HEALTH AND FAMILY WELFARE DEPARTMENT

3.2 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 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, the consumers were prone to serious health hazards.

Forty two cases were instituted by the Government during 1998-2003 for violation of Drugs and Cosmetics Act and Rules. Decisions of three cases went against the Government and only in one case, the accused was punished. Decisions in the remaining 38 cases were awaited. Of the sixty writ petitions filed against the Government during 1998-2002, the decisions of seven cases went against the Government while Government won only one case, details of the remaining 52 cases were not on record.

(Paragraph 3.2.3)

In Kolkata and five test-checked districts, 3488 manufacturing/selling units were operating without licence, which also led to loss of revenue of Rs 1.01 crore. No penal measures were initiated against the defaulters. Against 21837 applications received with fees during 1998-2001 for renewal of licence in Kolkata and five test-checked districts, only 347 renewal certificates were issued after conducting 3158 inspections.

(Paragraph 3.2.4)

In five test-checked districts, the percentage of shortfall in sampling of drugs ranged between 48 and 92 during 1998-2003 despite adequacy of funds for sampling. Inspection of only 4324 (5 *per cent*) of the 0.92 lakh licensed establishments could be conducted.

(Paragraph 3.2.5)

In violation of rules, 3094 reports were not issued in prescribed form by the State Drug Control and Research Laboratory against 6621 samples tested. Forty reports inclusive of 25 Not of Standard Quality (NSQ) reports were issued after the date of expiry of the tested medicines.

(Paragraph 3.2.6)

Several incidents of toxicity and death occurred at School of Tropical Medicine, Kolkata, Barasat District Hospital, Hooghly District Hospital and RG Kar Medical College and Hospital, Kolkata after administration of NSQ drugs. Sub-Standard drugs valuing Rs 78.85 lakh were consumed in absence of prompt and effective monitoring system.

(Paragraph 3.2.7)

Central Medical Store, Kolkata returned drugs (worth Rs 28.70 lakh) found NSQ after test to 41 suppliers during 1998-2003, but Director of Drugs Control neither seized those drugs nor initiated any penal measure against the suppliers.

(Paragraph 3.2.8)

[·] *The abbreviations used in this review have been listed in the Glossary in Appendix42 (page)*

Director, Drug Control did not take any action against 99 firms producing NSQ drugs facilitating unabated production of such drugs. Of the 378 complaints received during November 1999 to December 2002 action against 66 cases and enquiry report for 82 cases were awaited. Only 27 raids were conducted by the Director, Drug Control, during 2000-2002. No raids were conducted at all during 1998-2000.

(Paragraph 3.2.9)

The Drugs (Price Control) Order 1995 was not implemented in the State prior to 2002. There was no mechanism to check overpricing of drugs in the district offices test-checked.

(Paragraph 3.2.10)

In three test-checked districts 108 licensed shops were running without whole-time pharmacists in contravention of the Rules.

(Paragraph 3.2.12)

No action was initiated for wide publicity of the 69 categories of drugs banned by GOI to ensure non marketing/consumption of the same.

(Paragraph 3.2.13)

3.2.1 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; 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.

In West Bengal Sections 19, 27 and 32 of the D & C Act were amended to the extent that (i) the burden of proving the quality of drug would be on the person from whom the drug is seized, (ii) make the term of punishment as life imprisonment and (iii) make all offences under the Act as cognizable and non-bailable.

Main features of the Act

To ensure standards of Drugs and Cosmetics, Diagnostics and Devices.

To monitor quality of drugs and medicines imported, manufactured, distributed and sold.

To take punitive measures for dereliction 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/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.

A review on the implementation of Drugs and Cosmetics Act, 1940 and other related Acts and Rules thereunder was conducted by test check of the records for the period 1998-2003 of Health and Family Welfare (H&FW) Department, Director of Drug Control (DDC), West Bengal, State Drug Control and Research Laboratory (SDCRL), two (Bankura and Murshidabad) out of four regional divisions and five (Medinipur, Bankura, Murshidabad, Birbhum and Malda) out of 16 district drug offices covering a population of 2.50 crore (31 *per cent*) between January and May 2003. Results of test check are brought out in succeeding paragraphs.

3.2.2 Implementing Agencies: implementation arrangement

Secretary, H&FW Department is the administrative head. Director of Drug Control (DDC) West Bengal being the Licensing Authority and Controlling Authority (LACA) is responsible for implementation of the Act at the state level. DDC issues licences to all manufacturing units in the State and to retailers/wholesalers of drugs of Kolkata, Howrah and South 24-Parganas. Issue and renewal of licences to the wholesalers/retailers of other 16 districts are controlled by four divisional offices each headed by Deputy Director of Drugs Control (DDDC) who is assisted by 16 Assistant Directors of Drugs Control (ADDC). The State Drug Control and Research Laboratory (SDCRL) is the statutory laboratory in the State for testing of drugs and cosmetic samples.

3.2.3 Statistics of Prosecutions vis-à-vis cases filed

Infirmities in the Act/Rule for prosecution:

The following infirmities in the Act/Rule for prosecution were noticed:

Under Section 27A(i) whoever manufactures for sale or for distribution or sells or stocks or exhibits or offers for sale any cosmetic deemed to be spurious under section 17C shall be punishable with imprisonment for a term

which may extend to three years and with fine. But spurious cosmetics have been defined under Section 17D and not under Section 17C which deals with misbranded cosmetics.

Rule 46

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.

Rule 64

No clear-cut conditions were specified under drugs and cosmetics rules for storage of medicines and bulk drugs as indicated in labels (schedule P Rule 96) by the retailer/wholesaler/manufacturer.

No mention was made in D&C Act and Rules in respect of preservation of drugs stored (to be preserved in cold condition) for short spells (during transportation) resulting in violation of conditions of licence regarding preservation of properties of drugs as per Section 18C read with Rule 64.

There was no provision in the Act and Rules regarding drug licence to be obtained by the pathological laboratories for storage of blood.

Drawal of samples from consignments of imported drugs depends on the discretion of the Customs Collector (Rule 40).

Rule 72

The lacuna in the rule, that the licensee after submission of renewal application can continue to operate, on the strength of original licence, even after expiry of the licence until orders are passed on the application by the licencing authority, should be removed.

Poor progress in prosecution

It was noticed from the Case Register maintained by DDC that 60 Writ Petitions were filed in the Hon'ble High Court, Kolkata against the State Government during 1998-2002. In none of the cases, provisions of the law challenged by parties were on record. The nature of petitions for 32 cases was not on record and that for the remaining 28 cases was as follows:

Nature of petition	Number of cases filed
Inspection of selling premises	1
Selling of food supplements in chemist shop	14
Marketing of product	1
Unlicenced godown	1
Enhanced licence fee	1
Additional endorsement of products	1
Renewal of licence	1
Suspension of drug licence	1
Cancellation of drug licence	1
Grant of licence	6
	28

Of the 60 cases, the Hon'ble High Court passed orders for eight cases, of which seven orders went against the Government and in only one case the judgment was in favour of the Government. DDC did not furnish the reasons for defeat in seven out of eight cases. Details of the other 52 cases were not on record.

Scrutiny of Case Register revealed that 42 cases were instituted by the Government against firms for violation of D&C Act and Rules during 1998-2003. The details of the cases with full particulars were not on record due to non-receipt of information from the inspectors and non-maintenance of any centralised register as required to monitor the cases. Out of 42 cases, only four cases were disposed of. In three cases the accused were discharged by the Court while in one case the accused was fined and imprisoned. Decisions of 38 cases were awaited as of August 2003. The reasons for failure on the part of DDC to prosecute in three cases (75 *per cent*) as well as reasons for delay in finalisation of the cases were not stated though called for (August 2003).

3.2.4 Implementation of the Act : Survey and licensing procedures

Test-check of records of implementation of the Act disclosed deficiencies like non-renewal of drug licences and loss of revenue, poor coverage of sampling and inspection, adverse reaction on consumption of NSQ drugs, etc. as discussed below:

Loss of revenue due to non-renewal of licences

D&C Act envisages that all the manufacturers and dealers of drugs are required to obtain drug licences with validity period of two years (five years from the date of issue from August 2001) on payment of prescribed fees.

Non-renewal of licences – loss of revenue – Rs 1.01 crore

In test-checked units, out of 13856 eligible units only 10368 units had applied for renewal of licence up to June 2002. Thus there was a possibility of 3488 units running without renewal of licence in contravention of the statutory provisions of the Act. This not only led to loss of revenue of Rs 1.01 crore but also left scope of selling NSQ drugs, banned/expired drugs, non-observance of proper storage facility conditions and running of shops without pharmacists. The defaulting licensees were subject to penal action namely imprisonment and imposition of fines as envisaged in section 27(b) (ii).

Non-issue of Renewal Certificates (RC)

During 1998-2001, number of applications received for Renewal Certificates (RC), number of RC issued thereagainst is indicated below:

Name of the district	Number of applications received for renewal of license	Number of inspections conducted for renewal	Number of RC issued
Bankura	2206	566	9
Birbhum	2573	444	3
Malda	2032	129[4]	26
Medinipur	8707	1483	80
Murshidabad	4458	460	45
Headquarter			
Modern Medicine	1095	N.A.	165
Cosmetics	570	N.A.	2
Blood Banks	196	76	17
Total	**21837**	**3158**	**347**

Source: Application Register

[4] *only for 2001*

Only 347 renewal certificates were issued against 21837 applications

During 1998-2001 against 21837 applications 3158 inspections were conducted and only 347 RC were issued, while 2811 units failed to comply with requisite conditions.

Thus, Government allowed 2811 trading/manufacturing units to run their business by depositing licence fees only without ensuring fulfilment of the essential conditions of licence. The department also failed to conduct 18679 inspections and issue renewal certificates thereon.

3.2.5 Sampling and Inspection

Dismal performance in sampling

Despite adequacy of fund shortfall in sampling ranged between 48 and 92 *per cent*

Sampling of drugs (Rule 52) for getting them tested is a key function of inspectors to ensure supply of standard drugs to consumers. As per instruction of the DDC each inspector was required to draw 10 samples per month each belonging to a different batch. During 1998-2003 (upto September 2003) against 38880 drug samples required to be drawn in the state by 72 inspectors, only 8236 samples were drawn indicating a shortfall of 79 *per cent*. During 1998-2003 shortfall in sampling ranged between 48 and 92 *per cent* in five test-checked districts as shown below:

Name of the district	Number of inspectors during 1998-2003	Number of samples to be drawn	Number of samples drawn from			Percentage of shortfall
			District Reserve Stores	Urban market	Rural market	
Bankura	2 to 3	1500	151	24	Nil	88
Birbhum	1 to 3	1320	81	21	Nil	92
Malda	1 to 2	360	38	35	Nil	80
Medinipur	3 to 6	2820	1104	66	Nil	59
Murshidabad[5]	2	720	225	149	Nil	48
		6720	**1599**	**295**		**72**

Such poor performance in sampling left ample scope of consumption and use of sub-standard/spurious drugs and cosmetics by consumers.

Samples were not drawn for testing in respect of sera, vaccine and cosmetics. No sampling was done from interiors of districts and manufacturing premises.

Samples were also not drawn from Medical College Hospitals[6] to ensure use of safe medicines though medicines valuing Rs 19.10 crore were procured by these hospitals during 1998-2002.

DDC stated that non-availability of vehicles and fund for stationery items, cost of sending samples, shortage of locker/malkhana were the reasons for such dismal performance.

The reply was not tenable as against Rs 29.63 lakh available during 1998-2003 only Rs 2.06 lakh were spent for sampling of which Rs 0.37 lakh was diverted for other purposes.

[5] *Records for last three years available*

[6]

	Year	*Value of medicines procured (Rupees in lakh)*
Bardhaman Medical College and Hospital	*1998-2002*	*673.22*
Medical College and Hospital, Kolkata	*1998-2002*	*694.69*
NRS Medical College and Hospital	*1998-1999*	*110.81*
North Bengal Medical College and Hospital	*1998-2002*	*431.73*

Poor coverage in inspection of licensed units

Each Inspector was to inspect all establishments licensed for manufacture/sale of drugs within the area assigned to him not less than twice (once from September 2001) in a year.

In the test-checked districts the performance of the Inspectors during 1998-2003 was very poor as shown below:

Only 5 *per cent* licensed establishments of the test-checked districts were inspected

Name of the district	Number of inspectors	Number of inspections to be done	Number of inspections actually done	Percentage of shortfall
Bankura	2 to 3	9896	756	92
Birbhum	1 to 3	16507	542	97
Malda	1 to 2	5824	198	97
Medinipur	3 to 6	46364	1733	96
Murshidabad	2	13890	1095	92
		92481	**4324**	

ADDCs and DDC attributed the shortfall to shortage of Inspectors, non-availability of vehicles and insufficient fund for travelling allowance, etc.

In West Bengal 51 *per cent* of the sanctioned posts of Drug Inspectors remained vacant though Inspectors were the key functionaries to implement the D&C Act. Non-providing of such key functionaries indicated that Government was indifferent towards implementation of the Act.

The Headquarters office, Kolkata did not maintain any centralised inspection register showing the date of inspection, name of the units covered, date of issue of inspection reports, major findings, receipt of compliance reports from the manufacturing/selling units and important areas to be covered in next inspection indicating lack of State-level monitoring.

3.2.6 Working of Drug Testing Laboratories

On receipt of a sample of any drugs/cosmetics from an inspector, the Government analyst of the SDCRL was to analyse/test the sample expeditiously and furnish the report forthwith in accordance with the rules.

The performance of the SDCRL in terms of statutory samples received, samples tested, reports sent thereagainst etc. during 1998-2003 (September 2002) as per Sample Register of SDCRL was as under:

Year	Number of samples received	Number of samples tested	Number of samples not tested	Reports sent beyond 45 days but within a year	Reports sent after one year		Reports sent after date of expiry		Number. of 'no opinion' reports	No. of reports not furnished in prescribed form (Form 13)		No. of NSQ samples
					SQ	NSQ	SQ	NSQ		SQ	NSQ	
1998-1999	2045	1721	324	1448	21	3	12	12	2	332	23	102
1999-2000	1852	1535	307	1000	36	3	0	6	1	298	06	77
2000-2001	1385	1153	232	474	25	3	0	6	NIL	638	16	61
2001-2002	1363	1129	244	404	1	4	NIL	-	7	859	07	83
2002-2003 (up to September 2002)	1591	1083	508	962	NIL	NIL	3	1	4	908	07	65
	8236	**6621**	**1615**	**4288**	**83**	**13**	**15**	**25**	**14**	**3035**	**59**	**388**

From the above it would be seen that

20 *per cent* samples remained untested and 3094 reports (47 *per cent*) not issued in prescribed form

Out of 8236 samples received/drawn (1998-2003), 1615 (20 *per cent*) samples remained untested (January 2003). Therefore the medicines from which these samples were drawn were marketed without ensuring the quality.

As per rules, on receipt of a sample from an Inspector for test/analysis, the Government Analyst shall forthwith supply to the Inspector a report in triplicate of the results of analysis/test, together with full protocols of the test or analysis applied. The SDCRL in gross violation of the Rule did not issue 3094 reports (47 *per cent*) in Form 13 against 6621 samples tested during 1998-2003 (September 2002).

Delay in sending test reports

There was delay of more than one year in sending the test report to the concerned Inspectors in respect of 13 NSQ drugs. Forty (40) reports (including 25 NSQ reports) were issued even after the date of expiry of the medicines. Fourteen reports were issued without any specific/conclusive opinion.

Out of 388 samples found NSQ, 59 reports were not in Form 13 and as a result the inspectors did not initiate any action against the concerned manufacturers.

Thus, inordinate delay in sending test reports, reports not being prepared in prescribed form, non-testing of samples, etc. defeated the objective of ensuring supply of standard medicines and the manufacturers were able to market NSQ drugs freely.

3.2.7 Testing of sample medicines and drugs – time taken for reporting and adverse impact on reporting delays

Adverse reaction of NSQ drugs

Administration of alleged drugs caused toxicity and death of patients

Director, School of Tropical Medicine, Kolkata reported (April 2000) several cases of death (April 2000) at School of Tropical Medicine, Kolkata after administration of the alleged NSQ drug Sodium Stibo Gluconate (SSG) (Batch No. SA00598) manufactured by GL Pharmaceuticals. Different batches (along with Batch No. SA00598) of the same drug caused toxic reaction on patients at Barasat District Hospital also. Seven (7) people died in Bihar by use of SSG of the same batch as intimated by DDC, WB on 3 November 2000. The firm marketed the drug on the basis of test report issued by CDL, Kolkata. SDCRL, however, declared (24 January 2000) the drug as NSQ. A case was filed (May 2000) by DDC against the firm but the Hon'ble High Court dismissed the case on the basis of CDL certificates.

Patients suffered from rigors after administration of NSQ drugs

In Hooghly District Hospital and RG Kar Medical College Hospital, Kolkata some patients suffered (March 2001) from severe rigors at the time of administration of injection of 5 *per cent* Dextrose (Batch Nos. 0122A0A1 and 0122A011) manufactured by Senbo. The sample of the injection was sent for testing in SDCRL where it was declared (April and August 2001) NSQ. The reasons for non initiation of penal action against the firm by DDC were not on records.

Consumption of NSQ drugs

Not of Standard Quality Drugs worth Rs 78.85 lakh were consumed

When a medicine was declared NSQ by any statutory laboratory, the DDC was to direct the manufacturers to recall the entire batch from the market to prevent its further use. Due to delay in receipt of test report as well as consequential delay in issue of specific instruction to recall the batches from the DDC, medicines worth Rs 68.21 lakh were consumed.

In the test-checked districts, the CMOHs stated that they had received the test reports only after consumption of NSQ drugs (value : Rs 10.64 lakh) by patients.

Thus, due to lack of prompt and effective monitoring, consumption of NSQ drugs could not be prevented. The matter was admitted (July 2003) by the DDC, WB.

3.2.8 Non-seizure of Drugs

Section 18 (a)(i) of the Act provides that no person shall himself or by any other person on his behalf manufacture for sale or sell or stock or exhibit for sale, or distribute any drug which is not of standard quality or is misbranded, adulterated or spurious and if such offence is committed, the Inspector could seize the stock of such drug and any substance or article by means of which the offence has been or is being committed or which may be employed for the commission of such offence [Section 22(i)(c)].

No penal measure initiated against 41 firms supplying NSQ drugs

In CMS, Kolkata, medicines worth Rs 28.70 lakh received during 1998-2003 from 41 firms were found NSQ on test and were returned to the suppliers. The DDC neither seized the NSQ drugs nor initiated any penal action as laid down in section 27 of the Act against those delinquent firms for such supply. The DDC stated (July 2003) that the fate of the NSQ drugs at the manufacturers' end was under investigation.

3.2.9 Follow-up action for samples found sub-standard or spurious - effectiveness thereof

Inadequate action against manufacturers producing Not of Standard Quality (NSQ) Drugs

Reports against manufacturers producing NSQ drugs issued by the statutory laboratories of West Bengal and other states were received by the DDC, WB for enforcing penal measures for violation of D&C Act and Rules thereunder.

The position of NSQ reports received and action taken there against during 1998-2003 was as below:

From whom reports received	Number of reports on NSQ drugs	Number of cases where show cause notices issued	Number of cases in which warnings were issued	Number of firms against which action awaited	Number of reports referred to DC of other states	Number of cases referred to the manufacturing units for inspection	Cases where product suspended	Product/ licence cancelled
State Drug Control & Research Laboratory (SDCRL)	178 *	14	7	57	10	4	32	54
Central Drug Laboratory (CDL)	35	5	NIL	15	3	NIL	8	4
Drug Controller of other States	135	16	12	27	15	20	45	NIL
	348	**35**	**19**	**99**	**28**	**24**	**85**	**58**

Source: Sample Register of DDC

** As per records of DDC. It differs from the SDCRL figures which recorded detection of 388 NSQ samples. The discrepancy was due to non-consolidation of all reports at State Level.*

Inadequate action against firms producing Not of Standard Quality drugs

DDC had not taken any action against 99 firms (including those firms whose products were declared NSQ several times) producing NSQ drugs and took three to five months from the date of receipt of reports to initiate penal measures. There was no record to show enforcement of penalties imposed. DDC stated that enquiries were being made and final report was awaited as of July 2003.

Drugs manufactured in one State were permitted to be sold in other States. But DDC, WB did not send the Drug Controllers of other states the list of drugs declared NSQ during 1998-2003. The DDC, WB was also not aware of 320 drugs declared NSQ by the Drug Control Laboratory, Maharastra. Due to lack of coordination among the States, the possibility of continuance of marketing of NSQ drugs originating from other States could not be ruled out. The DDC stated (July 2003) that information in this regard was not available and that network for dissemination of information from other states was yet to be developed in West Bengal.

Complaints remaining unattended

Of 378 complaint cases action against 66 cases and enquiry for 82 cases remained pending

During November 1999 to December 2002, DDC received 378 complaints for violation of D&C Act and Rules viz. selling of expired/banned/substandard medicines, sale without licence, overpricing and even adverse reaction on consumption of drugs, etc. as shown below:

Sl. No.	Nature of complaint	Total number of complaints	Action taken	Action awaited	Enquiry ordered but report of enquiry awaited	Number of show cause notices issued but reply awaited
1	Substandard Drugs	81	37	29	11	4
2	Manufacturing without licence	7	3	1	3	NIL
3	Change of constitution	7	1	1	5	NIL
4	Overpricing	22	15	3	4	NIL
5	Adverse reaction on consumption of drugs, taking of bribes, etc.	43	13	9	20	1
6	Selling of drugs without licence, selling of banned/expired/sample drugs, etc.	93	69	14	7	3
7	Raid/seize	11	8	1	2	NIL
8	Duplication of drugs	8	1	NIL	6	1
9	Others	106	71	8	24	3
		378	**218**	**66**	**82**	**12**

Source: Complaint Register

From the above it would be seen that DDC did not initiate any action in 66 cases while no enquiry report was furnished in 82 cases till date. In 12 cases show-cause notices were issued but no reply was received as of May 2003. Thus non-pursuance of complaint cases might possibly have increased unauthorised activities. The DDC stated (July 2003) that the matter was under investigation.

The ADDC, Murshidabad received 19 complaints during 1998-2003. Of these, three complaints were unattended due to non-availability of police in time. The ADDC, Birbhum had not taken any action against two complaints out of three received during 2002-2003. No record regarding receipt of complaints during 1998-2002 was available. The ADDC, Medinipur received 44 complaints during 1998-2003 but fate of those complaints was not on record. No complaint register was maintained in Malda and Bankura districts.

Seizures and searches

Inadequate raids

Only 27 raids were conducted during 1998-2002

DDC (HQ) did not conduct any raid during 1998-2000. During 2000-2002 27 raids were conducted and violation of the Act was reported in 21 cases of which records of 15 cases were made available to Audit. Scrutiny of those cases revealed following shortcomings:

- There was delay ranging between three and twenty two months in filing petition of complaint (POC) to the Court in three raids.
- In three cases the DDC had not filed petition even after lapse of two to twelve months despite receipt of case diary from the police.
- Test reports of drugs seized during five raids were awaited.
- Case diary from the police was awaited for two raids.
- Drug sample of Pyregesic (Paracetamol I.P bearing Batch No. l1002) seized (June 2002) was found NSQ on test by the SDCRL (vide their No.A.R/132 dt.28.02.2003). The above test report was not sent by the DDC to Police for completion of investigation as of June 2003.
- In Ballygunge GRPS (case No.12/2002 dated 18.6.2002) illegal manufacture of Oxytocin injection was detected on raid (June 2002) and 31900 ampules (5 mg) were seized. The Hon'ble Court ordered (July 2002) to draw samples for testing from above seized drugs but the action was awaited as of May 2003.

During 1998-2003 no raid was conducted by the Malda, Medinipur, Bankura and Birbhum district offices. In Murshidabad, out of 12 cases four test reports were not sent to police for investigation and two test reports from SDCRL were awaited.

This indicated non-existence/poor control of the DDC over the functions of inspectors in this regard.

3.2.10 Non pursuance of Drugs (Price Control) Order (DPCO), 1995

Government of India fixed the maximum sale price of bulk drugs as specified in the first schedule to facilitate the consumer to purchase such drugs at a fair price under Drugs (Price Control) Order (DPCO), 1995.

Scrutiny of records of DDC, WB revealed the following irregularities:

- DPCO, 1995 was not implemented in the State prior to 2002.

Inadequate collection of price list to check overpricing

- Out of 540 manufacturers, as of March 2002, DDC was able to collect the price list only from 35 firms. It was seen that DDC had not taken any action against the defaulters.
- Out of 35 firms, the DDC had checked the price list of 25 firms. Fifteen overpricing cases were detected during the year 2002 and the same were forwarded to the National Pharmaceuticals Pricing Authority (NPPA) under the Ministry of Chemicals and Fertilisers. No records regarding follow-up action could be produced by DDC.

Test-check revealed that no mechanism to check over-pricing of drugs was in place in any of the five test-checked districts due to non-availability of price list from the manufacturers.

3.2.11 Non-return of standard medicines resulting in loss to Government

As per Section 23 (3 & 4) of D & C Act where an Inspector takes sample of a drug (cosmetic) for the purpose of test or analysis, he shall divide it into four portions. He shall restore one portion of a sample to the persons from whom samples are taken and dispose of the remainder as follows:

Samples though declared standard were not returned for use

One portion shall be sent to the Government analyst for test or analysis.

The second portion shall be produced to the court before which proceedings, if any, are instituted in respect of the drug (or cosmetic).

The third portion shall be sent to the manufacturer of the drug or his agent for distribution, if any, whose name and address and other particulars have been disclosed under Section 18 A.

The inspectors collected samples at a cost of Rs 23.45 lakh (Rs 22.78 lakh from Government Stores and Rs 0.67 lakh from shops) for analysis during 1998-2003 from CMS, Kolkata, CMOH and markets of five test-checked districts which were declared as of standard quality. Of these, samples worth Rs 12.72 lakh (Rs 12.22 lakh from Government Stores and Rs 0.50 lakh from shops) was returnable to Government stock. But the same was not returned for use to stock resulting in loss to Government.

3.2.12 Retail shops running without pharmacists

As per Rule 65 of D&C Rules, 1945, drugs are to be sold on the basis of prescriptions of registered medical practitioners under the personal supervision of a registered pharmacist.

Shops were running without whole-time pharmacist

In three districts, names of 104 pharmacists (Birbhum-39, Bankura-29 and Murshidabad-36) were mentioned in the 212 licensed shops (Murshidabad-72, Birbhum-81 and Bankura-59) indicating that at least 108 shops were running without a whole-time pharmacist in defiance of the Rules.

Malda district office did not maintain any Register to indicate engagement of pharmacists in the district.

3.2.13 Production/marketing of drugs banned by GOI

Action was not initiated to ensure non-consumption of banned drugs

Whenever a drug is banned by GOI, circulars are issued to the State Drug Controllers with the direction to give wide publicity to the contents of Notification through State Association of Manufacturers, Chemists and Druggists' Journals. But no notification was issued for 69 categories of banned drugs. DDC, WB stated that circulation was not done due to paucity of fund. Sale of four categories of drugs banned by GOI was detected by the DDC as shown below:

Name of the drugs	Name of the manufacturer	Date of banning	Year of detection of sale
ENTAKON TABLETS	KONTEST Chemicals Ltd.	23.7.1983	2001
CAROFIT	AJANTA PHARMA Ltd.	23.7.1983	2002
CIZOREN Plus (1.5 mg, 5 mg, 10 mg)	STADMED	12.3.2001	2001 and 2002
H. Dol	Pharmagen India(P) Ltd.	12.3.2001	2001

3.2.14 Appointment of LACA without having requisite qualification

Appointment of LACAs without prescribed experience

Sections 49A & 50A of the D&C Act, 1940 stipulate that officers acting as Licensing Authority and Controlling Authority (LACA) should have experience for a minimum period of five years in manufacturing or testing of drugs or enforcement of the provisions of the Act. But LACAs were appointed without having requisite experience during 1998-2003.

Reasons for such irregular appointment though called for were not furnished by the Government.

3.2.15 Training

In West Bengal there was no training institute to upgrade/develop the skills of key functionaries like Inspectors for enforcing D&C Act. In reply to audit query the DDC stated that whenever any proposal was received from GOI, Inspectors were sent for such training. But in absence of records, number of such trained inspectors could not be ascertained.

3.2.16 Absence of monitoring mechanism

Non-maintenance of essential records/registers

The department did not formulate any mechanism for obtaining periodical inspection reports and returns from various levels of functionaries. Essential records/registers for inspection, sample collection, complaints and cases, etc. were not maintained centrally for effective implementation of the Act.

For disseminating information as well as for getting feedback on the functions of the DDC, meeting/interaction with the pharmaceutical industry/trade/ consumers/ medical practitioners was essential. But DDC did not organise any such meeting/symposium during 1998-2003.

Implementation of the Drugs & Cosmetics Act, 1940 was never evaluated/ surveyed by any agency during 1998-2003.

3.2.17 Conclusion

The department made little impact in combating the marketing of spurious/sub-standard drugs due to poor coverage of sampling, inordinate delay in sending test reports as well as failure to send the reports in proper form, poor control over licensing, lax supervision, lack of monitoring and co-ordination. Administration of NSQ drugs caused several incidents of toxicity and death in different hospitals. Production of not of standard quality and banned drugs continued unabated due to inaction/belated action of the department against the manufacturer. Consumers in the State remained exposed to serious health hazards from spurious and not of standard quality drugs.

Recommendations:

- Rules should be amended to ensure that none of the manufacturing /selling units continue to transact their business without renewal of the licences by prescribing a time limit for renewal of licences and completion of renewal formalities before date of expiry of licences.
- Time lag between drawal of drug sample by the drug inspector and issue of analysis report by the statutory laboratory should be minimized by establishment of DTL at each of the Regional Division Offices.
- Special courts/tribunals should be created for prompt and timely disposal of prosecution cases against the manufacturers / sellers of spurious/ sub-standard drugs.
- Deterrent punishment should be provided against the manufacturers and sellers of spurious/sub-standard drugs so as to save the lives of innocent consumers.
- Immediate steps should be taken to fill up the vacant posts of DIs to augment the inspections and sampling.
- The Licensing Authority and Controlling Authority should be appointed having qualification as per Drugs and Cosmetics Act, 1940.
- Drug users units of the country are required to be brought under net-working with the DCGI for quick transmission of information of sub-standard/ spurious/ misbranded drugs detected.
- Adequate funds should be provided for advertisement/circulation on banned/NSQ drugs.

The matter was referred to Government in June 2003; reply had not been received (December 2003).