HEALTH AND FAMILY WELFARE DEPARTMENT

3.2 Review of implementation of the Drugs and Cosmetics Act/Rules

Highlights

Huge deficiencies in inspection, drawal and analysis of sample drugs and laxity in monitoring compliance with the results of analysis indicated that Department of Drugs Control had not discharged enforcement functions effectively. Improper decisions favouring licensees, reporting results of analysis after expiry of validity date of drugs and abnormal delay in a few other cases facilitated marketing of drugs found 'not of standard' quality. Drugs Controller had no information regarding number of seizures of sub-standard/fake drugs. In test-checked Circle Offices, such drugs were seized only in 48 cases (seven per cent) out of 671 'not of standard' drugs. Abnormally low percentage of seizures indicated lack of determination to prevent marketing of drugs found 'not of standard' quality. Drug testing laboratory was found deficient in equipment, manpower and methods of analysis, as a result of which 2,032 samples could not be analysed and were given 'no opinion' report. Performance of intelligence wing was unsatisfactory considering that action in respect of 826 cases (86 per cent) out of 961 complaints was pending for periods ranging from one to seven years.

There were shortfall in drawing samples and their analysis, drugs found 'not of standard' were neither seized nor replaced. Improper decision of Drugs Controller in three cases of drugs found 'not of standard' quality resulted in undue favour to licensees.

(Paragraph 3.2.5)

Out of 961 complaints received from public, pharma associations, hospitals, cases for prosecution were launched in 135 cases only.

(Paragraph 3.2.6)

Drugs Controller failed to detect selling of drugs at rates higher than those fixed by National Pharmaceutical Pricing Authority.

(Paragraph 3.2.7)

In disregard of instructions of State Government, Director issued 75 licences for manufacture of Ayurvedic/Unani drugs, though the required quality control wing was not set-up by them. No quality control measures were in place in respect of Homoeopathy and Ayurvedic drugs.

(Paragraph 3.2.8)

3.2.1 Introduction

In the context of large number of Indian and foreign companies undertaking manufacture/sale of drugs and cosmetics, a need arose for regulation of the

activity. Government of India, therefore, enacted Drugs and Cosmetics Act, 1940 (Act) and framed Drugs and Cosmetic Rules, 1945 (Rules). The main objective of Act and Rules was to regulate manufacture, storage and sale, distribution of drugs and cosmetics. Following are some of the main features of the Act:

- Regulatory measures to ensure availability of standard and quality drugs and cosmetics at reasonable prices
- Licensing of manufacture/sale/distribution etc.
- Establishing Drugs Testing Laboratory
- Punitive measures for non-compliance with provisions of Act/Rules

Provisions contained in other Acts viz., The Drugs and Magic Remedies (objectionable advertisement) Act (DMR Act), Drug (Price Control) Order 1995 are also applicable for manufacture, sale etc.

3.2.2 Scope of Audit

Grant of licences, inspections, recall of substandard drugs and cosmetics and prosecutions were the main areas of audit examination. The implementation of Act for the period 1998-2003 was reviewed during January 2003 to July 2003 through test-check of records of State Drugs Controller, Karnataka, Drug Testing Laboratory (DTL) at Bangalore, 10 Circle Offices, and one District Office out of 31, three divisions of Blood Banks and Intelligence Wing.

3.2.3 Implementation arrangement

The Drugs Controller (DC) is functioning under the administrative control of Principal Secretary to State Government, Health and Family Welfare Department. DC is the Head of the Department. In respect of Indian System of Medicine, Director is the Head of the Department. The Director is assisted by two Drugs Inspectors (DI) at the State level. In respect of Drugs Control Department, number of officers in position in the cadre of Assistant Drugs Controller (ADC) to Additional DC, were almost same as sanctioned strength. However, in the cadre of Drugs Inspectors (DI) and technical staff of Drug Testing Laboratory (DTL), sanctioned strength was reduced from 56 to 46 and 76 to 67 during 1998-2003 and the deficiency of men in position was 27 and 14 *per cent* respectively. No efforts had been made to provide sufficient staff for proper implementation of the Act.

3.2.4 Standing of the Law/Enforcement

Relationship with other laws

Advertisements claiming to cure/prevent certain ailments/diseases mentioned in schedule to DMR Act are prohibited. Schedule J to Rule 106 of Drugs and Cosmetic Rules which is not applicable to Homoeopathy, Ayurvedic and Unani drugs, also contain names of certain diseases/ailments which no drug may claim to prevent or cure. However, the names of ailments and diseases mentioned in these two schedules are not identical. There is need to ensure

uniformity between the two schedules in order to initiate action against advertisements on Ayurvedic, Homoeopathy and Unani drugs claiming to cure/ prevent any disease/ailment mentioned in Rule 106 but not in DMR Act.

Infirmities in Act/Rules for prosecution

Prosecution of manufacturer outside the jurisdiction of a Drugs Controller of a State

In case, manufacturing units of sample drugs found 'not of standard' are located outside the jurisdiction of DC of a State, the test reports are forwarded to DC of the concerned State for further action. This involves delay and possibility of not filing cases before expiry date of drug. DC for Karnataka stated (October 2003) that details (constitution of firm, persons responsible for manufacture, methods of analysis etc) would not be available in respect of such units and cases were transferred to DC of concerned State according to guidelines of Drugs Consulative Committee (DCC). However, it is imperative that DC under whose jurisdiction sample drug was tested, file cases against manufacturer and pursue the case. It is observed that the guidelines issued by DCC prescribed that either DC in whose jurisdiction sample was tested or manufacturer is located could file cases. Further, there are various case laws of courts regarding prosecution of manufacturers by courts in whose jurisdiction sample was tested/dealer situated irrespective of place of manufacture. In view of these facts, there is need for suitable provision in the Act empowering DC of a State to file cases against manufacturers irrespective of their location.

Furnishing a copy of Reports of Analysis and a portion of sample

According to existing provisions, sample drawn is divided into four parts, of which one part is sent to Government Analyst, one to person from whom sample was drawn, one to person whose name is disclosed under Section 18A (not being a manufacturer or dealer) and the last one is retained for being produced before the court. Similarly the Government Analyst furnishes his report in triplicate of which one is given to the person from whom sample is collected, one to the person named under Section 18A and the last one retained by DI. However, there could be a case where number of accused persons are more and all of them could not be provided with a copy of the report and sample. In that case, it would not be possible to secure conviction of the accused without furnishing copy of the Analyst's report and portion of the sample. There are case laws in this regard which imply that serving copy of the report and portion of the sample is mandatory. Hence there is need for suitable amendment to Sections 23 and 25.

3.2.5 Implementation of the Act

Licensing functions

- ***Deficiency in licensing procedure***

Rules do not contain provisions to issue licences to selling units of Ayurvedic, Unani and Sidda medicines and cosmetics whereas such provisions exist in

respect of allopathic drugs and cosmetics. The provisions thus, differentiates between selling units of the two systems. Thus, there is need to bring Ayurvedic, Unani and Sidda drugs/cosmetics selling units under licensing procedure.

- ***Non-renewal of licences***

An original or renewed licence was valid upto 31 December of the year following the year in which it was granted or renewed (five years in respect of licences granted/renewed after September 2001). If the application for renewal of licence was not made within six months of its expiry, licence would be deemed to have expired. It was seen in audit that 95 licensees did not apply for renewal of their licences whose validity expired during December 1995 to December 2001. DC passed orders for cancellation of these licences during September 2000 to April 2003 after delay ranging from nine to 58 months as detailed below:

Number of licences	1	7	28	17	21	1	20
Month in which expired	Dec. 1995	Dec. 1996	Dec. 1997	Dec. 1998	Dec.1999	Dec. 2000	Dec. 2001
Period of cancellation	Oct. 2000	Oct. 2000	Oct. 2000	Oct. 2000	Sep. 2000 (1) Oct. 2000 (20)	April 2003	Nov. 2002 to April 2003
Delay in cancellation (in months)	58	46	34	22	9 to 10	28	11 to 16

Premises of these licensees were not inspected either after expiry of validity period or cancellation of licences. No surveillance/survey was in vogue to ensure that such licensees closed their activity after expiry of the licence. DC attributed (October 2003) this non-inspection to shortage of staff.

- ***Licences pending renewal***

One hundred and forty seven[◈] applications were pending for renewal of licences from December 1999 to December 2002. DC attributed (October 2003) pendency to non-inspections on account of inadequate staff and non-compliance by applicants to show cause notices etc. The plea was not tenable as delay in disposing of the applications for renewal of licences enabled the applicants to continue their activity even if some of the conditions for renewal were not fulfilled and it was the responsibility of the DC to ensure fulfilment of conditions.

- ***Non-cancellation of licences in respect of blood banks***

Applications for renewal of licence submitted by 27 blood banks were pending

In respect of blood banks also, original licence continued to be valid if applied within six months of expiry of original licence unless cancelled. Twenty seven blood banks applied for renewal of licences for 2000-02. These applications were still (December 2003) pending for various reasons[◆]. Scrutiny of inspection reports of nine blood banks revealed that these blood banks continued to function without certain essential equipment (Dielectric tube sealer, Blood agitator). Position in respect of remaining 18 blood banks

[◈] Two from December 1999, five from December 2000, 20 from December 2001, nine from January 2002, five from May 2002, 106 from December 2002

[◆] (a) non-receipt of compliance to verification reports, (b) not conducting joint inspections and (c) under review

could not be verified in absence of inspection reports. Failure of DC to conduct inspection and not ensuring compliance to inspection reports facilitated these blood banks to function without continued fulfillment of licence conditions.

Inspections

- ***Manufacturing and selling units***

As prescribed under Act/Rules, DIs were to inspect every manufacturing and selling units twice a year (reduced to once a year from September 2001) so as to ensure that licensees comply with Act/Rules/good manufacturing practices. However, there were huge shortfalls in inspections as indicated below:

Year	Number of			Number of		
	Manufacturing units existing	Inspections prescribed	Inspections conducted	Selling units existing	Inspections prescribed	Inspections conducted
1998-99	732	1,464	290 (80)	12,747	25,494	14,053 (45)
1999-2000	697	1,394	339 (76)	13,659	27,318	15,053 (45)
2000-01	707	1,414	201 (86)	15,009	30,018	14,074 (53)
2001-02	600	600	273 (55)	15,500	15,500	16,001
2002-03	635	635	220 (65)	17,921	17,921	14,579 (19)

Note: Figures in bracket indicate percentage of shortfall

Huge shortfall in inspections were indicative of ineffective monitoring on working of these units

Assistant Drugs Controllers (ADCs)/DIs had not maintained any control register indicating period and other details of inspection unit-wise. In the absence of such register, whether every unit was inspected periodically as per norms could not be verified. However, it could be derived from the above data that at least 327 to 506[⊕] manufacturing units during 1998-2003 and 935[♣] and 3,342[Ψ] selling units were not inspected even once during 2000-01 and 2002-03 respectively considering one inspection per unit. Even after reducing scale of inspection, deficiency persisted. DC attributed huge deficiency of inspections to shortage of DIs. However, percentage of vacancy of DIs was only 27 *per cent* and as such there was no justification for overall shortfall of 55 to 86 *per cent* in inspection.

- ***Blood banks***

According to instructions issued (February 2000, January 2003), by DC, every DI was to inspect two blood banks per week. As against 960 inspections in Bangalore Division and 480 inspections to be conducted each in respect of Gulbarga, Hubli and Mysore Divisions on the basis of DIs in position[◎], shortfall was 83, 68, 48 and 38 *per cent* during 1998-2003.

⊕ 732-290 = 442, 697-339 = 358, 707-201=506, 600-273=327, 635-220 =415

♣ 15,009-14,074 = 935

Ψ 17,921-14,579 = 3,342

◎

Division	Number of DIs in position					Total
	1998-99	1999-00	2000-01	2001-02	2002-03	
Bangalore	2	3	3	1	1	10
Mysore	1	1	1	1	1	5
Hubli	1	1	1	1	1	5

Sampling/analysis

- ***Shortfall in sample analysis***

Vital functions aimed at detecting 'not of standard' drugs not performed to a large extent

Act/Rules envisaged drawal of drug samples for analysis from manufacturing and selling units to ensure that drugs conform to prescribed standard and quality. Details of samples drawn, analysed etc., as against targets in respect of Allopathic medicines were as follows:

Year	Number of chemists in position	Targets	Number of samples drawn	Samples analysed	Rejected	Not of standard
1998-99	8	2,400	1,973 (18)	1,796	4	163
1999-00	21	6,300	2,623 (58)	2,201	29	241
2000-01	21	6,300	2,899 (54)	3,019	17	253
2001-02	19	5,700	2,848 (51)	2,852	40	486
2002-03	27	8,100	3,119 (62)	3,273	85	267
Total		28,800	13,462 (53)	13,141*	175[@]	1,410

Note: Figures in bracket indicates percentage of shortfall

* Includes 2,032 samples (15.5 *per cent* of samples tested) declared as 'no opinion'

[@] Rejected for want of facilities

While the shortfall in drawing samples against targets was 53 *per cent*, there was shortfall in analysis of 17 *per cent* (including samples declared as no opinion). Out of 13,462 samples, only 432[◈] were drawn from manufacturing units as against 732 to 635 units in existence in each year from 1998-2003. Thus, samples were not drawn from large number of manufacturing units ranging from 696 (95 *per cent*) in 1998-99 to 531 (84 *per cent*) in 2002-03. Similarly, samples were also not drawn from selling units ranging from 81 to 85 *per cent*[Ψ]. Thus, the most vital statutory function aimed at detecting 'not of standard[Φ]' drugs was largely not performed.

DC attributed (April 2003) shortfall and delay in analysis to shortage of chemicals and supporting staff, non-receipt of method of analysis for propriety and multi-gradient drugs from manufacturers. As there was no shortage of funds for purchase of chemicals and Department/State Government had not initiated action for recruitment of staff, reply was not tenable. DC had not also exercised authority vested with him under Act/Rules to obtain necessary details on the methods of analysis from manufacturers.

- ***Non-drawal of legal samples***

Under National Survey on Quality of Essential Drugs (Central Scheme), DIs were to draw one strip of sample drug referred as informal sample and send them to Deputy Drugs Controller, Central Drugs Standards Organisation

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[◈] 36 in 1998-99, 95 in 1999-00, 174 in 2000-01, 23 in 2001-02 and 104 in 2002-03

[Ψ]

Total samples	1,973	2,623	2,899	2,848	3,119
Less relating to manufacturing units	36	95	174	23	104
	1,937	2,528	2,725	2,825	3,015
Selling units	12,747	13,659	15,009	15,500	17,921
Percentage	85	81	82	82	83

[Φ] Drugs 'not of standard' means not conforming to standards prescribed in Indian/British/ United States Pharmacopoeia

(DDC), Chennai. DDC, Chennai was to arrange analysis of such samples through Central Drug Testing Laboratory, Kolkata. DDC, Chennai forwarded to DC, five♠ test reports declaring samples as 'not of standard' quality and also the concerned DIs of Bellary and Hassan who had sent these samples to the former.

DC instructed DIs of only these two districts to draw legal sample (four strips of sample drugs following the procedure prescribed in Section 23 of the Act) after delay of three months in one case and 21 months in another case. DC did not take any action on the remaining three test reports. ADCs/DIs of other districts were not instructed for drawing sample of these drugs. ADCs/DIs even in Hassan and Bellary districts did not draw the samples but furnished non-availability of drugs. Thus, the belated instructions and failure to take action on remaining reports by DC facilitated marketing of 'not of standard' quality drugs and rendered exercise of drawal and analysis of informal samples by DDC, Chennai futile. DC stated that copies of the reports were sent to DCs of Maharashtra, Delhi, Gujarat and Andhrapradesh in whose jurisdiction such manufacturers were located. However, DC, Karnataka had no details of action taken.

Drug testing laboratory (DTL)

DTL had been functioning in Bangalore under the supervision of DC with the objective of testing and analysing sample drugs referred to it from various ADCs/DIs and report results of analysis. However, there were deficiencies in manpower, equipment and other facilities leading to delay in analysis, furnishing no opinion report and rejection of samples etc., as discussed below.

Delay in analysis and reporting results in respect of drugs found 'not of standard' quality

Abnormal delay in sample analysis and reporting results thereof facilitated marketing of substandard drugs, delayed/ prevented prosecutions

DC was to arrange allocation of samples received in DTL, Bangalore among its different branches, to ensure timely analysis and reporting of results. DTL was to deliver reports of analysis of sample drug to concerned officers on the same day on which sample drug was analysed. There were abnormal delays in allocation, analysis of samples and reporting the results as indicated below:

- Delay in allocation of samples ranging from 15 to 60 days (374) and 61 to 90 days (42)
- Delay in analysis of samples ranging from three to six months (3,004), seven to 12 months (1,127), 13 to 24 months (420)
- Delay in reporting results of analysis to Circle Office, Bangalore from DTL ranged from 10 to 15 days (20) and 16 to 30 days (six) though both were located within the same building.

♠

Month of report	Name of drug/batch number	Source of drawing sample
March 2001	Analgin	Ambika Medical Stores
February 2002	Erithromycin, 23, 00562-75 -498	1. Rajat medicals, Nelamangala 2. City Drug House, Hassan, 3. Gururaghavendra Medicals, Mysore
March 2002	Ampicillin C/31	Prasad Medical Stores, Channarayapatna

- Reporting the results of analysis to other circle offices were delayed by 10 to 15 days (28) more than 15 days (84).
- On receipt of reports of analysis from DTL and other States, DC issued showcause notices to 21 concerned manufacturers located in Karnataka after delay ranging from 30 to 60 days (13) and 61 to 90 days (six). In respect of manufacturers outside Karnataka, delay in reporting result of analysis ranged from 30 to 450 days (19).
- In respect of nine sample drugs, results of analysis were reported to concerned officers within and outside the State after expiry date of drugs, while in another 44 sample drugs, in the same month in which validity of drugs expired though sample drugs were received in DTL one to four months before expiry date. Evidently, this indicated lack of prioritisation by DTL and facilitated marketing of such drugs and ruled out prosecutions. Thus, the whole exercise of drawing and analysis were rendered futile.

(Note: Figures in bracket indicates number of samples/reports).

Lack of facilities at DTL

Underutilisation of available manpower, idle equipment and lack of facilities/ insufficient trained personnel rendered performance of DTL ineffective

Two thousand and thirty two sample drugs (15.5 *per cent* of samples tested) after testing for one or two ingredients were declared as 'no opinion' due to lack of facilities for testing remaining ingredients. Another 175 sample drugs were also rejected for reasons like insufficient quantity (eight), receipt of sample after expiry date (seven), samples not being a drug (11), technical grounds/instruments not available (38) and reference standards/methods of analysis not available (103), chemicals not available (eight). The procedure adopted by DTL for conducting sterility test (by direct inoculation method using lamino flow of air) was different from that prescribed by good manufacturing practices due to non-availability of necessary facilities. DTL was not equipped with facilities for analysing blood, sera and vaccine also.

Vacancies

Details regarding sanctioned strength in technical and non-technical cadres and men in position were as follows:

Cadre	Sanctioned strength		Working strength				
	1998 to 2000	2001-2003	1998-99	1999-2000	2000-01	2001-02	2002-03
Technical staff	76	67	34	49	50	50	58
Non-technical staff	52	49	44	44	40	39	38

As against overall deficiency of 55 *per cent*♣ in sample analysis, the vacancy was 21♦ *per cent* (Technical staff) and 20 *per cent*♦ (Non-technical staff) during 2001-03. With the available staff, 20,100 samples could have been analysed as against 9,144 during 2001-03. This indicated underutilisation of even available manpower.

♣ Total samples to be drawn from 2001-03 = 20,100
Total samples analysed from 2001-03 = 9,144
Percentage of shortfall = 55

♦ Technical staff
50+50 +58 = 158/3 = 53/67 = 79

Non-technical staff
40 +39+38 = 117/3 = 39/49 =80

Idle equipment

While on one hand several samples could not be analysed for want of facilities, on the other, 12 equipment costing Rs.26.42 lakh remained idle for periods ranging from two to 52 months (as of March 2003) for want of repairs. No action has been taken for repairs despite availability of funds under Equipment Maintenance and Material Supplies. Certain tests like partial analysis of Vitamin B1 and B2, Antibiotics, Chemicals/Ingredients could not be conducted for want of Spectrofloro meter, High performance liquid Chromograph and Gas Chromograph.

Training

As against 34 to 58 technical officers in position during 1998-2003, 11 officers were trained. No specific programme had been prepared to impart training to staff.

Ineffective follow-up action on analysis reports in respect of sample drugs found "not of standard"

Improper decision of DC on sample analysis report

DC favoured manufacturers through decisions disregarding Act/Rules

According to Section 25(4) of Act/Rules in respect of sample drugs reported as 'not of standard' quality by Government Analyst, if a person from whom the sample was drawn, furnished within 28 days of receipt of such report, evidence in contravention of the report, Court may on its own or at the request of either Department or person could refer sample to Central Drug Testing Laboratory for analysis. However, in the following three cases of drugs reported as 'not of standard' quality, decision taken by DC was improper and contrary to provisions of Act/Rules:

Sl.No	Particulars	Audit comment
1	A. Medrich Formulations Ltd., Bangalore B. Polyvitamin Tablets C. 12.9.2001 from DTL, Bangalore	Though DC had no authority to arrange re-analysis of sample drugs, he ordered (March 2002) for the same. According to Section 25 of the Act, reanalysis was permissible only on orders of court. DC further ordered drawal of second set of samples though there was no provision in the Act. DC stated (October 2003) that as a technical officer he decided on re-analysis/drawal of second set of samples. The reply was not tenable as his action contravened provisions of Act/Rules besides, facilitating marketing of such sub-standard drugs.
2.	A. Bal Pharma Ltd, Bangalore B. Spasmonar tablets C. 2.5.2002 by DTL, Bangalore`	On receipt of explanation from the licensee challenging test report (attributing the defect to storage conditions), DC ought to have filed case in the court for a decision on the test report as required under Section 25(4) of the Act. Contrary to this, DC ordered drawal of sample out of the control sample though he had no authority/provision in the Act. Neither the records indicated whether the control sample was drawn and tested as ordered by DC, nor reply (October 2003). No further action was also taken.
3.	A. Medrich Sterilab Ltd, Bangalore B. Augumentin syrup C. 24.10.2002 by Government Analyst, Ghaziabad	DC delayed by 2 months issue of show-cause notice to the licensee on the test report received from Drugs Controlling Authorities, Delhi. DC's acceptance of explanation of the licensee challenging test report on the ground of indicating incorrect weight in test report was improper as drugs failed beyond permissible limit°. However, this was later investigated (June 2003) jointly by Drugs Control Authorities of Delhi and Karnataka State. Manufacturer had filed (September 2003) case in the High Court of Karnataka.

A = Name of the firm, B= Name of the Drug, C= Date of reporting

° Weight as per lable 28.5 mg/5 ml, Actual weight as per test report 15.2 mg/5ml, variation 13.3 mg, permissible variation 2.85 mg

Failure to seize/prevent marketing of drugs 'not of standard' quality

Out of 671 cases of drugs found 'not of standard' quality in test-checked Circles/ Divisions, drugs were seized/ replaced in 48 cases only

Out of 1,595 sample drugs (1,410 detected by DTL, Bangalore and 185 reports received from other States) found 'not of standard' quality details regarding number of cases where such drugs were either seized/replaced were not available with DC. DC stated (July 2003) that it was difficult to furnish the same. The reply evidently indicated that DC had not monitored this important activity. However, in test-checked circles/divisions involving 671 sample drugs found 'not of standard' quality, there were no seizures at all in six circles, one case in each of three circles and 45 cases of seizure in another five circles. Thus, percentage of seizure in test-checked circles was seven.

Poor progress on prosecution cases

Out of 1,595 sample drugs, manufacturers of 276 sample drugs (185 + 91) were located in Karnataka. Of these, action against 84 cases (nine cases of 1998-99, five cases of 1999-2000, 26 cases of 2000-01, 23 cases of 2001-02 and 21 cases of 2002-03) were pending with DC. Reasons for the same had not been furnished. In remaining cases, DC issued warning (113), suspended/cancelled the licences (60), cases filed in court (nine). No action was taken on remaining cases (10).

Laxity in follow-up actions, delay in reporting, ineffective discharging of enforcement functions

In respect of 1,319 sample drugs, manufacturers were located outside the State. Analysis reports were sent to DCs of respective states though DC in Karnataka could have filed cases against manufacturers according to various case laws. The DC also did not pursue the matter with Drugs Controlling Authorities of other States and the action taken by the latter was also not available. Thus, there was no system to monitor compliance with analysis reports.

3.2.6 Performance of intelligence wing

An intelligence wing was created during August 1998 with 11 staff (four DDCs, seven DIs). Functions of intelligence wing inter alia consisted of detection of spurious, misbranded, 'not of standard' drugs, investigation of complaints and blood bank monitoring.

Scrutiny of records revealed the following:

- As against 961 complaints received from public, hospitals and pharma associations, cases for prosecution were launched in respect of 135 only during 1998-2003 and all these cases are still pending. Investigation of remaining 826 complaints (86 *per cent*) were pending from 1998-99 (96) 1999-2000 (194), 2000-01 (195), 2001-02 (167) and 2002-03 (174). Reasons for pendencies had not been furnished to audit.
- A team headed by an ADC, Circle-I, Bangalore investigated a complaint against Karnataka State Small Industries Marketing Corporation (KSIMC) and a few dealers registered with it regarding sale of disposable hypodermic syringes and needles without licence and also on its quality. The team submitted (October 1998) report to DC who sought (July 2000)

permission of State Government after delay of 21 months to initiate action against KSIMC and latter granted (August 2003) permission after further delay of three years. Action against officers of KSIMC is yet to be initiated. No action had been initiated against dealers also though no such permission was required.

3.2.7 Non-compliance with the Drugs Price Control Order/ Guidelines

Approval of new formulations without informing National Pharmaceutical Pricing Authority

DC failed to report to NPPA grant of licences for new drugs

Government of India issued Drugs Price Control Order, 1995 and further guidelines (October 1999) which inter alia empowered National Pharmaceutical Pricing Authority (NPPA) to fix maximum retail price for drugs. According to the guidelines, DC was to report cases of granting licence for manufacture of new drugs/formulations or new dosage for existing scheduled formulations. Though DC granted (October 1999 to December 2002) licences for manufacture of 154 new drugs/formulations, the same was not intimated to NPPA.

Failure to detect marketing of drugs at higher rate

In one case, ie., Ibuprofen (400 mg)+ Paracetamol (333 mg) tablets, NPPA had fixed (July 2002) price of Rs.5.24 plus excise duty and local tax per strip containing 10 tablets. Against this, six♣ firms marketed the drug at the rate ranging from Rs.7.26 to Rs.13.80. DPC cell/intelligence wing failed to detect selling of drug at higher rate. DC stated that his officers had not come across the said formulation (Ibuprofen 400 mg + Paracetamol 333 mg) after August 2002. However, scrutiny revealed that one firm had informed DC during May 2003 that they had been manufacturing the said formulation and furnished price list (as of April 2003) which indicated the price at Rs.12.94 per strip. The contention of DC was therefore contrary to that borne in his own records. Evidently, monitoring of this aspect was quite ineffective.

Idle staff

State Government created (August 1998) a drug price control cell (Cell) with seven officers (one DC, two ADCs, four DIs) to investigate 137 cases of overpricing of drugs reported (1997-98) by ADC, Tumkur. However, these cases could not be investigated as manufacturers filed (December 1998) cases in High Court and NPPA notifications fixing prices were set aside (July 2000). Yet Cell was continued. During 1999-2002 Cell had not conducted any searches/seizures to detect cases of overpricing though they were empowered. Thus, Cell virtually remained non-functional resulting in nugatory expenditure of Rs.9.78 lakh.

♣ Allule Remedies, Talent Lab, Recon, Rekuvina Lab, Bal Pharma, Sky Marketing

3.2.8 Indian system of medicine and Homoeopathy

Irregular appointment of licensing authority in respect of Homoeopathy system

According to Act/Rules (49A), graduate qualified in Pharmacy or Pharmaceutical Chemistry or Medicine was to be appointed as licensing authority for Homoeopathic units. However, contrary to the provisions, State Government had appointed (order of October 1984) a graduate in Ayurvedic medicine as licensing authority for Homoeopathy system. Director, while admitting appointment as illegal attributed the same to non-amendment of provisions.

Grant of licences

Details of licences granted and renewed for manufacturing units under Ayurvedic/Unani and Homoeopathy by Director were as follows:

Year	Ayurvedic and Unani		Homoeopathic	
	Fresh licences	Renewals	Fresh licences	Renewals
1998-99	21	80	1	6
1999-00	36	94	3	4
2000-01	35	93	-	6
2001-02	23	115	1	4
2002-03	17	110	4	3

Scrutiny of records revealed following lapses:

Ayurvedic/Unani drugs had not been subject to quality control measures

Ayurvedic/Unani manufacturing units in existence as of June 2000 were to provide quality control section (QCS) within two years or obtain quality control certificate (QCC) from State Government approved laboratory. New licences were not to be granted unless QCS/QCC was provided. However, State Government had not approved any laboratory for this purpose so far and 261 units (Ayurvedic-252, Unani-nine) engaged in manufacturing as of June 2002, had also not provided the said facility. These included 75 licences issued subsequent to June 2000. Grant of these licences to those who had not provided QCS was contrary to Rules and therefore irregular. Renewal of licences in respect of existing Ayurvedic manufacturing units on obtaining undertaking to the effect that licensees would provide quality testing section was also irregular. Director replied (June 2003) that Ayurvedic/Unani units had expressed their inability to establish quality control sections as they were small units. Evidently drugs manufactured by these units had not been subjected to any quality control measures.

Inspections

Act/Rules prescribed inspection of every manufacturing unit twice a year under Ayurvedic/Unani system. In respect of Homoeopathy system, both manufacturing and selling units were to be inspected twice a year reduced to

once a year from September 2001. However, inspections were less than the scale prescribed as detailed below:

Year	Ayurvedic/ Unani and Homoeopathy (manufacturing) units in existence	Inspections		Homoeopathy selling units	Inspections	
		Prescribed	Conducted		Prescribed	Conducted
1998-99	262	524	144 (73)	170	340	190 (44)
1999-00	258	516	98 (81)	170	340	130 (62)
2000-01	278	556	110 (80)	172	344	35 (90)
2001-02	272	534	105 (80)	165	165	50 (70)
2002-03	272	533	135 (75)	164	164	44 (73)

Note: Figures in bracket indicates percentage of shortfall

Director attributed (May 2003) huge shortfall in inspections to shortage of staff. However, no proposal was sent to State Government to fill up the vacant posts. It was also observed that DI for Ayurvedic/Unani system had inspected Homoeopathic units which adversely affected the quality of inspection.

Non-drawal of samples

Though Act provided for drawal of sample drugs for analysis from both manufacturing and selling units under Homoeopathy system and only from manufacturing units under Ayurvedic system, samples were not drawn under both systems during 1998-2003 as State Government did not notify Government Analysts till July 2002. Even after notifying (July 2002) DIs and providing facility for analysis, samples were not drawn at all. Evidently, standard and quality of drugs had not been ensured.

3.2.9 Monitoring

Monitoring implementation of various functions was ineffective as evident from the following:

- Abnormal delays at all stages in analysis of sample drugs and reporting results. No measures had been taken to avoid such delays.
- In respect of reports referred to other States, no data regarding number of cases against whom prosecution were launched, seizure of drugs etc., was available and no system was in place to watch receipt of compliance in respect of such reports.
- Failure to prevent marketing of drugs found 'not of standard' quality.
- 86 *per cent* of complaints received were pending for one to seven years with intelligence wing.

3.2.10 Conclusions

There were huge deficiencies in inspections, drawal of sample analysis and delays in reporting results of analysis. Marketing of drugs 'not of standard' had also not been prevented. Drug Testing Laboratory was deficient in terms of manpower and equipment. Action taken by intelligence wing on complaints was grossly inadequate.

3.2.11 Recommendations

- A suitable provision needs to be incorporated in the Act/Rules empowering DC to obtain necessary data from manufacturers located outside their jurisdiction and file cases before courts having jurisdiction in places from where samples for analysis are drawn.
- DC should ensure proper surveillance before renewal of licences.
- Drugs Testing Laboratory needs to be strengthened in terms of manpower and equipment.

3.2.12 The matter was referred to Government in August 2003; reply is awaited.