Medical and Health Department

3.2 Implementation of the Drugs and Cosmetics Act

Highlights

Medical and Health Department was responsible for enforcing the implementation of the provisions of the Drugs and Cosmetics Act and Rules framed thereunder, to ensure availability of standard and safe drugs and cosmetics, at fair and affordable prices to the consumers and to see that the drugs were promoted through projection of factual information. The department, however, did not have adequate manpower to effectively enforce the regulatory functions. There was shortfall of 59 per cent in inspections of drug units to check compliance of provisions of the Act. In large number of cases, the firms continued their business without getting their licences renewed. Testing facilities for Ayurveda and Unani drugs and certain vaccines under Allopathic system were neither available with the State Drug Laboratory nor any alternative arrangements were made by Regulatory Authority and sub-standard drugs of these types, manufactured or sold, if any, remained undetected. Collection of drug samples for quality control was arbitrary as sample was not collected from large number of units for several years. Sub-standard and spurious drugs were in sale in the market and were supplied even to the Government hospitals. Punitive action against the defaulting units was not taken properly and promptly. The department thus, failed to achieve the objectives enshrined in the Act. Important points noticed in audit were as under:

Shortage of Drug Inspectors (68 *per cent*), as compared to the norms recommended by the Task Forces of the Central Council of Health and Family Welfare, led to a shortfall in inspection of Allopathic/Homeopathic drug selling units by 59 *per cent* during 1998-2003. For inspection of 230 to 366 Ayurvedic/Unani drug manufacturing units in the State, shortfall was 37 *per cent* during 1998-2003.

(Paragraph 3.2.11,3.2.24 and 3.2.25)

Testing facilities for large number of Allopathic drugs, articles, all Homeopathic, Ayurvedic and Unani medicines were neither available with the State Drug Laboratory nor any alternative arrangements for testing these items were made.

(Paragraph 3.2.14)

Seventy four *per cent* of the drug samples were tested after the prescribed period of 45 days from the date of collection of samples. The delay ranged between one and half month and one and half year. Licences of 25 out of 38 Blood Banks in the State were not renewed for the last two to seven years although they were in operation.

(Paragraph 3.2.15 and 3.2.17)

25 out of 64 drugs manufacturing units in the state have not been inspected and their samples were not tested during the period 1998-2003.

(Paragraph 3.2.18)

Prosecution cases increased from 324 in 1997-98 to 522 in 2002-03. The department did not take up the case for setting up special designated courts with the Government for their speedy disposal.

(Paragraph 3.2.28)

Records of complaint cases, of the violation of the provisions of the Act, were not maintained properly. Details made available disclosed that 227 cases were pending as of March 2003. Test-check disclosed that appropriate speedy action was not taken against the defaulters.

(Paragraph 3.2.29)

Adequate in-service training to staff was not imparted under Ayurveda/laboratory staff during 1998-2003.

(Paragraph 3.2.30)

Introduction

3.2.1 Government of India (GOI) enacted the Drugs and Cosmetics Act, 1940 (the Act) and framed Drugs and Cosmetics Rules 1945 to regulate the import into, manufacture, distribution and sale of drugs and cosmetics in the country and also to ensure availability of standard quality drugs and cosmetics to consumers, which otherwise pose a serious problem to public health. For keeping the prices of drugs under control, GOI also issued Drug (price control) order, 1995. The objectives of the legislation were to:

- ensure availability of standard and safe drugs and cosmetics;
- ensure availability of drugs at fair and affordable prices to the consumers and
- ensure that drugs are promoted through projection of factual information.

To achieve these objectives, the State Regularity Authority viz. State Drug Controller was entrusted with the functions of granting and renewal of

licences for manufacture, distribution and sale of drugs, carrying out inspections, testing of samples, vigilance and surveillance over the manufacturers/traders; and taking consequential legal/administrative action against the defaulters.

Regulatory machinery

3.2.2 The State Drug Controller (under the administrative control of the Director General, Health Services) and the Director, Ayurveda were the regulatory and licensing authorities for Allopathic/Homeopathic and Ayurvedic/Unani drugs respectively. The State Drug Controller was assisted by a Deputy State Drug Controller and three Assistant State Drug Controllers at State level. There were seven Senior Drug Inspectors at zonal level and 23 Drug Inspectors at District level.

Director, Ayurveda was assisted by an Assistant Director at State level and four Ayurvedic Medical Officers in the field.

A State drugs laboratory, headed by a Government Analyst, was functioning at Chandigarh since 1976 for testing the samples of Allopathic/Homeopathic medicines and cosmetics (except vaccine and sera).

Regulatory procedure

3.2.3 The licences for manufacture of drugs other than Ayurvedic and Unani drugs and their wholesale trade were granted and renewed by the State Drugs Controller while for the retail sale, by the Senior Drug Inspectors at zonal level. Licences for manufacture of ayurvedic drugs were granted and renewed by the Director, Ayurveda. Licences unless suspended or cancelled, were valid upto 31 December of the year following the year of their issue/renewal. However, licences issued and renewed after August 2001 were valid for five years from the date of their grant/ renewal. If a licencee failed to apply for renewal of licence within a period of six months after the date of its expiry, the same would be deemed to be invalid thereafter.

Drug Inspectors were responsible for inspection of the premises of allopathic and homeopathic drug manufacturing and sale units at least twice a year (once a year from September 2001). To ensure the quality of drugs/cosmetics, the samples were collected by inspectors from the manufacturing/selling units and sent to State Drug Laboratory for testing purposes.

If any person willfully prevents the inspector from discharging his duties or any serious offences are detected/suspected on the basis of sample testing or inspections, search and seizure, cases are filed against offenders in the courts of Chief Judicial Magistrates of the area for suitable penalty/punishment.

Audit coverage

3.2.4 Records relating to implementation of Act for the period 1998-2003 in the offices of the Director General Health Services, State Drug Controller, Government Analyst Haryana at Chandigarh and 10[2] out of 19 districts were test checked. Audit findings are discussed in the succeeding paragraphs.

Deployment of resources

Financial outlay and expenditure

3.2.5 Details of budget provision, expenditure and revenue receipts under Allopathic and Homeopathic systems for the period 1998-2003 were as under:

Year	Budget provision			Expenditure			Revenue receipts	
	(Rupees in lakh)							
	State	Central	Total	State	Central	Total	Budget Estimates	Receipts
1998-99	147.28	-	147.28	119.52	-	119.52	15.00	16.16
1999-2000	138.85	12.50	151.35	138.82	12.50	151.32	15.00	15.51
2000-01	140.86	12.50	153.36	140.80	12.48	153.28	20.00	20.00
2001-02	141.41	-	141.41	141.08	-	141.08	22.00	22.22
2002-03	151.84	-	151.84	146.32	-	146.32	23.00	23.00
Total	**720.24**	**25.00**	**745.24**	**686.54**	**24.98**	**711.52**	**95.00**	**96.89**

Note: No funds were provided for the implementation of the Act under Ayurveda and Unani systems of medicines.

Expenditure of Rs 7.12 crore comprised of plan expenditure of Rs 0.39 crore (seven *per cent*) of which Rs 0.25 crore was Central grant as indicated in the table above.

Scrutiny of records revealed that:

95 *per cent* of the expenditure was on establishment

3.2.6 Of the total expenditure of Rs 7.12 crore during 1998-2003, Rs 6.74 crore (95 *per cent*) were spent on establishment, three *per cent* on other contingent expenditure and merely two *per cent* spent on infrastructure.

Diversion of funds

3.2.7 Further, the expenditure included Rs 47.53 lakh spent by the Chemical Examiner, Karnal and Public Analyst, Haryana during 1998-2003 towards salary of staff sanctioned under state non-plan scheme but not deployed for the activities connected with the implementation of Drugs and Cosmetics Act.

Central assistance neither utilised nor refunded to GOI

3.2.8 GOI, Ministry of Health and Family Welfare released grant of Rs 12.50 lakh in October 1999 for strengthening of Haryana State Drug Laboratory. Since the funds could not be utilised during 1999-2000, GOI

[2] Ambala, Bhiwani, Hisar, Faridabad, Karnal, Narnaul, Panchkula, Panipat, Rohtak and Sonipat.

revalidated (August 2000) the sanction for utilisation of funds during 2000-01. Out of this, Rs 5.32 lakh were drawn by the Government Analyst, Haryana, Chandigarh in March 2001 for purchase of laboratory equipment (four electronic single pan balances) but balance Rs 7.18 lakh were neither utilised nor refunded to GOI (March 2003).

3.2.9 An expenditure of Rs 24.98 lakh was booked during 1999-2000 and 2000-01 against Central grant in the books of the Accountant General (A&E), Haryana through Transfer Entries (TEs) proposed by the department. As details of these TEs were not available in the offices of Director General, Health Services, Haryana, authority of expenditure and the basis of preparing these TEs could not be verified. Matter was also referred to the State Government to which reply had not been furnished (July 2003).

Procedure for reconciliation of receipts with treasury not followed

3.2.10 Fees for issue/renewal of licences were deposited in the government treasury by licencees directly. The Financial rules required that the departmental authorities should maintain a daily collection register. At the end of each month, credits, as entered, were to be reconciled with the treasury and certificate to this effect obtained from the Treasury Officer. Daily collection registers were not maintained and reconciliation of receipts with treasury records not done, which was fraught with the risk of serious financial irregularities, if not getting detected in time. SDC, Haryana stated (July 2003) that proper procedure for reconciliation of receipts had now been adopted.

Manpower

State Drug Controller, Haryana

3.2.11 As laid down in the Drugs and Cosmetic Act, Drug Inspectors were responsible for inspection of premises of manufacturers and sellers, drawing samples of drugs and cosmetics to determine their standards, etc.

Against the requirement of 50 Drug Inspectors, 16 were in position

As per recommendations of the task force of the Central Council of Health and Family Welfare, there was a requirement of 50 drug inspectors. However, as on 31 March 2003, there were only 23 sanctioned post of inspectors, against which 16 inspectors were in position. Thus there was shortage of 34 inspectors in comparison to the norms recommended by the task force, which resulted in delayed action against defaulting units, lesser number of inspections, delayed attending of complaint cases, etc., as discussed in paragraph 3.2.20 to 3.2.26. As the State Government had imposed (April 1999) complete ban on fresh recruitments, vacancies were not filled. Shortage of drug inspections adversely affected the implementation of the 'Act'.

Director, Ayurveda

Lack of staff resulted in deficiencies in drug control activities

3.2.12 There was no separate staff for implementation of Drug Control Act under Director, Ayurveda. Central Council of Health and Family Welfare of Indian Systems of Medicine passed a resolution in January 1997 for strengthening of Drug Control Cell in the Directorate of Ayurveda by establishing an independent drug control branch. Director, Ayurveda,

however, failed to send any proposal to the State Government for sanction of the posts of inspectors/doctors.

Due to lack of staff, proper scrutiny of records relating to grant, renewal and cancellation of licences and inspection of manufacturing premises suffered. On being pointed out in audit, the Director, Ayurveda accepted (November 2002) the deficiencies in performing the drug control functions.

Manufacturing and selling units

3.2.13 As of 31 March 2003, there were 445 manufacturing, 8,051 selling units for Allopathic drugs and cosmetics and 366 manufacturing units for Ayurveda and Unani medicines in the State. Though the State Drug Controller, Haryana was the licensing authority for drug manufacturing, yet the records/registers maintained in his office were not updated as a result of which details of 409 manufacturing (out of total of 445) units was only available and supplied.

No survey was conducted by the department during 1998-2003 for detecting manufacturing and selling units operating in the State without valid licences.

Testing infrastructure

3.2.14 The State had only one Drug Testing Laboratory at Chandigarh which was set up in the year 1976 for testing samples of drugs and cosmetics with the objective to determine their quality standards. Of the 15 sanctioned posts of laboratory technical staff, three to five posts remained vacant during 1998-2003, due to ban on recruitment imposed by the Government.

Testing facilities for certain drugs/devices did not exist

Testing facilities for determining the standards and quality of Sera vaccines, toxins, antigens, anti-toxins, oral polio vaccine, anti-sera for veterinary use, intra-uterine devices, Homoeopathic and Ayurvedic medicines were neither available at State Drug Laboratory nor any other alternative arrangement was made by the department.

The laboratory maintained a register indicating the details of drug/cosmetic samples received from the inspectors; and also recorded test results of such samples. Test results were communicated to the inspectors in the prescribed form. At the beginning of 1998-99, 993 samples were pending in the laboratory for testing, 13,910 samples were received during 1998-2003. Out of which 13,938 samples were tested and 14 samples rejected leaving a balance of 951 samples untested. Out of 13,938 samples tested at the laboratory during the above period, 59 were found spurious and 853 sub-standard.

Further scrutiny revealed the following:

Testing samples of medicines and drugs – time taken for reporting and the adverse impact on reporting delays

3.2.15 Against the target of 15,780 sample collection during 1998-2003, 13,910 samples (88 *per cent*) were collected and sent to Haryana Government Analyst for testing.

Abnormal delay in testing of samples

A test-check of records of laboratory revealed that of 13,938 samples tested at the laboratory during 1998-2003, 10,295 (74 *per cent*) were tested after the prescribed period of 'within 45 days' and the delay ranged between 45 and 562 days. The department attributed (January 2003) the delay to shortage of manpower. Since, only three to five posts of laboratory technical staff were vacant (out of 15 sanctioned), delays were not proportionately commensurate with the shortage of manpower.

As stated by Government Analyst, Haryana, capacity of the laboratory for sample testing was not fixed due to variation in time required for testing different samples.

Samples for blood not collected/ tested

3.2.16 To guard against spread of AIDS diseases, testing of units of blood stored in blood banks was necessary but no sample of blood units was collected for testing at the State Laboratory.

3.2.17 Thirty eight blood banks in the State were granted licences as on 31 March 2003. Out of these, licences of 25 blood banks were not renewed for the last two to seven years although these were in operation. In reply (June 2003) the SDC, Haryana stated that licences in most of the cases were not renewed due to non-conducting of inspection by joint inspection committee of Central/State inspectors and blood bank experts.

Arbitrary sampling

3.2.18 Of the 69 manufacturing units (64 drugs and five cosmetics) in three[3] districts, no sample was collected from 28 units (25 drugs and three cosmetics) during 1998-2003. Further, no sample was collected from any of the six blood banks in existence in these districts. As a result, drug/cosmetics manufactured and blood stocked by the concerned units remained untested. On the other hand, samples from 29 individual units were collected repeatedly i.e. two to six times during 1998-2003.

[3] Ambala, Panchkula and Yamunanagar.

Regulatory captures

Standing of the law

3.2.19 Under the Drugs and Cosmetics Act, and rules thereunder, there were no legal provisions for issue of licences to sellers of Ayurvedic and Unani drugs and such selling units being unlicenced, were also not covered under departmental inspections. As a result, there was no control of the department over these units for ensuring sale of standard and quality drugs.

Issue and renewal of licencees

Continuation of business without getting the licences renewed

3.2.20 Test-check of records of State Drug Controller and in districts test checked revealed that 104 drug selling units did not apply for renewal of their licences within the prescribed period of six months and thus their licences were deemed to have expired, but these firms continued their business unauthorizedly and the department did not initiate any action against them.

Inordinate delay in renewal of licences

3.2.21 The rules did not lay down any time limit for issue and renewal of licences after the receipt of applications. The department also had neither fixed any time limit nor devised any system to keep watch over the receipt and disposal of applications for issue/renewal of licences in a time bound manner. Scrutiny of records of 448 cases in the districts test checked revealed that there was delay of one to eight years in 95 cases in renewal of licences.

State Drug Controller attributed (July 2003) the delay to shortage of manpower. The reply was not justifiable as against the sanctioned posts of 14 District Drug Inspectors in districts test checked, only four were vacant. This important function should have been given due priority.

3.2.22 The District Drug Inspector, Hisar proposed (March 2002) the cancellation of licence of a firm of Hansi because the drugs were being sold by them without the supervision of a qualified person, but no action was taken by the Senior Drug Inspector, Hisar for cancellation of licence (January 2003).

Irregular grant of manufacturing licences under Ayurveda

Licences issued without consulting the approved expert

3.2.23 As laid down in Drugs and Cosmetic Rules, a licence to manufacture for sale of any ayurvedic or unani drugs was required to be issued by the Licensing Authority after consulting the expert appointed for the purpose by the State Government. No such expert was appointed/approved by the State Government. However, the Director, Ayurveda, Haryana constituted a committee of three officers to scrutinise the formulations presented by the firms before issuing manufacturing licences. Since no expert was associated with the process, the licences issued by the Director for manufacture of Ayurveda medicines were in violation of the provisions of the Drugs and Cosmetics Rules.

Director, Ayurveda stated (June 2003) that he himself being a qualified person, there was no need of getting further approval or appointment of such

expert from the Government. The reply was not in line with the mandatory requirement under the Act.

Adequacy of inspection

3.2.24 The department had not devised any system to ensure that all the sale units were inspected as per prescribed frequency of at least once/twice a year.

Year-wise position of inspections of Allopathic/Homeopathic drug selling units was as under:

Shortfall in conducting of inspections

Year	Selling units	Inspections required	Inspections conducted	Shortfall	Percentage of shortfall
1998-99	6,200	12,400	3,277	9,123	74
1999-2000	6,100	12,200	4,524	7,676	63
2000-01	6,200	12,400	4,401	7,999	65
2001-02	7,862	7,862	4,555	3,307	42
2002-03	8,051	8,051	4,716	3,335	41
Total		**52,913**	**21,473**	**31,440**	**59**

There was a shortfall of 59 *per cent* in conducting the inspection of selling units as a result of which large number of selling units continued their business without valid licences as discussed in paragraph 3.2.20 to 3.2.22. The State Drug Controller attributed (February 2003) the shortfall to shortage of inspecting officers. Reply was not convincing since the shortfall was proportionately of alarming magnitude even if the shortage of staff is taken into account.

In the districts test checked, 522 inspections were carried out against the requirement of 2,064 (for 358 Allopathic units) resulting in shortfall of 1,542 inspections (75 *percent).* State Drug Controller, Haryana attributed (July 2003) the shortfall to manpower constraints, non-provision of facilities of vehicles and the number of licenced units being high. The contention was not convincing as shortage in these districts was negligible.

3.2.25 Under Ayurvedic and Unani systems of medicine, against requirement of 2,978 inspections of 230 to 366 manufacturing units in the State, 1,887 inspections were carried out during 1998-2003, resulting in shortfall of 37 *per cent*.

Ayurvedic and Unani drug selling units were not being inspected

There was neither any provision for periodical inspection of Ayurvedic and Unani drugs selling units in the Act/Rules nor any inspection was conducted by the department. In the absence of any quality control over sales and distribution of Ayurvedic and Unani medicines, possibility of passing on spurious/fake drugs to the consumers could not be ruled out.

Follow-up action on samples found sub-standard or spurious; effectiveness thereof

3.2.26 In the districts test checked, 78 cases of spurious (34) and sub-standard (44) drugs were test checked. It was noticed that out of 34 spurious

drug cases, court cases were launched against the offenders in 30 cases, which were pending in various courts. Remaining four cases were under process for launching the cases in courts. Out of 44 substandard cases, 26 cases related to manufacturers from other States for which matter was reported to the concerned State Drugs Controllers for taking suitable action against the offenders, but no follow up action was taken by the SDC, Haryana. Further, details of supply of these sub-standard drugs in Haryana were not obtained from the SDCs of the other concerned States to initiate action for recalling the sub-standard drugs from the market. As regards manufacturers of Haryana, licences were suspended in 16 cases and cancelled in two cases, but no action was taken to recall sub-standard drugs from the market.

Instances of specific drugs procured by various civil hospitals which were found sub-standard on testing in Government Laboratory were as under:

Sr. No	Sample collecting authority	Sample collected from	Name of drug	Total quantity	Quantity withdrawn	Balance quantity
1	District Drug Inspector (DDI), Ambala (August 2002)*	Civil Surgeon, Ambala	Prochloroperazine 5 mg tablet (Batch: AT-1,526)	4.04 lakh	0.31 lakh	3.73 lakh
2	Senior Drug Inspector (SDI), Panchkula (April 2002)*	Civil Surgeon, Panchkula	CPD bags	25,000 bags	-	24,603 bags (397 bags used)
3	DDI, Ambala (October 2002)*	PMO, Ambala and Karnal	Triful perazime 5 mg (Batch: AT-01,529)	10,000 9,400 tablets	3,400 -	6,600 9,400
4	DDI, Ambala (November 2002)*	Civil Surgeon, Ambala	Biscodyle tablet 5 mg (Batch: PT-77)	7.6 lakh	-	7.6 lakh

* Month/year of sample collection.

As evident from the above table, negligible quantity of sub-standard drugs was withdrawn/replaced while for the bulk of quantities, there was nothing on record of SDC, Haryana as to whether these were withdrawn or not. Circulation of sub-standard drugs posed a serious problem to public health.

3.2.27 Lists of spurious drugs were not circulated to the trade associations, Government and semi-government hospitals, ESI dispensaries/hospitals, recognized consumer associations, etc. to avoid their use. Publicity in leading daily newspapers and over electronic media regarding such spurious drugs and their manufacturers was also not given to make people aware of spurious/ adulterated drugs. While admitting the failure, the SDC, Haryana stated (May 2003) that the compliance would be done in future.

Statistics of prosecutions vis-à-vis cases filed

Increasing trend in prosecution cases

3.2.28 When a drug was found spurious, adulterated or grossly sub-standard, prosecution was to be launched against the concerned firm. Details of prosecution launched, cases decided and pending in courts during 1998-2003

were as under:

Year	Pending cases at the beginning of the year	Prosecution launched	Total	Decided	Pending
1998-99	324	90	414	17	397
1999-2000	397	45	442	22	420
2000-01	420	54	474	28	446
2001-02	446	28	474	18	456
2002-03	456	91	547	25	522
		308		**110**	

Poor progress in prosecution

Out of 522 pending cases, 228 were more than five years old. Though the prosecution cases were on the increase, the department did not take up the matter with the Government for considering setting up special/designated courts for their speedy disposal. SDC, Haryana replied (July 2003) that an average of 25 cases per district were under trial in the State, which did not suggest necessity of setting up of special/designated courts. The fact remains that a large number of pending cases pertained to very old period and department should devise appropriate system for their speedy disposal in case setting up of special/designated courts is not necessitated.

Out of 110 court cases decided during April 1998 to March 2003, 44 cases (40 *per cent)* ended in acquittal. A scrutiny of 23 acquittal cases revealed that acquittals were due to launching of cases before issue of notification by the Government empowering the Chief Judicial Magistrates to try such cases, launching of cases after the expiry date of the drugs, declaration of the drug as standard by Central Drug Laboratory, Kolkata, change of statements by witnesses and launching of cases after the prescribed period of three years, etc. Thus, the department failed to defend their cases properly. Acquittals by default in large number reduced the fear of punishment in the minds of offenders.

Establishment of intelligence-cum-legal cells

3.2.29 The State Government did not set up any intelligence and legal Cell to tackle the problem of manufacture/sale of spurious and mis-branded drugs upto July 2002. In August 2002, the Cell, comprising one Assistant Drug Controller was set up which conducted 10 raids upto March 2003. During these raids, 40 units were checked and 221 samples were seized. Permission for launching prosecution was granted only in two cases and licence of only one unit was cancelled. No such Cell was set up for Ayurvedic and Unani systems.

Cases of spurious/sub-standard drugs/cosmetics, coming to notice of the department, were to be dealt with and investigated properly for taking departmental/legal action against the offenders.

Records of complaint cases not maintained properly

There was, however, no system in the office of the State Drug Controller for recording in a register such complaints, their disposal and pendency, indicating delay in taking follow up action. Details made available for the State disclosed that 227 complaints were pending as of March 2003. Of the 55 complaints test checked in eight districts, 10 were pending for one to four years. SDC, Haryana attributed (July 2003) non-disposal of complaint cases to non-availability of vehicles for making enquiries.

To collect information relating to offences under the Act, no system of co-ordination with other organisations like airport customs, vigilance and investigating authorities existed in the department.

Training

Training to staff not imparted

3.2.30 Implementation of regulatory functions under the Act required well trained staff but it was noticed that in-service training was not imparted to the drug inspectors under Ayurveda during 2001-02 and 2002-03 while during 1998-99 and 2000-0l, against the target of imparting training to two Drug Inspectors each year, training was imparted to only one inspector in each year. No training was imparted to laboratory technicians during 1998-2003. Under Allopathic system, two districts drug inspectors were given training for five days during 1998-99 and two senior drug inspectors for 11 days during 2002-03. No training was given during 1999-2002. Director Ayurveda replied (June 2003) that inspectors would be given training in coming years. As regards training to laboratory staff, Government Analyst, Haryana stated that training could not be imparted due to shortage of staff.

Monitoring

3.2.31 Enforcement of various regulatory functions required close monitoring to ensure that the objectives of Drugs and Cosmetics Act/rules were achieved efficiently.

The Drug Inspectors in the field submitted monthly/yearly reports to the State Drug Controller indicating the progress in regard to achievements of targets. The reports were simply compiled at the Directorate Office. Remedial steps were, however, not taken to improve the performance and achievements.

Registers/records of drug manufacturing and sale units inspected during a particular year, giving details as to whether licencees had got their licences renewed on time, were not maintained.

In a meeting of Inspectors held on 3 May 2002 at Panchkula under the Chairmanship of Minister of State for Health and Medical Education to monitor the working of the Drug Inspectors, it was decided that such meeting of inspectorate staff were to be held at least twice a year. However, no such meeting was held thereafter despite lapse of almost a year.

Meetings and interaction jointly with the Industry Associations could be helpful to disseminate information on manufacture and sale of spurious drugs and persons involved in it. The department did not fix any periodicity for organising such conferences/symposia at State level. However, the department decided (January 2001) to hold such meetings at district level at least once in three months. Four State level meetings at Chandigarh (January and May 2001) and at Panchkula (October 2001 and January 2002) and one district level meeting at Faridabad (January 2002) were held during 1998-2003. No meeting was held after January 2002. This aspect was thus not given adequate attention.

Conclusion

3.2.32 Acute shortage of drug inspectors and laboratory technicians with the State Drug Controller and Government Analyst resulted in shortfall in inspection of Allopathic/Homeopathic drug selling units and sub-standard drugs were in circulation in the market. Renewal of licences for manufacturing/sale units were delayed in a number of cases. State Drug laboratory lacked testing facilities for a number of Allopathic drugs/substances while for Homeopathy, Ayurvedic and Unani drugs, there was no facility at all.

These points were referred to the Commissioner and Secretary to Government, Haryana, Medical and Health Department (May 2003); reply had not been received (September 2003).