HEALTH AND FAMILY WELFARE DEPARTMENT

3.2 Implementation of the Drugs and Cosmetics Act

Highlights

A review of the implementation of the Drugs and Cosmetics Act, 1940 in the State during the period 1998-2003 revealed vital lapses in enforcement of major provisions of the Act by the State Drug Control Authorities (SDCAs). There were shortfalls in inspection of premises of the units licensed for manufacture and sale of drugs. Medicine shops, blood bank and manufacturing units of Large Volume Parenterals (LVP) were allowed to continue without valid licence. While the State Drug Testing and Research Laboratory lacked infrastructure to test all types of allopathic drugs, there was absence of a State level laboratory for testing of ayurvedic and homoeopathic drugs. Besides, the State machinery was not effective in recalling from the market drugs declared not of standard quality, to check their further use.

- **Five manufacturers of drugs were granted conditional licences although the Act and Rules do not permit issue of such licences.**

(Paragraph 3.2.9)

- **Medicine shops, manufacturing units for Large Volume Parenterals (LVP) and Blood Bank were allowed to continue without valid licence.**

(Paragraph 3.2.9)

- **Licences were granted for manufacture of a cosmetics paste i.e. 'Dantaghasa Gudakhu' which contained harmful tobacco despite prohibition to do so in public interest by Government of India.**

(Paragraph 3.2.9)

- **Inspection of licensees' premises and sale units was negligible. The shortfall ranged between 73 and 84 *per cent* in allopathic sector, 97 and cent *per cent* in homoeopathic sector and 63 and 79 *per cent* in ayurvedic sector during the period 1998-99 to 2002-03.**

(Paragraph 3.2.7)

- **State Drug Testing Laboratory (ISM) for Ayurvedic sector could not function despite release of Central grant of Rs.54 lakh in 2000-2001.**

(Paragraph 3.2.8)

- **Lack of infrastructure facilities in the State Drug Testing and Research Laboratory resulted in arriving at no opinion on the standards of 69 samples and diversion of 149 samples to Central laboratories.**

(Paragraph 3.2.8)

- **419 batches of drugs were declared Not of Standard Quality (NSQ) during 1998-99 to 2002-2003 as per laboratory test reports, but no**

effective steps were taken to recall them from the market to check further use of such drugs and prosecute the offenders.

(Paragraph 3.2.9)

- **No action taken against supply of NSQ drugs i.e. Ethambutol Hydrochloride IP (400 mg) in Government hospitals/dispensaries because of faulty sampling of drugs sent for testing.**

(Paragraph 3.2.9)

- **Non-prosecution of the units manufacturing NSQ drugs and selling to Government for ultimate use by patients of the State.**

(Paragraph 3.2.9)

3.2.1 Introduction

Background

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[1] 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".

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

[1] 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 4 December 1961

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

Scope of Statutory Functions

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 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 and 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 all drugs and cosmetics manufacturing units and sales establishments under allopathic and homoeopathic sectors (b) licensing of drug testing laboratories (c) approval of drug formulations for manufacture (d) monitoring of quality of Drugs and 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 non-standard drugs.

3.2.2 Scope of Audit

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 dereliction occur particularly in the areas of licensing, approval, monitoring, prosecution, inspection and recall of non-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 May 2003 based on the test check of records of the Drug Controller (DC), Orissa, Bhubaneswar and his subordinate officers[2], the Director, Indian Medicines and Homoeopathy, Orissa (DIMH) and Deputy Director (DD), State Drug Management Unit (SDMU), Bhubaneswar

[2] Three Deputy Drug Controllers (DDCs) of South Zone, Berhampur, West Zone, Sambalpur and Research Programme (RPT) in charge of the State Drug Testing and Research Laboratory, Bhubaneswar (SDTRL), Six Drug Inspectors (DIs) (Cuttack-III, Puri, Berhampur, Jeypore, Sambalpur and Keonjhar)

functioning under the administrative control of the Director, Medical Education and Training (DMET), Orissa.

3.2.3 Implementing Agencies/arrangement

The DC as the Licensing Authority (LA) as declared by the State Government was responsible for implementation of various provisions of the Act and Rules for all the systems of medicine from October 1982. In respect of homoeopathic and ayurvedic including Sidha and Unani medicines, the DIMH was vested (July 1997) with the powers of LA. The Act provided specific technical qualification for appointment of LA in respect of homoeopathic discipline. As the DIMH did not have the requisite qualification, his appointment as the LA in respect of homoeopathic discipline was withdrawn (October 2002) from him and the DC was again vested with the said power with effect from November 2002. In respect of the ayurvedic, siddha and unani sectors, the DIMH continued to be the LA as the Act was silent about any specific qualification.

The DC assisted by 4 DDCs, 3 Assistant Drug Controllers (ADCs) and 17 DIs issued original and renewal licences of all the cosmetic manufacturers and the allopathic drug manufacturers except the renewal licence of allopathic drug selling units of west and south zones which were delegated to the respective zonal DDCs. The DIMH issued the original and renewal licences of ayurvedic drug manufacturing units. However, licences under the homoeopathic drug manufacturing/selling units were issued by the DIMH up to October 2002 and by the DC thereafter. The inspection of firms, sampling of drugs and launching of prosecution cases under the Act and Rules were assigned to the ADC-cum-DIs, DIs under the DC and the DIs under the DIMH. The testing of sampled drugs and reporting thereon was assigned to the State Drug Testing and Research Laboratory (SDTRL) and in some cases the help of Central Drug Laboratories (CDL) outside the State was being taken.

3.2.4 Statistics of prosecution vis-a-vis cases filed

Infirmities in the Act/Rules for prosecutions

In Orissa, as per the Act, a DI can order an offender not to dispose of stock suspected to be of spurious/non-standard quality etc. for a maximum period of 20 days. However, the DIs have no power to close and seal the manufacturing/selling units under lock pending orders of the Court of Law.

Tardy progress in prosecution

Review of records of DC revealed that in respect of the allopathic sector, 179 prosecution cases were pending as on 1 April 1998 to which 81 cases were added during 1998-2003 taking the total to 260 cases. But only 2 cases were disposed during the said period leaving the pendency at 258 cases including 2 cases on spurious drugs as on 31 March 2003. No separate legal cell was created under the DC/DIMH to monitor and effectively follow up the court cases.

3.2.5 Implementation of the Act

Survey and licensing procedure

No regular surveys were carried out by the SDCAs through their technical staff posted at Ranges to identify drug or cosmetic units engaged in illegal

manufacturing/selling activities without valid licences. However, on receipt of applications from interested applicants alongwith requisite challan in support of deposit of licence/inspection fees etc. for grant or renewal of manufacturing/selling licences of drugs or cosmetics, the ADC-cum-DIs and the DIs inspect the premises of the applicants to verify the correctness of documents furnished by them and study the feasibility or otherwise of the proposed units with respect to the provision of Acts / Rules and then forward the same to the LAs alongwith their views/recommendations etc. The LAs issue the licences in the prescribed forms for specified periods after examination of the therapeutic rationale, stability studies of formulation, compositions and ingredients etc., testing method employed, facility available, process of manufacture adopted by the firms and compliance of the conditions attached to the Act / Rules.

Absence of database on pendency of application for grant/renewal of licences

The pendency of applications as on 31 March 2003 could not be furnished by the DC. Test check of records of DDC (WZ) and 6 DIs revealed that 1113[3] numbers of application for fresh/renewal of licences for sale of drugs were pending for one to five years as of 31 March 2003 as the reports/returns submitted by field units were not compiled in his office due to shortage of staff.

Non - renewal/non-deposit of licence fee

Scrutiny of records of DC and DIMH for the period 1998-03 revealed that fee of Rs.61.19 lakh towards renewal of licence was not collected at the prescribed rates from 1448 firms after expiry of the term of their licences as detailed below.

Name of the authority	Number of firms not renewed		Amount of non-deposit of licence renewal fee at prescribed rate (Rupees in lakh)
	Sector	Number of units	
DC	**Allopathic drug manufacturers**	**164**	**60.67**
	Cosmetics manufacturers	**15**	
	Sales units of drugs	**1130**	
DIMH	**Homoeopathic manufacturers**	**6**	**0.38**
	Homoeopathic sales units	**85**	
	Ayurvedic drug manufacturers	**48**	**0.14**
	Total	1448	61.19

The DC stated (August 2003) that the licences were deemed to have been cancelled since the licensees failed to apply for renewal as per the DC Rules. He further added that these firms closed down their business and there was no need to cancel the already expired licence. The fact, however, was that the licences were not cancelled in the licence register and there were no records available supporting the actual closure of the units.

[3] DIs : Berhampur : 205, Cuttack-III : 285, Jeypore : 155, Keonjhar : 194, Puri : 100, Sambalpur : 174

3.2.6 Sampling

Inadequacy of Sampling

The samples drawn under the allopathic sector were as shown below as per the DI-wise targets fixed by DC every year:-

Year	Number of running units			Number of samples drawn			
	Manu-facturing Units	Selling Units	Total Units	Manu-facturing Units	Selling Units	Govern-ment Hospitals	Total samples drawn
1998-99	319	13542	13861	135	1322	747	2204
1999-2000	327	14068	14395	57	1163	735	1955
2000-2001	340	14713	15053	48	1105	645	1797
2001-2002	343	15336	15679	39	1113	721	1872
2002-2003	348	16224	16572	95	1302	628	2025

Considering that each unit manufactured/sold varieties of drugs, the average number of samples (1971) drawn annually would seem to be inadequate against the average 5052 inspections carried out annually during 1998-2003. The Department attributed the inadequate sampling to shortage of staff, paucity of funds to meet the cost of samples drawn, travelling allowances of the staff etc.

In the homoeopathic sector, only 32 samples were drawn during 1998-2000 out of 1083 manufacturing and selling units licensed up to October 2002. Thereafter, no samples were drawn. No reasons for non-drawal could be adduced by DIMH. As regards ayurvedic medicines, no samples were drawn during 1998-2003, due to non-existence of testing facilities/laboratory in the State and refusal (September 1999) by Central Indian Pharmaceutical Laboratory (CIPL), Ghaziabad to receive samples for testing. Hence the LA could not ensure the standard/quality of homoeopathic drugs manufactured and sold in 1083 units and ayurvedic drugs manufactured in 171 units in the State during 1998-2003.

Cosmetics samples were not drawn at all as there were no facilities for testing them in the SDTRL. It was also stated by the DC that the cosmetic samples were also not accepted by any of the laboratories situated outside the State for testing. As such, the LA could not discharge its duty of ensuring the quality of cosmetics manufactured in the State.

3.2.7 Adequacy of Inspection

As per DC Rules, 1945 an Inspector was to inspect the premises of licensed selling and manufacturing units under allopathic, homoeopathic and cosmetics sectors at least twice in a year up to September 2001 and thereafter once in a year. Review of records revealed that the extent of shortfall in inspection varied from 73 to 84 *per cent* in respect of allopathic sector and 97 to 100 *per cent* in respect of homoeopathic sector during 1998-2003. In ayurvedic sector, the annual shortfall in inspection with reference to prescribed norm varied from 63 to 79 *per cent* during 1998-2003. Thus, the mandatory inspection conducted covered an insignificant number of units.

The DC/DIMH stated (November 2002) that due to lack of manpower and scarcity of funds under travelling allowance head, the prescribed number of inspections could not be achieved in respect of allopathic and ayurvedic sectors. No reason for shortfall was given in respect of homoeopathic sector.

The DC stated (August 2003) that as per the recommendation of Hathi Committee approved by the Central Government, the State required 200 Drug Inspectors. But the sanctioned strength of DIs in the State was 24 and 17 posts only were operating during 1998-2003. This was inadequate for implementation of the provisions of the Act and Rules in allopathic sector. No posts of DI were also sanctioned to look after 1000 sales and manufacturing units under homoeopathic sector.

3.2.8 State Drug Testing and Research Laboratory

State Drug Testing and Research Laboratory for ayurvedic sector could not function although funds were not a constraint

The State Drug Testing and Research Laboratory was set up at Bhubaneswar on 2 October 1975 for testing the drug/cosmetic samples. It has been functioning with 17 drug testing personnel (Government Analyst: 8, Junior Scientific Officer: 2 and Senior Laboratory Assistant: 7) against the sanctioned strength of 25 during the period covered in review under the overall supervision of DDC (RPT), Orissa. There was no separate Drug Testing Laboratory at State level in the homoeopathic sector and ayurvedic sector. However, for strengthening of the Drug Testing Laboratories of Indian System of Medicine (ISM), Government of India sanctioned Rs.70 lakh towards purchase of instruments and equipment (Rs.60 lakh) and manpower (Rs.10 lakh) during 2000-2001 and released Rs.54 lakh in the first instalment during 2000-2001. The amount was kept unutilised in a bank as of March 2003 because of non-completion of construction of building in the premises of the Government Ayurvedic Hospital, Bhubaneswar.

Diversion of drug samples to Central laboratories due to lack of infrastructure facility in SDTRL

The SDTRL was not adequately equipped with modern apparatus and testing methodology, despite receipt of Central grant of Rs.39.50 lakh (1996-97: Rs.31 lakh, 2000-01: Rs.8.50 lakh) of which expenditure of only Rs.27.23 lakh were incurred during 1999-2001. The remaining amounts were parked in bank (Rs.3.77 lakh) and in Civil Deposit (Rs.8.50 lakh). Hence no opinion on the quality of drugs could be made by the Laboratory in respect of 218 samples. Of this, 69 samples and 149 samples were referred to CDL, Kolkata and Central Indian Pharmaceutical Laboratory, Ghaziabad respectively for testing during 1998-2003. Moreover, 25 important drugs widely used in the State for treatment of common ailments were debarred from testing in the SDTRL with effect from 27 July 2002 for want of reference standards, intermediate compounds, testing facilities, non-repair of idle machinery and non-procurement of vital equipment etc.

Delay in testing of samples by 3 to 12 months by the SDTRL involved consequential hazards to the patients

No time limit was either prescribed by the Act/Rules or fixed by the Central/State Government for testing of drugs samples and sending the test results. In the absence of this, the correctness of working norms prescribed for the testing personnel by the DDC (RPT) could not be examined. Thus, drugs were tested at the convenience of the SDTRL/CDLs and considerable delays of over 3 to 12 months were noticed in declaration of results in 120 out of 372 NSQ drugs.

The belated declaration of the drugs as NSQ left little scope for the DIs to recall the same from the market as the same would have been already consumed by the patients causing serious health hazards.

Non-testing the standards of Ayurvedic drugs

Non-availability of testing facility of ayurvedic drugs samples in the State had adverse impact upon the general health of patients. It was seen that 115 bottles of 'Mritusanjivani Sura' which was being used as alcoholic intoxicant rather than a medicine were seized (August 1999) by a joint raid of police, excise and drug control officers in Boudh-Kandhamal district. Although five manufacturers in Orissa and four outside the State were involved in preparation of such stock, no action could be taken against them due to non-testing of statutory samples.

3.2.9 Irregular grant of Licences

Conditional licences were issued in contravention of the Act

Test check of records of DC revealed that five drug manufacturing licences were renewed with stipulation to rectify certain defects/deficiencies within a period of one month from the issue of licence (Appendix-XXI) although the Act and the Rules do not permit issue of conditional licence. The defects included major deficiencies like non-cleaning of drainage system, non-testing of raw materials, non-mentioning batch number in the labels etc. which violated the minimum requirements of schedules M and S of the DC Rules and no monitoring was done by the DC to see that the conditions were complied with by the firms.

The DC licensed 15 units for manufacture of Dantaghasa Gudakhu /tooth paste having tobacco as the main ingredient despite prohibition by Central Government

Government of India, Ministry of Health and Family Welfare Department in their notification dated 30 April 1992 prohibited the manufacture and sale of all cosmetics licensed as tooth paste/tooth powder containing tobacco having risk for human being in terms of Section 26 A of the Act in public interest.

"Dantaghasa Gudakhu" was a cosmetics paste intended to be rubbed against human teeth and it contained tobacco as the main ingredient. However, it was noticed that 15 units all over the State were licensed by DC to manufacture "Dantaghasa Gudakhu" during May 1993 to September 2002 in addition to 100 units licensed between October 1972 and February 1991.

On this being pointed out, the DC stated (August 2003) that Dantaghasa Gudakhu was not licensed as tooth paste/tooth powder category containing tobacco under the Act and the licences were issued as per clarification received from the Law Department of Government. The reply was not tenable since granting of licence for manufacture of "Dantaghasa gudakhu" under the camouflage of cosmetics having harmful tobacco as main ingredient was not in consonance with the spirit of the prohibitory orders of Government of India made in April 1992 in the interest of public.

Four medicine stores were running without valid licence

Scrutiny of records of DDC (WZ), Sambalpur revealed that four medicine shops (namely Mahabir Medical Hall, Sai Medical Store, Life Medical Store and Solace Medicare) were operating in Sambalpur town without valid licence in contravention of the provisions of the Act / Rules. The DDC (WZ) in July 2002 ordered the DI concerned to conduct surprise raids of the said firms with the help of police. This was followed by similar orders of DC in

August 2002 and reminder in August 2003. However, no such raid was carried out by DI, Sambalpur range (August 2003).

Running of Blood Bank without valid licence in the district headquarters hospital at Sonepur

Records of DC revealed that the Orissa Red Cross Blood Bank (ORCBB) was licensed (26 February 2002) to operate a blood bank for processing of whole human blood IP at the district headquarters hospital, Sonepur subject to fulfilment of 25 conditions. The ORCBB started functioning from 22 March 2002. However, it was noticed that the licence was meant for the period 11 August 2000 to 31 December 2001. Thus, the ORCBB had been functioning at the above place without a valid licence since its inception. The DC stated (August 2003) that the application for issue of certificate of renewal for prospective period was sent (May 2003) to the Deputy Drug Controller General (India), Kolkata and licence would be renewed after observing all formalities.

Production and sale of LVP fluids without renewal of licences

Scrutiny of the records of DDC (WZ), Sambalpur revealed that a firm named M/s Bindlish Chemical and Pharmaceuticals Works, Sambalpur whose licence expired on 31 December 1999, manufactured 21742 bottles of LVP fluids during January to June 2000 despite the instruction of DC (January 2000) to stop production/sale of drugs. The firm distributed 19082 bottles between January and July 2000 and the Range DI seized the balance of 2660 bottles. The Superintendent of VSS Medical College Hospital, Burla procured 8600 bottles (March 2000) and issued 4670 bottles to patients; the balance of 3930 bottles were seized by the Range DI. Drug recall in respect of the distribution of the balance of 10482 bottles was not effected (May 2003) and no action was taken to prosecute the offender. The DC stated (August 2003) that the DI, Sambalpur failed to issue the drug recall letter as well as to submit the prosecution case and was asked to explain. Similarly, six[4] other firms of the State continued the production and sale of such LVP fluids without valid licence beyond 31 December 1999 upto the dates of their cancellation (February 2001). But the details were not available with DC. The concerned DIs were, however, instructed in March and July 2002 to report the activities of the firms. Further development in the matter was awaited (August 2003).

Manufacture and sale of unauthorised ayurvedic preparations

Scrutiny of records of the DIMH revealed that show cause notices were issued in June 2000 by the Directorate against four offenders, who were manufacturing and selling 13 Ayurvedic medicines in contravention of Section 33EEB of the Act and also advertising them through media agents as magic remedies for all types of ailments/health hazards warranting punishment under Act and also under the Drugs Magic Remedies (Objectionable Advertisement) Act, 1954 and the Rules made thereunder. But none of the notices have been responded to by the offenders and no further action was taken to prosecute the offenders under the Act.

[4] M/s Orissa Drugs and Chemicals Limited, Bhubaneswar, Kelvin Pharmaceuticals and Om Pharmaceuticals, Cuttack, Jaybee Pharmaceuticals, Unipharma Laboratory and Tarisha Pharmaceuticals, Berhampur

Substandard drugs were allowed for circulation causing threat to the health of the patients

As per the provisions of the Act / Rules, on receipt of a drug testing report from a GA regarding NSQ drug, action was to be taken by the LAs through the DIs posted in the Ranges to recall the unused NSQ drugs by screening the market and check further use of the same in case of own State manufacturers of the said drugs. In case of NSQ products manufactured in other States, the concerned DCs were to be asked to initiate action under the Act/Rules.

It was stated by the DC that against 9853 samples drawn by DIs of the State during 1998-2003, 9151 samples were tested in SDTRL and CDLs outside the State and 419 samples were declared NSQ by the GAs concerned.

The details of drugs recalled in respect of each NSQ case, prosecution cases lodged against manufacturer/seller of these drugs, penalty imposed etc. were, however, not available with the DC due to non-maintenance of relevant registers to monitor follow up action. Test check of records of six DIs revealed that in 114 cases[5], no concrete/expeditious steps were taken by the concerned DIs or the DC to recall the NSQ drugs well before the expiry dates from circulation both inside/outside the State except issue of formal letters to drug supplier/manufacturers and LAs of other States concerned. In most of the cases, there was no response. As such, the major quantity of NSQ drugs were allowed to be marketed causing threat to health of the patients. The DC stated (August 2003) that in most of the cases, by the time the reports are received by the DI, stocks of the particular batch of the NSQ drugs are found sold in the market.

Further, scrutiny of NSQ files of DI, Cuttack-III and Puri ranges revealed that six drugs (DI, Cuttack-5 and DI, Puri-1) were declared NSQ by SDTRL, through test reports which were challenged by the firms on different grounds. But no details as to action taken to meet such challenges were available in the files. The samples were also not sent to CDL/CIPL for authoritative test of standards. Some more interesting cases of inaction by DC are detailed at Appendix-XXII to this report.

Failure to take action in case of anti-TB NSQ drug consumed by the patients

M/s Panacea Pharmaceuticals of Berhampur, Orissa supplied 143 lakh tablets of Ethambutol Hydrochloride IP (400 mg), an anti-TB drug to SDMU, during 2000-01 which were distributed throughout the State. The drug was reportedly declared as of Standard Quality (SQ) by the authorised testing laboratories to whom the samples were sent by DD, SDMU, Bhubaneswar as per terms of the supply agreement with the manufacturer. However, tests on certain samples drawn from Khurda and Phulbani districts were found to be sub-standard. Hence Government decided that the DC would draw samples from all batches in all the districts and test them both at SDTRL and CDL, Kolkata. The test results were confusing. Some samples found by SDTRL to be SQ were found to be NSQ by CDL, Kolkata and vice versa. When DC ordered the manufacturer to stop production of the drug, the latter appealed to the State Government and some interesting arguments were put forward by the manufacturer. One of the arguments was that Ethambutol is highly hygroscopic and therefore even if it is SQ initially, it could become NSQ later.

[5] (i) DI, Cuttack : 30 cases, (ii) DI, Puri : 15 cases, (iii) DI, Berhampur : 16 cases, (iv) DI, Jeypore : 14 cases, (v) DI, Sambalpur : 19 cases and (vi) DI, Keonjhar : 20 cases.

It is, however unlikely that the reverse would happen i.e. a sample which is NSQ becomes SQ later. Test results showed that some samples, which had been found to be NSQ earlier, were found to be SQ in a subsequent test. In view of such conflicting results, the Government set aside the orders of the DC allowing benefit of doubt to the manufacturer except for 3 batches of the drug whose samples were found NSQ by both SDTRL and CDL, Kolkata. These three batches were ordered to be replaced by the manufacturer immediately which was done. This showed that necessary precautions had not been taken during sampling and despatching the same to testing laboratories. In fact during hearing before the Principal Secretary, Health and Family Welfare Department, the Drug Control Organisation could not even refute the argument of the manufacturer that samples could have been damaged during transit to the testing laboratories.

Non-prosecution of manufacturers supplying NSQ drugs to Government Hospitals/ Dispensaries

Under the Central Purchase System of allopathic drugs for consumption in Government Hospitals and Dispensaries, the Deputy Director, State Drug Management Unit (SDMU), Bhubaneswar procured huge stock of medicines during 1998-2003, of these 365 batches of different drugs were declared as NSQ by the reputed private testing laboratories outside the State where such batches were sent for testing after sampling by the staff of DD,SDMU as per decision of Government. The supplying firm replaced 146 batches and the replacement details of 47 batches could not be made available to audit by DD,SDMU. Fifty-four NSQ drugs were declared as SQ on challenge by the firms in second and subsequent tests. The patients of the State were administered with 118 NSQ drugs. But no legal action under the Act could be initiated against the suppliers of these NSQ drugs including 37 blacklisted suppliers because the samples were not statutorily drawn by the concerned DIs and NSQ reports were not obtained from the CDL/SDTRL. It was observed that no clause was included in the contract agreement made with the suppliers of such drugs by the DD, SDMU to punish them under the Act in case of supply of NSQ drugs.

Absence of intelligence-cum-legal cell/Searches and Seizures

Section 22(c)(iii) of the Act empowers the DIs to search any manufacturing/selling premises and seize suspected drugs to be of NSQ/ clandestine stock for sale and take action for suspension and cancellation of licences and disposal of stocks in the manner prescribed under the DC Rules. However, no intelligence-cum-legal cells were established by the LAs so far to gather information on clandestine activities of drugs/cosmetics manufacturers/ traders and movement of NSQ/spurious items of drugs and cosmetics inside the State. No search and seizure case was noticed during the period under review. This was obviously due to non-functioning of intelligence cells and shortage of manpower under the LAs. The DC stated (August 2003) that Government had been requested to provide more staff and create the cell.

3.2.10 Training

To impart training and update the knowledge of the DIs, the Central Government had been conducting training programmes at Mumbai, Kasauli, Kolkata and Ghaziabad to which officers were deputed depending upon feasibility and suitability. It was noticed that 4 out of the 17 DIs in position

have not undergone any training and no training facilities exist in the State for developing/upgrading the skills of DIs.

3.2.11 Monitoring

The only State level activity to monitor and gear up performance of the Drug Controller's Organisation was holding of periodical meetings of all Drug Control Officers under the aegis of the Principal Secretary, Health and Family Welfare Department. Creation of a computerised database of manufacturers and sales licensees did not materialise, reportedly owing to financial constraints. The computerised management information system and monitoring system modules also did not start for the same reason. The State level Drug Advisory Committee which was set up by the Government in December 1999 to suggest measures for better implementation of the Act and Rules as well as other allied Acts/Rules did not meet until the Committee was re-constituted in December 2002. Even the minutes of the first meeting of the Committee held in February 2003 were not made available to audit since the Government as of May 2003 did not clear the same.

Lack of interface with the pharmaceutical industry/trade, consumers and medical profession

Generally, conferences/symposia are organised jointly with the Industry/Trade Association/Medical Practitioners etc. to enable the State authorities to get speedy and timely information on the regulatory issues involved and the problems, if any, in the implementation of the Act. During the period from April 1998 to March 2003, no such symposia/conferences were organised. The DC stated (August 2003) that meetings and discussions were being held with the trade associations as and when possible. His reply, however, was silent about the outcome of such meetings/discussions and the impact on drug control activities.

In the ayurvedic sector, however, two meetings were held in November 2001 and August 2002 with the licensed drug manufacturers of the State to discuss basic issues of implementation of the Act and Rules, setting up of a State level Advisory Board and other vital points including the Good Manufacturing Practice (GMP) which was made mandatory for the firms with effect from June 2002.

In the homoeopathic sector, no interface was created during the period covered under the review due to non-existence of any recognised association of manufacturers/traders.

Lack of follow up action on press reports

The Press plays an important role in unearthing the deficiencies of administration and at times it focuses on the plight of people through its reports. It was noticed that as many as 25 press clippings were brought to the notice of DC during 1998-2003 regarding circulation of fake drugs with/without valid drug licence. However, the response and follow up action to examine the correctness behind such allegation were very poor as the DC simply endorsed the same to the DIs concerned without pursuing any further action. In the homoeopathic and ayurvedic sectors, no watch was at all kept on Press report/clipping on the circulation of fake/NSQ drugs.

Inaction against NAQ report of survey samples

The Act/ Rules did not provide for drawal of any non-statutory survey samples by the DIs of the State. It was revealed from the records of DC's office that 20 Non Acceptable Quality (NAQ) reports were received by the DC during 1998-2003 from CDL/SDTRL due to drawal of non-statutory drug samples by nine[6] DIs of the State as detailed at Appendix-XXIII to this report.

The details of subsequent statutory sampling of such drugs for getting NSQ reports and initiation of legal action against the manufacturers could not be made available to audit by DC.

Thus, the whole exercise of survey sampling was futile and the patients of the State had to be administered with NAQ drugs manufactured by the above firms.

3.2.12 Conclusions

Enforcement of the D&C Act, 1940 was deficient in many major areas. There were shortfalls in the required inspection of the premises of licensed selling and manufacturing units. Expeditious steps were not taken by the Drug Inspectors to recall the Not of Standard Quality drugs well before the expiry dates. Licences were granted for manufacture of cosmetics prohibited by Government of India. Legal cells were not established in the State Drug Control Authorities to monitor the search and seizure and prosecution cases, nor were intelligence wings functioning to gather information on non-standard and spurious drugs and cosmetics. Testing facilities in the State Drug Testing and Research Laboratory were not adequate. Above all, due to lack of administrative arrangements, scanty release of funds, absence of sufficient staff and proper monitoring, an important piece of legislation ensuring proper standards of drugs and cosmetics could not become effective.

Recommendations

- Adequate funds, manpower etc. should be provided to the Drug Controller/Director, Indian Medicines and Homoeopathy for effective implementation of the Act.

- Vigilance and legal cells may be opened at appropriate places in the State to gather information on the offenders and prosecute them under the Act.

- Early steps should be taken for starting a drug testing laboratory in the Ayurvedic sector.

- Proposals should be sent to Drug Controller General (India) for fixing (a) the norms for sampling drugs and cosmetics by the DIs and (b) specific time limit for testing of each type of drugs in the testing laboratories for early reporting of the quality thereof.

[6] Cuttack-III(5), Dhenkanal (1), Ganjam-II(3), Keonjhar(1), Phulbani (1), Mayurbhanj(2), Puri (2), Rayagada (1) and Sundargarh (4)

- Arrangement should be made for statutory sampling of drugs purchased by the Deputy Director, State Drug Management Unit under central purchase system before they are despatched to Government hospitals and dispensaries of the State.
- Above all, the State level advisory committee should be convened regularly (a) to aid and advise the SDCAs to monitor the various lapses as discussed in this report and (b) to recommend to the appropriate authorities the necessary amendments to the Act in the interest of effective enforcement.

APPENDIX-XXI

(Refer paragraph 3.2.9 at page 60)

Statement showing the details of the licensees who were issued with conditional drug licence by the Drug Controller, Orissa during 1998-2003

Sl. No.	Name of the licencee	Category of licence granted	Date on which licence granted/ renewed	Period for licence granted	Deficiency noticed in audit
1.	M/s Orichem Laboratory, Puri	Renewal of licence with conditions	6 September 2002	January 1994 to December 2006	Conditional licence was granted for manufacture of 15 items against 8 items recommended by the drug control officials during inspection on 20 May 2002. The firm was notified (12 September 2002) to rectify 5 number of defects within 30 days.
2.	M/s Syamakali Weaving Factory, Gopinathpur	-do-	12 March 2001	January 2001 to December 2002	The firm was notified (8 March 2001) to rectify 7 deficiencies within one month (provision of cutting machine, bleaching of the product in own unit, testing of finished products, uniform health care of the workers, etc.). The DC stated (August 2003) that the deficiencies were complied vide letter dated 27 March 2001. However, no evidence could be shown to audit that the complied conditions were verified.
3.	M/s Maa Surgical, Nuapatna, Tigiria	-do-	31 July 2002	January 2002 to December 2006	The firm was notified (30 July 2002) to comply 8 deficiencies within 30 days (improvement of hygenic condition, provision for testing of raw materials, check of health condition and supply of uniform to workers, fresh consent letter from the approved laboratory of testing, specification of batch size and obtaining test reports from the testing laboratory, labeling of batch with name manufacture and date of manufacture etc). The DC stated (August 2003) that the firm complied with the conditions vide letter dated 10 September 2002. However, no evidence of verification of complied conditions could be shown to audit.
4.	M/s Magnum Pharmatech (P) Ltd. Bhubaneswar	Conditional certificate for renewal of 13 items of cosmetics	1 June 2001	January 2001 to December 2002	As per DC's letter dated 1 June 2001, 5 defects were to be rectified within one month. The DC stated (August 2003) that the firm complied the defects vide the firms letter dated 10 March 2003. However the reply is silent about the verification of the complied conditions.
5.	M/s Asian Drugs and Chemicals, Berhampur	Conditional Certificate of drug licence	8 August 2002	January 2002 to December 2006	As per the certificate dated 8 August 2002, 14 vital deficiencies were to be rectified within 30 days. However, none of the deficiencies were rectified as of March 2003. The DC stated (August 2003) that the firm complied the conditions vide the 'firms letter' dated 25 June 2003. However, the reply was silent about the verification of the complied conditions.

APPENDIX-XXII
(Refer Paragraph 3.2.9 at page 62)
Statement showing the poor follow up action in respect of NSQ drugs

Name of the firm/ Validity of licence	Name of drug. Batch No. and Date of Manufacture	Date of declaration of NSQ	Remarks
M/s Trio Pharma, Ahmedabad / Not known	Vitaprot, Batch No VT128 Manufactured on 3 July 1998	17 January 2000 (CIPL)	The ambiguous report dated 19 November 1999 about the drug as "SQ but spurious" was finally modified to "NSQ and spurious" on 17 January 2000 by CIPL, Gaziabad when expiry date was over on 2 January 2000. Hence no prosecution case could be launched by DC against the firm. DC's request to the Commissioner, Food and Drug Control Administration, Gujarat State in February 2000 for taking suitable action under the Act against the firm was not responded as of August 2003.
M/s Paras Pharmaceu-ticals, Sambalpur/Up to December 1998	a) Cotrimexazole Tab. DS (IP) B.No.22, Manufacturing date: January 2000	16 March 2001	Firm is running without licence. Prosecution cases in respect of (a) and (b) were launched only in August 2002 the results of which were awaited (August 2003). No case was launched against (c) by the DI, Sambalpur on seizing the available stock/purchase and sale bills, other records, raw materials etc. despite instruction of DC to do so (January 2003) followed by reminder (July 2003).
	b) Syrup U.Sol (BP). Batch .No :Tu 107 Manufacturing date: January 2000.	27 December 2001	
	c) Prufen Plus Batch . No.- R-21 Manufacturing date: February 2000	26 August 2002	
M/s Sunny Pharma-ceuticals, Sambalpur/ December 2006	a) Enzyspa Liquid. Batch No- EZ0 14, Manufacturing date: February 1999	7 June 1999	Firm recurrently manufactured an NSQ drug. Show cause notice (June 2002) of DC was not responded. DC stated (August 2003) that the firm was served with a notice in July 2003 for personal hearing and disposal of the case.
	b) Enzyspa Liquid Batch No. 036 Manufacturing date: December 2001	15 May 2002	
M/s Bio-tech Medical Private Mehboobnagar (AP)/ Not known	Bathadoxin-12 Batch.No. BM-002 Manufacturing date: March 2000	30 March 2001	No prosecution case was launched as of August 2003 although 3000 phials of the drug were consumed in Cuttack alone by the time the test report was received (May 2001). The DC stated (August 2003) that the DC, Andhra Pradesh was moved for taking action (May 2001) since the firm was located under his jurisdiction. The reply was silent about any follow up action.
M/s Gayatri Pharmaceutical Private Ltd. / Not known	Bactecine suspension Batch No.8809(96) Manufactured: September 1996	May 1998 (SDT and RL)	In response to Drug Recall letter of DI, Jeypore, the local druggist M/s Mancheswar Pharmaceutical from whom the sample was drawn explained that 144 phials of drug were procured from the manufacturing firm in December 1996. Out of this, 67 phials were returned (No details), 33 phials were broken (No details) and balance 44 phials were sold to local dealers (33 phials in March 1996 and 11 phials in July 1996). This was fallacious because sale could not precede the date of procurement. The DI agreed (February 2003) to investigate into the matter at belated stage when the expiry date of drugs was over in August 1998. Further reply awaited (October 2003).

APPENDIX-XXIII
(Refer paragraph 3.2.11 at page 65)
Statement showing the details of Not Accepted Quality (NAQ) reports

Sl.No.	Name of the DI	Year of drawal of non-statutory samples/Month of receipt of NAQ reports	Name of the manufacturing firm	No. of drugs declared NAQ	Name of the testing laboratory
1.	Cuttack-III, Cuttack	1998-99 July 1998	M/s Orissa Red Cross Blood Bank Limited, Cuttack	5 LVP fluids	SDT and RL
2.	Puri	1998-1999 June 1997 and March 1999	M/s. Lupin Laboratory, Mumbai and M/s Neelachal Chemicals	1 Cephalexin 1 New Phenyle	CDL under NSQED SDT and RL
3.	Ganjam-II, Chatrapur	2000-01 November 2000	M/s Chemie India, IE, Cuttack	3 Gauze and bandage items	CDL under NSQED
4.	Keonjhar	2000-01 November 2000	M/s Brij Textiles, Delhi	1 Gauze and bandage items	CDL under NSQED
5.	Phulbani	2000-01 November 2000	M/s Maa Durga Handloom Industries, Cuttack	1 Gauze and bandage items	CDL under NSQED
6.	Dhenkanal	2000-01 November 2000	M/s B.K.Surgicals, Madhya Pradesh	1 Gauze and bandage items	CDL under NSQED
7.	Sundergarh	2000-01 November 2000	M/s. Rabindra Handloom WCS Limited, Sambalpur M/s Adertin, Kolkota M/s B.K.Surgicals, Madhya Pradesh M/s. JP Industries, West Bengal	1 Gauze and bandage items 1 Gauze and bandage items 1 Gauze and bandage items 1 Gauze and bandage items	CDL under NSQED CDL under NSQED CDL under NSQED CDL under NSQED
8.	Mayurbhanj	2000-01 November 2000	M/s Ananda Bandage, Uttar Pradesh M/s Joycot Industries, Andhra Pradesh	1 Gauze and bandage items 1 Gauze and bandage items	CDL under NSQED CDL under NSQED
9.	Rayagada	2000-01 November 2000	M/s Ananta Bandage Pvt. Ltd., Uttar Pradesh	1 Gauze and bandage items	CDL under NSQED