	402	417	229	66
2000-01	29235	229	822	559	492	78
2001-02	31846	492	732	632	592	37
2002-03	32263	592	1407	894	1105	42
Total	**146218**		**4352**	**3247**		**352**

*NA- not available

It would therefore be evident that only 2978 samples were tested and analysed during 1998-2003 against the requirement of testing of 146218 samples @ one sample per unit per year. *Thus, there was hardly any enforcement of the provisions of the Act in the state.*

Further, details of sub-standard drugs being adulterated, spurious and fake was not on record. Shortfall in testing and reporting of samples was attributed by the GA to inadequate infrastructure such as chemicals, power supply, testing equipment and manpower. As regards Ayurvedic and Homeopathic system of medicine, drug testing facility was not available in the State. Besides, there was no time limit for analysing the samples.

3.2.8 Prosecution

No punitive/deterrent action on reporting of sub-standard drugs

As a token of supervisory control, the DC was required to initiate action against the drug offenders on the reports of the DIs. However, the DC did not initiate punitive and deterrent action on 122 cases of sub-standard drugs reported by five Regional Licensing Authorities during 1998-2003.

Status of prosecution cases under four Regional Offices was as under :

(In number)

Year	Prosecution cases (opening balance)	Prosecution cases launched during the year	Total prosecution cases	Conviction	Cases pending at the end of the year
1998-99	10	-	10	-	10
1999-00	10	2	12	-	12
2000-01	12	19	31	-	31
2001-02	31	17	48	12	36
2002-03	36	17	53	-	53

NB : Four other Regional Offices test-checked did not give information.

Pending prosecution cases

During 1998-99 to 2002-03, 65 prosecution cases were initiated by the DIs of four Regional Licensing Authorities (Patna, Muzaffarpur, Darbhanga and Bhagalpur). Against this, 12 sellers of drugs of Muzaffarpur region who violated the provisions of the Drug and Cosmetics Act were convicted by the courts of law. However, decisions of the courts of law on remaining 53 prosecution cases were awaited (May 2003).

Surprise raids on manufacturing and selling units not conducted

Although the post of flying squad DI was created and filled in at the State level to conduct surprise raids on manufacturing and selling units, the incumbent did not conduct surprise raids but functioned as Regional Licensing Authority at Patna. However, it was noticed that in 9 districts[3] altogether 35 seizures of drugs and equipment were made by 12 Drug Inspectors for breach of the Act and the rules thereunder.

3.2.9 Interface with regulatory authority

No interface with the Pharmaceutical industry, the consumers and medical professionals

Interface of the State drug regulatory authority, with the pharmaceutical industry/trade, consumers and medical professionals was not on record. This adversely affected dissemination of information and feedback on the functioning of the enforcement authorities.

3.2.10 Intelligence and training

No intelligence branch and no training facility for officials

No intelligence branch was set up by the Drug Control Administration for keeping a watch on the illegal manufacturer of drug and trade activities. No training had been imparted to the DIs and other officials of the Drug Control Administration in matters concerning development of intelligence, detection,

[3] *Betia, Chapra, Motihari, Madhubani, Muzaffarpur, Patna, Samastipur, Siwan and Sitamarhi*

investigation, preparation and filing of complaints and court procedure etc. which could have been useful for achieving efficient control measures.

3.2.11 Price control mechanism

Price control mechanism not in vogue

DC stated (April 2003) that there was no price control mechanism in vogue in the State. He also stated that DIs of the districts concerned were delegated to enforce the Drugs (Price Control) Order'1995 as prescribed by the Government of India. However, only one DI detected (March-April 2003) seven cases of overpricing of medicines. Those cases were reported by the DI, Patna to the DC (April 2003), but no action was taken as of June 2003.

3.2.12 Manpower management

The number of staff sanctioned and men-in-position for administration of Drug Control in Bihar was as detailed below:

Shortage of required numbers of officials

Name of post	Sanctioned strength	Men-in-position
Drugs Inspector	221	43
Asstt. Drug Controller	One	One
Dy. Drug Controller	One	One
State Drug Controller	One	One

There was no post of DI for Homeopathy and Unani system of medicines.

Posts created without consulting Finance Department

The Department created 184 posts of DIs in 1991-92 without the approval of the Finance Department though required as per the Recruitment Rules for the DIs.

3.2.13 Monitoring and evaluation

Schedule of inspections for field visits by Supervisory officials was not drawn

As a token of administrative control, schedule of inspections prescribing minimum number of field visits for each supervisory level functionary was to be drawn up by the DC for effective implementation of the provisions of Drugs and Cosmetics Act. No such schedule of inspections was prescribed by the authority concerned. The implementation of the Act and Rules was not evaluated by the Government or any other outside agency. Thus there was lack of monitoring and evaluation mechanism to ensure effective implementation of the Drugs and Cosmetics Act, 1940 and Rules framed there under.

3.2.14 Conclusions

The Drugs and Cosmetics Act was implemented in lackadaisical manner. The manpower available with the DC was quite inadequate to carry out the inspection of selling and manufacturing units in a large State. The inspections conducted by the DIs were negligible in comparison to the requirements under the Act. Further, the samples were also not collected during inspections in large number of cases. Even follow up on the drug samples collected was poor. Prosecution cases launched and those convicted under the Act was insignificant to have any impact. Thus, in nutshell, there was hardly any enforcement of the provisions of the Act in the state of Bihar.

3.2.15 Recommendations

- ❖ The Act needs to be amended to prescribe the time schedule for disposal of renewal applications by DC also.
- ❖ 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 minimize the number of litigants.
- ❖ Deterrent penalty should be provided in the Act for manufacture or sale of adulterated/ spurious or misbranded drugs irrespective of their intensity.
- ❖ The Drug samples collected need to be tested and analysed within a tight time frame, giving full details of the case so that prosecution cases under the Act can be launched effectively.
- ❖ Prosecution cases need to be followed up effectively by the department.
- ❖ The price control mechanism is non-existent in the State. This needs to be strengthened to protect the interests of the consumers.

The points were referred to Government (August 2003); their reply had not been received (March 2004).

WELFARE DEPARTMENT

3.3 Welfare of handicapped

Highlights

Welfare of Handicapped is a complex social issue involving coordination of curative, promotional and rehabilitational activities directed at different forms of handicap and a multitude of measures. Further, the definition of handicapped for the purpose of coverage is so widely dispersed over such a large area of disabilities that no single focus emerges automatically from the disparate efforts undertaken by different agencies entrusted with the delivery of programme objectives. Welfare activities for the handicapped are governed by the provisions of Persons with Disabilities (Equal opportunities, Protection of rights and Full participation) Act, 1995 and Mental Retardation and Multiple Disabilities Act, 1999 . These Acts aimed to bring people suffering from different kinds of disabilities into the main stream of social life.

The review revealed that various provisions of the Acts remained unimplemented during 1998-03 and the schemes taken up suffered from mismanagement emanating from lack of co-ordination and supervision. As a result, a major chunk of GOI funds remained unutilised and the performance of the schemes was either nil or negligible. Thus the welfare of the handicapped remained neglected.