E.C. NO. 1042

SIXTIETH REPORT

ESTIMATES COMMITTEE
(1983-84)

(SEVENTH LOK SABHA)

MINISTRY OF HEALTH AND FAMILY WELFARE
DRUG STANDARDS

Presented to Lok Sabha on 22nd December, 1983

LOK SABHA SECRETARIAT
NEW DELHI

December 1983/Pausa, 1905 (Saka)

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CORRIGENDA TO
THE 60TH REPORT OF ESTIMATES COMMITTEE ON
'DRUG STANDARD'

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INTRODUCTION

I, the Chairman of Estimates Committee having been authorised by the Committee to submit the Report on their behalf, present this Sixtieth Report on the Ministry of Health and Family Welfare—Drug Standards.

2. The Committee took evidence of the representatives of the Ministry of health and Family Welfare on 26th and 27th September, 1983. The Committee wish to express their thanks to the officers of the Ministry for placing before them the material and information which they desired in connection with the examination of the subject and giving evidence before the Committee.

3. The Committee also wish to express their thanks to Shri K. N. Rao, President, IMSA for giving evidence and making valuable suggestions to the Committee.

4. The Committee also wish to express their thanks to all other Organisations/Institutions for furnishing memoranda on the subject to the Committee.

5. The Report was considered and adopted by the Committee on 19th December, 1983.

6. For facility of reference and convenience, recommendations and observations of the Committee have been printed in thick type in the body of the Report, and have also been reproduced in a consolidated form in the Appendix to the Report.

NEW DELHI ;

December 21.1983
Agrahayana 30, 1905 (Saka)

BANSI LAL,
Chairman,
Estimates Committee.

CHAPTER I
DRUG STANDARDS

A. Magnitude of the Problem of Drug Standards

The total output of the drug industry in India today is of the order of Rs. 1550 crores and we are the twelfth largest drug producing country in the world. Export of bulk drugs and formulations has also registered an appreciable increase in the last two or three years. Export is of the order of Rs. 65 crores. While the fact that the export of drugs from India is steadily increasing would show the confidence other countries have in the quality of drugs produced in the country, as stated by the Secretary, Health Ministry during evidence before the committee during September, 1983, there is certainly scope for improvement in the conditions of manufacture and standards of drugs. The total value of import of drugs and formulations is at present of the order of Rs. 150 crores per annum.

1.2 There are about 8000 manufacturers of Allopathic drugs in the country who have been licenced under the Act. Out of them, 130 are in the organised sector, that is, medium and large sector. The remaining are in the small scale sector. In addition there are 1.7 lakh traders in the drug trade.

1.3 The manufacture, sale and distribution of drugs is governed by the Drugs and Cosmetics Act, 1940 and the Rules framed thereunder as amended from time to time. Under the Constitution 'Drugs' is a subject included in the Concurrent List. Administration of the Drugs and Cosmetics Act, 1940 is, therefore, the responsibility of both the Central Covernment and the State Governments. This Act stipulates, *tnter alia*, that no person shall himself or by any other person on his behalf manufacture for sale, or for distribution or sell, or stock or exhibit or offer for sale, or distribute any drug which is not of standard quality, or is misbranded or spurious. If he does so, he shall be liable to punishment for a term which shall not be less than one year but which may extend to ten years and shall be also liable to fine, and in certain circmstancesu where

use of the drug causes grievour hurt or death for a term of five years extending to life term and with fine of not less than ten thousand rupees.

1.4 Under the Act the expressions 'Standard quality', 'Misbranded drug, 'Adulterated drug' and 'Spurious drug' have been defined as follows : —

1. 'Standard quality' means in relation to drug, that the drug complies with the standard set out in the Second Schedule ;

2. A drug is deemed to be 'misbranded' :
   (a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is ; or
   (b) if it is not labelled in the prescribed manner ; or
   (c) if its label or container or anything accompanying the drug bears any statement design or device which makes any false claim for the drug or which is false or misleading in any particular.

3. A drug is deemed to be adulterated :
   (a) if it consists in whole or in part, of any filthy, putrid or decomposed substance ; or
   (b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health ; or
   (c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health ; or
   (d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed ; or
   (e) if it contains any harmful or toxic substance which may render it injurious to health ; or
   (f) if any substance has been mixed therewith so as to reduce its quality or strength.

4. A drug is deemed to be spurious :

(a) if it is manufactured under a name which belongs to another drug ; or

(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its lable or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug ; or

(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist ; or

(d) if it has been substituted wholly or in part by another drug or substance ; or

(e) if it purports to be the product of a manufacturer of whom it is not truly a product.

1.5 The provisions of the Act and Rules are applicable to all drug manufacturing firms which are required to comply with these provisions. It has been stated by the Ministry that these provisions if effectively implemented are quite adequate for regulating the quality of drugs manufactured, sold or distributed in the country.

1.6 It has, however, been stated in a memorandum submitted to the Committee by a non -official that the Drugs and Cosmetics Act 1940 has been amended from time to time to make the punishments more and more stringent obviously in the hope that such penalties will act as a deterrent to the manufacture of sub-standard drugs. Discussions in Parliament have indicated that inspite of the progressively enhanced punishment provided from 1955 to 1982 these have not had a visible impact on the reportedly high incidence of sub-standard drugs in the market.

1.7 When asked if the Ministry of Health agreed that the Drugs and Cosmetics Act enacted more than 40 years back had failed to make any dent on the problem of manufacture, sale and distribution of sub-standard drugs, the Health Secretary stated during evidence :

" it would not be correct to say that the Drugs and Cosmetics Act has failed to make any dent in the manufacture of sales or distribution of the drugs. When the Drugs Act was enacted in 1940, the total production of drugs in the country was about Rs. 10 crores. As against this, the present production is about Rs. 1,550 crores. India, which was an importing country at that time of most of the drugs, has today become exporter of drugs. Taking into account the increased production of drugs in the country, the prevalance of substandard drugs cannot be considered high. I would like to make in clear that we do not want to be complacent in the matter of detecting spurious drugs That is not the intention. But we are determined that much more has to be done to detect spurious drugs."

1.8 The following analysis of the statement was furnished to the Committee by the Ministry of Health and Family Welfare indicating the drug samples tested during the last five years and those found sub-standard : —

	1977-78	*1978-79*	*1979-80*	*1980-81*	*1981-82*
Samples tested	17685	16151	18393	19463	18856
Samples found sub-standard	3,829	2,496	2,835	2,932	3,457
% of samples found sub-standard	21.6	15.4	15.4	14.5	18.3

1.9 It would be seen from the above statementthat during 1981-82 alone out of 18, 856 samples tested in the various States/Union Territories 3457 samples *i.e.* about 18 per cent were found sub-standard commenting on the seriousness of the problem of sub-standard drugs prevailing in the market as seen from the above figures, the Health Secretary pointed out during evidence that : —

"I would like to submit that it is true that percentage of samples found sub-standard during 1981-82 was about 18%. However it may be pointed out that these samples are drawn by drug

inspectors who generally pick up samples from those batches of drugs against which either there are some complaints against the medicine or the manufacturers or in some cases where the quality of the drug is a suspect or from visual sight also something wrong is found in the medicine. It is therefore to be expected that the percentage of sub-standard samples inspected is high. But the point is that it would not be correct to say that 18% of the drugs moving in the market are sub-standard."

1.10 When the Committee pointed out that it could be a higher percentage also, the Secretary stated that 80% of the total drug production was in the large and medium scale sector. A large number of samples tested were from small scale sector comprising of about 7000 units which contributed only 20% of the total production. Therefore, although 18% were found to be sub-standard, it did not reflect that 18% of the drugs moving in the market would be sub-standard. The Secretary added that large scale sector had better technical resources and each batch in that sector was being subjected to a test. The same situation could not be expected in the case of small scale manufacturers.

1.11 The Committee wanted to know the number of samples drawn from large and small scale units and found defective during the last 3 year. In reply the Ministry explained that under the provisions of the Drugs and Cosmetics Act and Rules thereunder Drug Licensing Authorities appointed by the State Government regulate manufacture and sale of durgs by grant of licences. The State Drug Control Authorities had been requested by the Drugs Controller (India) to furnish the requisite information. Later the Ministry of Health furnished to the Committee a Statement containing the above break-up only in respect of 21 States/UTs.

Date in brief is as follows :—

Year	Large Scale	Samples	Small Scale	
	Samples tested	Sub-standard	Samples tested	Samples sub-standard
1980-81	1599	115	7921	1593
1981-82	1601	104	9355	1996
1982-83	1695	119	10888	1806

1.12 The Health Ministry also furnished to the Committee a list of 857 manufacturers of drugs whose samples were found to be sub-standard during 1978-79, 1979-80 and 1930-81 based on the information received by the Drugs Controller (India) from two Central Government laboratories viz., Central Drugs Laboratory, Calcutta and Central Indian pharmacopoeia Laboratory, Ghaziabad which are Central Laboratories and are acting as Government Analysis for a number of States/Union Territories, who either do not have their own testing facilities or where testing facilities are inadequate. Out of the 857 units so tested as many as 29 were large units.

1.13 The Committee wanted to know the percentage of drugs that was being subjected to sample-testing.

The Health Secretary stated that :—

> "I would like to submit that there are nearly 8,000 licensed manufacturers and the total production of the formulations is of the order of Rs. 1,550 crores. The number of batches that are manufactured will run into several hundred thousands because each production has so many batches. It is not possible, therefore, to make any assessment of the percentage of products produced in the country that are subjected to testing by the Drugs Controller. So it is difficult to hazard a guess on that. However, I may point out that under the Drugs and Cosmetics Act all the manufacturers... ..are required to test every batch of their finished product before it is released for sale. It is a part of the conditions of the licence which has been given to the manufacturer under the Drugs and Cosmetics Act. Our sample-picking either at the manufacturer or at the retailer or in the process of carrier is only a supplementary effort to check."

1.14 As the statement giving state-wise information regarding drug samples tested and found sub-standard furnished by the Ministry did not contain data in respect of the States of Bihar, Himachal Pradesh, Jammu and Kashmir, Orissa and U.P., the Committee desired to know the reasons therefor. In reply, the Health Secretary stated during evidence :

"The States of Bihar, Himachal Pradesh, Jammu & Kashmir and Uttar Pradesh have drug control organisation but this is not well organised ..... they apparantly have difficulties in collecting and compiling this information. Despite our best efforts and DO letters we have not been able to collect this information from these States."

1.15 The drug industry in india has registered a phenomenal growth in recent years. The output of the industry has touched Rs. 1550 crores enabling India to become the 12th largest drug producing country in the world. The total value of import of drugs and formulations into the country is at present only of the order of Rs. 150 crores per annum as against the export of drugs of the value of Rs. 65 crores. It is in this context that the Committee examined the quality of the drugs and the quality control measures.

1.16 The manufacture, sale and distribution of drugs is governed by the drugs and Cosmetics Act, 1940 and the rules framed thereunder, as amended from time to time. Since under the Constitution, 'Drugs' is a Concurrent subject the administration of this Act is the responsbility of both the Central Government as well as the State Governments. There are said to be about 8000 manufacturers of allopathic drugs in the country who have been licensed under this Act. Out of them 130 are in the organised sector i.e. medium and large sector and the remaining are in the small scale sector. There are as many as 1.7 lakh traders in the drug trade. The Act stipulates, *inter-alia*, that no person himself or by any other person on his behalf shall manufacture for sale, or distribute any drug which is not of standard quality, or any misbranded or adulterated drug, etc. If a person does so, he is liable for imprisonment which may in certain cases extend to life imprisonment. A non-official organisation has expressed the view that despite progressively enhanced punishment provided in the Act from 1955 to 1982, these have not had a Visible impact on the high incidence of sub-standard drugs in the market. According to the statistics made avilable to Committee by the Ministry of Health and Family Welfare, of the drug samples tested during the period 1977-78 to 1981-82 the percentage of samples found sub-standard ranged between 14.5 to 21.6. The percentage of samples found sub-standard in 1981-82 was 18.3.

The Health Secretary pointed out in evidence that the percentage of drugs found sub-standard should not be viewed as unduly high for two reasons. Firstly, the production of drugs in the country had gone up substantially, Secondly, the large number of samples tested were from the small scale Sector numbering 7000 units which contributed only 20 per cent to the total drug production. As much as 80 per cent of the total drug production was accounted for by the large and medium scale sector. The Health Secretary also pointed out that the fact that 18 per cent of the samples tested were found to be sub-standard in a year did not mean that 18% of the drugs moving in the market were all sub-standard. This displays a complacent attitude. Any complacency or laxity in the maintenance of drug standards can pose grave danger to the health of the people. The Committee, therefore, desire that a stricter vigil should be kept in this regard, particularly on the drugs and formulations produced and distributed by multinationals and Government Undertakings.

1.17 The Committee find that under the drug and Cosmetics Act every manufacturer of drugs is required to test every batch of the finished product before its release for sale. In fact this is a part of the condition of the drug licence under which the manufacturer produces drugs. The quality of drugs has also to be ensured by the drug Central Authorities. The Committee are however, surprised that no indication is at present available as to what percentage of drugs produced in the country is being subjected to testing either by the Drug Controller of India or by the State Drug Controller Authorities The Ministry of Health and Family Welfare have, on the basis of information received by the Drug Controller, India in respect of two Central Government Laboratories viz. Centrol Drug Laboratory, Calcutta, and Central Indian Pharmacopoeia Laboratory Ghaziabad, which act as Government analysis for a number of States/Union Territories, intimated that during the years 1978-79, 1979-80 and 1980-81, the drugs of as many as 857 manufacturers (including 29 large scale units) were found sub-standard. The Committee strongly feel that it is incumbent upon Government to test check on a regular basis a minimum percentage of production of each unit engaged in the production of drug under licence from Government, be they multinationals or Government Undertakings. The sample testing should not be confined only to cases where as a result

of complaint or otherwise there is *Prima facie* suspicion. Maintenance of drug standards is the responsibility both of Central Government and the State Governments and cannot be left to the manufacturers.

B. *Action against Defaulters* :

1.18 According to the existing practice the existence of sub-standard drugs with manufacturers or dealers can be detected only by drawing samples and getting them tested. In some cases where there is visible deterioration such as discolouration of tablets, presence of fungus in transfusion solutions etc. Which would render the drug sub-standard this can be detected whitout any test. Drug Inspectors inspecting manufacturers or dealers premises could, therefore, during these inspections detect such cases of sub-standard drugs.

1.19. On the question of making the checks more systematic and foolproof so as to ensure that as far as possible sub-standard drugs are not produced and even if such drugs are produced they do not find their way into the market, the secretary, Health stated that :

> "The responsibility for ensuring the quality of drugs produced is primarily that of the manufacturer. It is not possible for any governmental machinery to check every batch of the drug manufactured for quality before it is released because a suggestion was made to that effect. This is impossible. It requires a very large organisation in view of the very large number of small scale units. It can happen that whatever drug that is produced is of a standard quality but due to storage or transportation it becomes deteriorated. It is for this reason that sampling from the dealer's premises is resorted to."

1.20 While manufacturers are expected to exercise quality check themselves, the Committee wanted to know if some involvement of the drug control. Authorities could be evolved at the manufacturing stage itself with a view to making the drug control system more meaningful. The Health Secretary pointed out that with 8000 drug manufacturers in the country it woud not be possible to create a machinery to check the quality at the manufacturing stage as it would involve huge costs and in turn push

up prices of drugs. He informed the Committee that this practice was not being followed anywhere.

1.21 In a note furnished to the Committee, after evidence, the Ministry of Health have intimated that in developed countries quality control is carried out at all stages of manufacture and is not limited to checks on samples of finished products.

1.22 The Committee enquired whether there was a procedure of delicensing manufacturers, who did not adhere to minimum standard and if so, what was the number of units which were delicensed during the last three years on this ground. The Secretary explained in evidence that :

> "Rule 85 of the Drugs and Cosmetic Rules provides for suspension or cancellation of the licence, if the licensing authority is of the opinion that the licensee has failed to comply with any of the conditions of the licence or any provision of the Act or rules made there under. Since the manufacturing licences are granted by the State Drug Control Authority who are only authorised to suspend or cancel the licences, the number of cases where the licences have been cancelled during the last 3 years has to be collected from the State Drug Control Authority. This information is not available. This, I would admit, is a laxity on our part .....If we have not been able to collect, I would like to assure that we will ask from the States. This is the normal information which, as a coordinating authority and as a guidance authority at the central level, though we are not the executing authority, ws should have".

The Secretary conceded, further that :

> "I would agree with you that rules are not followed, otherwise this problem would not have arisen. There should be stringent checks on sale of drugs. If these are strictly observed, such complaints would not be there".

1.23 The Committee wanted to know the action taken on the 3457 samples found substandard in 1981-82 as to whether the drugs were destroyed and what action was taken against the manufacturers, the Secre-

tary stated that this action was to be taken by the State Drug Controllers and that normally the drugs are destroyed in such cases. Asked if such information should not come to the Central Authority in monthly or quarterly statements, the Secretary stated :

"This is not being dene at present but we can do it".

1.24 The Committee suggested during evidence that where quality of drugs was found to be sub-standard, the name of the manufacturing unit, the name of the drug and its batch number should be given out in the Press, Television and Radio. The Secretary pointed out that after a conviction was done publicity could be given under the law, but not before conviction. The witness, however, assured that :—

"Your suggestion is very practical and good. The reputation of the manufacturer whose names appears in the Newspaper, Radio and Television will be affected. We can consider this matter after looking into its legal aspects and in consultation with the States".

1.25 Dealing with the question of imported drugs, the Central Drug Controller informed the Committee in evidence that mainly bulk drugs were being imported, 99.5 per cent of imported drugs were the bulk drugs and these were being imported only at specific points, viz. Bombay Madras, Calcutta and Delhi by air. Most of the imports were form developed countries. At all these places the Drug Control Authority had offices in the Customs House. Every consignment and every bill import went through these offices and it was there that samples were drawn and sent for testing. The total number of samples drawn in 1980-81 was 3183 out of which 78 were found substandard. In 1981-82, 2890 samples were tested out of which 50 were found substandard and in 1982-83 out of 2540 samples tested 60 were found to be substandard.

1.26 The Committee were informed during evidence that so far as the formulations were concerned not many of them were being imported. About 70 to 80 specific preparations were being imported. But requirements in respect of some of the drugs was very small. The Secretary stated, however, that licence and production aspects whether of life saving

or other drugs was within the purview of the Department of Chemicals and Fertilizers who were being constantly pressurised by the Health Ministry to ensure that all the requirements of the essential drugs were available in the country and that they were preferably produced in the country.

1.27 The Committee understand that in developed countries quality control of drugs is carried out at all stages of manufacture. In our country it is limited to samples of finished drugs. The Health Secretary pleaded that if the system of quality control at all levels of manufacture is introduced in India "it would involve huge cost and in turn push up prices of drugs". They accordingly recommend that atleast selectively multi-stage quality control should be enforced progressively on the basis of the need as disclosed by experience gained so far.

1.28 The Committee regret that neither the Central Drug Control Authorities nor the Ministry of Health and Family Welfare have any statistics as to the number of cases in which the licences of drug manufactures were suspended or cancelled by the State Drug Control Authorities during the last 3 years for manufacturing sub-standard drugs. The Health Secretary was unable even to confirm whether the drugs involved in the 3457 samples found sub-standard in 1981-82 were physically destroyed to avoid such smaples finding their way into the market. The Secretary admitted in evidence that such information ought to be available at the Central level. The Committee recommend that a suitable mechanism may be evolved for collection of this data. Further, it should be ensured that the batches of drugs samples of which are found to be sub-standard are destroyed so that they do not find their way into the market.

1.29 Under the existing law if a sample is found to be sub-standard, the name of the drug and its batch number alongwith the name of its manufacture can be given out to press only after the accused manufacturer is convicted by a Court of law. When the Committee pointed out to the Health Secretary that the fact that a particular sample has been seized and found substandard after a test in a Drug Control Laboratory, should be given out to the Press, Television and radio to foreward the public against the use of such drugs, the Health Secretary welcomed the suggestion. He assured the Committee that he would look into the legal aspects and take

a decision in consultation with the State authorities. The Committee recommend that an early decision should be taken in this regard and if necessary the law should be changed.

1.30 As regard drugs imported into the country the Committee note that 78 out of 3183 samples were found sub-standard in 1980-81. In 1980-82, 50 out of 2890 samples were found sub-standard. Out of 2540 samples of imported drugs tested in 1982-83, 60 were found to be sub-standard. The Drug Controller informed the Committee that each and every consignment of imported drugs is not tested The Committee would urge that imported drugs should also be subjected to rigorous test and on a much widerscale than at present to ensure that no spurious or sub-standard drugs are allowed to be imported. If necessary, the law should be made more strict than what it is now.

CHAPTER II

DRUG TESTING FACILITIES

A. *Durg Laboratories*

2.1 There are two laboratories functioning under the Drugs Controller (India) namely the Central Drugs Laboratory, Calcutta and the Central Indian Pharmacopoeia Laboratory at Ghaziabad. The Central Drugs Laboratory is responsible for testing of all imported drugs and also functions as appellate laboratory under Drugs and Cosmetics Act. The Central Indian Pharmacopoeia Laboratory in addition to testing of statutory drug samples, also assists the Indian Pharmacopoeia Committee in Drawing up standards for drugs to be included in the Indian Pharmacopoeia. The Secretary, Health stated during evidence that in addition, these laboratories provide facility to some States or Union Territories which do not have testing facilities.

2.2 The Committee enquired whether adequacy of drug testing facilities developed by the Centre and requirements therefor had been examined. In reply, the Secretary Health stated during evidence that it was proposed to augment the existing capacity for testing facilities from 6500 samples a year to 10,000 samples a year in both the laboratories. This work, he said, had been taken in hand. When asked if the existing capacity, when completed, would be sufficient, the Secretary stated that :

> "If the States also increase their facilities, then we hope that some of our work which we are doing on behalf of the States should go back to the States, because really we are testing drugs on behalf of 21 States and the Uuion Territories at least the Schedule C drugs. With expansion we will concentrate more on imported drugs and other life saving drugs."

2.3 During the Fifth Five Year Plan Central Assistance had been given to the eight States of Andhra Pradesh, Assam, Bihar, Uttar Pradesh Jammu & Kashmir, Madhya Pradesh, Tamil Nadu and Rajasthan for

setting up combined Food and Drug Laboratories for testing both foods and drugs. The Task Force on Sub-Standard drugs had in its Report (1982) observed that the States of Andhra Pradesh, Gujarat, Haryana, Karnataka, Kerala, Maharashtra, Orissa, Rajasthan and West Bengal had established facilities for testing of drugs. Even these facilities needed augmentation to keep pace with the growth of the industry. The Task Force noted that Andhra Pradesh, Tamil Nadu, Madhy Pradesh, Uttar Pradesh, Bilhar and Rajasthan had taken steps to set up their drug testing laboratories However, these laboratories had still not started functioning fully.

2.4 The Task force had observed further that :

> "...some progress in establishing of drug testing laboratories in States was achieved when the Central Government assisted the States in setting up the laboratories. The Task Force is of the view that Central Government should continue to assist the State Governments for strengthening the drug testing facilities and for this purpose a 100% Centrally sponsored scheme should be formulated. The Task Force would like to point out that the Central Government earns considerable revenue in the form of Central Excise duty which runs into more than 100 crores. The expenditure for a Central Sponsored scheme for assisting the States would be quite small and it should not be difficult for the Central Government to allocate funds for this purpose."

2.5 When asked why the responsibility pertaining to testing facilities should not be taken over by the Centre, the Secretary, Health expresed the view that :

> "We expect the State Governments to be equally responsible. For instance, a number of State Covernments have very good testing facilities. .....Five States which have fully equipped laboratory are Maharashtra, Gujarat, Karnatak, Tamil Nadu and probably West Bengal.....Barring the North Eastern States and the union territories all States have the testing. Of course, the union territories do not have testing laboratories. Even Delhi does not have a testing laboratory. I mentioned a number

of States where our effort should be to emphasize, pursue and prevail upon State Government to set up additional testing facilities, or augment them wherever they are. Each State should have testing facilities availble with it... Centrally also we are doing it. We should do this, rather than take over the entire testing facilities under a single umbrella. Otherwise, we will get bogged down with administrative problems".

He reiterated :

"We would like all the States to set up their own testing facility. In fact it is necessary, where they have got the facility, they should augment it and where they do not have, they must set up one. In this regard the Task Force has gone into the question. Our Health Minister has also written to the Chief Ministers some months back that they must have on a time-bound basis these facilities installed in their States. The Deputy Minister in the Ministry has also written to all the State Health Ministers as recent as May, 1983 again. We in the recent forum of Health Secretariat have emphasised this point. In fact, yesterday, I mentioned I ensure drug sub-standard control aspect of the medicine is included as an item of agenda at least in all the meetings in the last two years".

2.6 In regard to the suggestion made by the Task Force for 100% Centrally Sponsored Scheme for assisting the States in strengthening the drug testing laboratories the Secretary observed :

"...In the Five Year Plan, there was a scheme which was centrally sponsored scheme to assist the States 100 per cent in establishing testing facilities. Then it was transferred to the States after three years. Now the Task Force has recommended that we should have a scheme 100 per cent centrally sponsored for assisting the States. We will examine it in consultation with the Planning Commission and the Finance and take a view in the matter".

2.7 The Committee find that so far only 5 States have set up adequate durg testing facilities in the country. These states are Maharashtra Gujarat, Karnataka, Tamil Nadu and West Bengal. Central Government laboratories are carrying out tests in respect of other States. In fact the

two Central Drug Testing Laboratories viz. the Central Drugs Laboratory, Calcutta and the Central pharmacopoeia laboratory at Ghaziabad are between themselves assisting 21 States and Union Territories in testing atleast schedule C Drugs. This is in addition to the other responsibilities assigned to them such as testing imported drugs, Exercising appellate functions and assisting the Indian Pharmacopoeia Committee in drawing up standards for drugs to be included in the Pharmacopoeia. The Union Territories have no testing facilities and surprisingly even Delhi does not have them. This situation is highly unsatisfactory. In the absence of adequate facilities it cannot be said that the State drug control authorities are in a position to enforce standards satisfactorily.

2.8 The Committee understand that the Task Force appointed by Government had in 1982 suggested a 100% centrally sponsored scheme to Create testing facilities in the States. The Task Force had observed that with Central Government earning a revenue in the form of excise duty to the tune of Rs. 100 crores it will not be difficult for them to bear the small expenditure on this scheme. The Committee are in agreement with this recommendation of the Task Force and recommend that a 100% centrally sponsored scheme as suggested by the Task Force to create edequate facilities for drug testing in the country should be drawn up and launched with out deloy.

B. *Renewal/Cancellation of Licences for lack of testing facilities*

2.9 The Committee wanted to know the number drug manufacturing units in case of which the licences were renewed during the last 3 years (1980-81, 1981-82 and 1982-83), the number of cases where licences were cancelled for lack of testing facilities and the number of cases where licences were renewed despite manufacturing units having failed to create testing facilities. The Ministry could furnish information to the Committee in respect of 21 States/Union Territories only. A statement giving the position regarding each category is given below :—

Sl. No.	Names of the States/UTs	No. of licences renewed	No. of licences cancelled for lack of testing facilities	Licences renewed despite maunfts. having failed to create testing facilities
1.	Andhra Pradesh	346	—	—
2.	Assam	35	—	—
3.	Arunachal Pradesh	—	—	—
4.	Andaman & Nicobar Islands	—	—	—
5.	Chandigarh	—	—	—
6.	Delhi	133	—	6
7.	Dadra & Nagar Haveli	5	—	—
8.	Gujarat	1120	—	95
9.	Goa	47	—	7
10.	Haryana	156	—	—
11.	Karnataka	206	—	—
12.	Kerala	80	—	—
13.	Madhya Pradesh	447	11	—
14.	Maharashtra	1194	—	604
15.	Meghalaya	1	—	—
16.	Orissa	161	—	20
17.	Pondicherry	28	1	—
18.	Punjab	132	—	—
19.	Rajasthan	91	—	—
20.	Tamil Nadu	380	—	121
21.	West Bengal	1353	1	—
		5916	13	853

2.10 At present under the Drugs and Cosmetics Rules drug manufacturers are required to provide their own testing facilities. Where however sophisticated testing is involved, the rules do provide for drug manufacturers to got their products tested in approved laboratories.

2.11 A non-official has stated in his memorandum to the Committee that the pious suggestion that every drug manufacturing house need to have its own built-in testing unit or laboratory which would act as a guarantee against release of sub-standard material into the market may sound like an idealistic scheme, but has not succeeded over the last 40 years nor has checked sub-standard drugs in the country. It has been added that considering the vastness of the country, the overwhelmingly large numbers of big and small manufacturing houses, the inadequacy of capital investment for equipment and recurring expenditure, shortage of space to house such testing units, the dearth of trained and approved quality control personnel working under the influence of their pay-master, the proposal is neither economically feasible nor practicable. Further that Govt. is not satisfied with internal audit but insist on external audit to ensure impartial and competent third party check.

2.12 It has been represented to the Committee in this connection that there is need for encouraging the growth of a net-work of Approved Testing Laboratories all over the country with full Govt. backing for them to procure technology, import precision instruments and equipment, chemical reagents and reference standards etc. so as to enable them to cover the entire field of work by providing a dependable and objective quality control infrastructure for the drug industry and act complementary to the Govt. efforts to provide the public with drugs of standard quality.

2.13 The Secretary, Health explained the policy of the Government thus :

> "Prior to June, 1977, the Drugs and Cosmetics Rules did not require every manufacturer to have his own testing facilities. The rules permitted the drugs manufacturers to get the drugs tested in the approved laboratory. In 1977 the Rules were amended requiring the drug manufacturing units to have their own testing facilities. It did not require the use of sophisticated instruments. Where sophisticated tests were required, the licensing authority could permit such tests to be carried out in an approved laboratory. The position changed after June, 1977. The Government of India had given a grace period upto 1980. A new manufacturer will not be given a licence unless they have already provided them. The Task Force has recommended

that this provision should be implemented ; and from the information which we have, it appears that this provision is being implemented in the States".

2.14 Asked if all the manufacturers had laboratories by 1980 as stipulated in the rules, the Drug Controller stated :

"Last week I had a meeting with them. They have been saying that they are insisting on this. It is being done".

2.15 Asked about the constraints being experienced in this regard, the Durg Controller replied :

"They have said that they can get these tests carried out in the approved laboratory. The main constraint is Finance. It will cost Rs. 2½ lakhs, for each manufacturer.

The Secretery, Health added to this :

"It is a sizeable amount for a small manufacturer. But this is now being forced upon. The policy of the Government is that a manufacturer must have his own testing laboratory".

2.16 The Committee have been informed that there are 68 approved laboratories in the country.

2.17 Prior to June 1977, if the manufacturers of drugs did not have drug testing facilities they could have their drugs tested in any approved drug testing laboratory. The number of approved drug laboratories in the country is 68. By an amendment made in June 1977 to the Drugs and Cosmetics Rules 1945 it was stipulated that a new manufacturer will not be issued a licence unless he had drug testing facilities at his premises. Existing manufacturers were, however, allowed a grace period to create such facilities by 1980. The Committee are dismayed to find that instead of enforcing this provision rigidly, the licences of a large number of manufacturers were renewed despite these manufrcturers having failed to create the requisite testing facilities. During the last three years i.e. 1980-81 to 1982-83 the licences of as many as 853 manufacturers in 21 States/UTs were renewed. As against this the number of cases in which the licences were cancelled for lack of these facilities during this period was only 12. The Committe would urge that the statutory provision in this regard should strictly adhered to and no further liniency should be shown

C. *Incentives for Manufacturers :*

2.18 The Task force had in its Report (1982) observed that the drug testing was increasingly getting more sophisticated and the cost of the equipment was very high in many cases. In order to encourage purchase of the epuipment, either imported or indigenous, the manufacturers needed encouragement, by way of following incentives :—

1. Easy bank loans from institutions at concessional rate of interest.
2. Import of testing equipment under O.G.L.
3. Porcurement of equipment under Hire-Purchase system.
4. Exemption of Customs duty in case of imported equipment.
5. Capital investment in the purchase of sophisticated equipment should be treated as revenue expenditure for the purposes of Income Tax calculations.

2.19 Asked if the aforesaid incentives were available to the drug industry, the Secretary, Health stated :—

> "These are the various recommendations of the Task Force and we have written to the concerned Ministries about each and every item like import of testing equipment under OGL with the Ministry of Commerce—like this we have referred them to various Ministries. The information available from the Chief Controller of Imports and Exports is that they have put sophisticated testing equipment under OGL in the current import trade control policy. They have already included it and stated that anybody can import it under OGL. The Ministry of Finance has not agreed to our recommendation for exemption of customs duty. The approved testing laboratory people earn money. It is an income proposition and why should we allow the waiver of customs duty ? This point can be again taken up with them. I only want to bring to your notice that one or two Ministries had reacted to this already. We have referred the suggestions to all of them and their reactions are awaited.....we will pursue it with them."

2.20 The Committee recommend that adequate incentives such as those suggested by the Task Force like availability of easy bank loans at concessional rates, procurement of equipment under hire purchase system, exemption of customs duty in case of imported equipment, treating capital investment in purchase of sophisticated equipment as revenue expenditure for the purposes of income tax calculations etc, should be made available to the drug manufacturing units to facilitate the creation of in-house testing facilities.

CHAPTER III

ORGANISATIONAL SET UP

A. *Organisational set up*

3.1 The Drugs and Cosmetics Act, 1940 regulates the import, manufacture, sale and distribution of drugs in the country. The standards to be complied with by imported drugs and by drugs manufactured for sale, sold stocked or exhibited for sale or distributed are laid down in Second Schedule to the Drugs and Cosmetics Act. The responsibility for enforcing the provisions of the Drugs and Cosmetics Act is distributed between the Central and the State Governments. The State Governments are responsible for exercising control over the quality of drugs manufactured, sold and distributed in the country through the State Drug Control Organisations.

3.2 The Ministry have stated in a note that every State is required to establish a Drug Control Organisation consisting of the Drugs Controller, Drug Inspectors and other staff for enforcing the provisions of the Drugs and Cosmetics Act. The State Governments are also required to establish drug testing laboratories for testing samples of drugs drawn by the Drug Inspectors. Control over the quality of drugs is exercised through a system of licensing of manufacturing and sale premises. The Drugs and Cosmetics Rules prescribe the conditions that have to be complied with before a manufacturing licence is granted and also the conditions which a licensee has to comply with during the tenure of his licence. Similarily pre-requisite and running conditions are also prescribed in respect of licences granted for sale of drugs.

3.3 The Ministry of Health have stated in a note to the Committee that the organisational set up in the States is not uniform and varies depending upon the concentration of the drug industry in the State. Thus in States like Maharashtra and Gujarat which have a high concentration of drug industry the drug control organisation is fairly large consisting of a head-quarters organisation headed by a full-time technically qualified Drug Controller and regional offices headed by Joint Drug Controller/

Deputy Drug Controller assisted by adequate number of Drug Inspectors. However, in States which are small there are no regional offices as such although Drug Inspectors are posted with one or two districts as their territory.

3.4 It has been stated by a non-official organisation in a memorandum that :—

> "Health being a concurrent subject, the administration of the Drugs and Cosmetics Act 1940 is done both by the Centre and States with their own machineries, though a bulk of coverage is done by the drugs control administration at the State level. And it is here, that it lacks in uniformity.....It is this lack of uniformity that is at the root of the present problem of maintenance and control of Drug Standards. Because the Drug Control Administration in cetain states is poor, the manufacturers and traders in substandard drug take advantage of this and same is transported to even such States where the Drug Control Administration is fairly good. It is in such States where the vigilance wing is active, that the substandard commodities are detected and given publicity so that a stranger unconversant with the State of affairs is likely to get away with the impression that all is not well in the States where the substandard drugs are detected."

3.5 On the question of non-compliance of the provisions of the Act, the Secretry, Health stated :—

> "the main reason for the laxity in the strict and uniform implementation of the Drugs and Cosmetics Act is the fact that the Drug Control Administration in the States is not up to the mark. A task force has gone in detail into the problems of substandard and spurions drugs and it has identified the are a where drug control machinery is required to be strengthened. The drug testing facilities in the country are also not adequate, although there has been considerable improvement during the the last few years. Nevertheless, unless the Drug Control Organisations in the States are adequately staffed and provided with the necessary resources, the enforcement of the Act would continue to be unsatisfactory.

Unless there are adequate number of trained Inspectors, the necessary testing facilities, an independent Cell in the Drug Control Organisation, and above all, a conscious and consistent attempt on the part of the Government to pursue all cases of spurious drugs, the Drug Control organisation will not be able to achieve the results."

3.6 When asked if the Ministry agreed that the uniformity in implementation of the Drugs and Cosmetics Act and Drug Rules was lacking in States, the Health Secretary conceded that :—

"It has to be admitted that implementation of Drugs and Cosmetics Act is not uniform in the State. This is because some of the Drug Control Organisations in the States do not have the necessary infrastructure which is essential for tackling the problem of substandard and spurious drugs. These States are Haryana, U.P. Bihar, Rajasthan, Madhya Pradesh, Himachal Pradesh, Assam and Jammu & Kashmir. These are the States where there is lot to be done in making the Organisation an effective instrument of combat this serious problem."

3.7 During evidence it was pointed out that when the question of spurious or sub-standard drugs had figured in a number of debates in Parliament, it was obvious that it was because of the failure of State Governments to have a requisite machinery in their respective States that this activity proliferated. Even the States mentioned by the Health Secretary having a weak organisation included the major States and again the States in which this activity had gone on a very big scale were U.P., Bihar and Madhya Pradesh. In this context and also in view of the fact that the subject of drugs was in the Concurrent List the Committee wanted to know whether Government proposed to fix up a time-limit within which the requisite machinery would be set up in the States and the Central Government would supervise it :

3.8 The Health Secretary assured :—

"To be frank, though we have, after the Task Force Report, after the recent amendment to the Drugs and Cosmetics Act, paid special attention to this matter, so far we have not laid down as yet any target before them. And I think if we can take a cue from the very good suggestion of the hon. member,

we will, in the Ministry, try to lay down a specific date by which these organisations must set up their machinery."

3.9 Asked if some pressure could not be brought on the State Governments that no financial allocation would be made they set up the machinery. The Secretary Health responded thus : "I agree, we will put it to the States and we will inform you."

Central Drug Control Organisation

3.10 The Central Drug Control Organisationg consists of a Headquarters Organisation comprising the Drugs Controller (India) assisted by two Deputy Drugs Controllers (India), two Assistant Drugs Controllers (India), one Biochemist and one Pharmacologist in addition to Technical Officers, Technical Assistants and other Ministerial staff. The Central Drug Control Organisation has four Port Offices located at Bombay, Calcutta, Madras and Cochin for regulating the quality of imported drugs. While the first 3 Port Offices are headed by an Assistant Drugs Controller (India), the Port Office at Cochin is headed by a Technical Officer. In addition, there are four Zonal Offices located at Bombay Calcutta, Madras and Ghaziabad which are headed by Deputy Drugs Controller (India), and assisted by Drugs Inspectors.

Role of Central Drug Standard Control Organisation and its Zonal Offices :

3.11 The Ministry of Health have stated in a note that the responsibility for enforcing the provisions of the Drugs and Cosmetics Act is distributed between the Central and the State Governments. The Central Government through the Central Drug Standard Control Organisation headed by the Drugs Controller (India) is responsible for (1) controlling the quality of imported drugs (2) laying down regulatory measures and standards for drugs, and (3) granting approval to new drugs proposed to be manufactured or imported in the country and (4) coordinating the States and advising on matters relating to uniform administration of the the Act in the country.

3.12 The State Government are responsible for exercising control over drugs manufactured, sold and distributed in the country through their State Drug Control Organisations.

3.13 It has been stated in a memorandum submitted to the Committee, however, that :—

"This division of responsibilities fails to take into account the role of overvll coordination of control that the Central Drug Control Organisation should play. They Committee of Economic Secretaries of the Government of India recognised this shortcomiug and stressed the importance of the Central Government assuming responsibility for (in addition to the present role of advising on)" statutory enforcement and control over the manufacture of drugs all over the country" and also for supervising "their wholesale distribution among the various States".

3.14 Since some of the States were reported to have failed and since' 'Drugs' was a concurrent subject the Committee asked if the Central Drug Controller's Organisation should be strengthened to make up for the laxity on the part of same the States. The Health Secretary stated that the Task Force had recommended that the Central Drug Control Organisation should be strong and a proposal for strengthening the organisation had been drawn up. He added, however, that since the powers for issuing licences for manufacture and sale of drugs rests with the Drug Control Organisations in the States, the Central Organisation can play only a coordinating role, a role of guidance, of monitoring but not a directly executive role in the matter.

3.15 Asked if the Central Drug Control Authority needed to be vested with a more effective statutory enforcement and control over the country, the Health Secretary stated during evidence :—

"As already mentioned, the drug industry is fairely large and scattered all over the country. There are roughly 8000 allopathic manufacturing units. There are more than 2 lakhs wholesalers and retailers in the country dealing in this business. If the control over the manufacture and distribution of drugs is to be vested with a Central control organisation, then the set up of the organisation, will have to be suitably strengthened. The State Governments may not also be willing to part with the powers that they presently enjoy. In any case it would be difficult to control such a large number of drug manufacturing units spread throughout and length and breadth of the country, through a single organisation situated at Delhi. This is another aspect."

He added :—

"It is a point essentially of the Centre-State relation and the question is where in an area it is practically very difficult for a single organisation to tackle the entire length and breadth of the country where 2 lakhs dealers with so many small units are there and it will require an army apart from the Drug Inspectors whether it is more feasible to deal with them through a limited effective State Organisation."

3.16 In regard to the working of the zonal offices the Drug Controller stated during evidence that the Zonal Offices had been carrying out inspections in respect of firms against which the complaints were received. In some cases, cancellation of licenes had resulted as a result action taken by zonal offices. He added however that the Zonal Officers were very small. They were essentially coordinating organisations. There were in all about 34 Inspectors in the four Zonal offices. The Task Force had observed that the existing zonal offices had to cover several States with the result that they were unable to maintain effective rapport with the State Drug Control Organisations. The Task Force had therefore recommended that offices of the Central Drug Standards Control Organisations should be located in major States headed by Deputy Drugs Controller (India) or Assistant Drug Controller (India) depending on size and concentration of Industry. Priority in establishing such offices should be given to those states where the Drug Control Administration was comparatively ineffective. The Task Force had observed further that that the zonal offices had been experiencing constraints in their functioning. The main constraint had been inadequate budget provision especially for travelling allowances and purchase of samples for analysis.

3.17 The Health Secretary stated during evidence that :—

"We assist them to the extent possible. We are thinking of extending zonal organisations. Basically we must be able to have a one Drug Organisation in each State."

3.18 The Committee wanted to know if the pattern of drug control administration in the country was similar to those followed in foreign countries, the Secretary stated :

> "One thing I would say that drug control administration in most of the developing countries is very important and effective department. But I don't know for various reasons here nothing can move. Once they say no, nothing moves thereafter. But I am afraid to that extent neither the machinery has been there, nor I think the built-in systems are there and we have to cover a lot of ground in that regard."

3.19 Asked if the Central Ministry/Drug Control Authority had powers to control the standrads and norms to maintain quality of drugs, the Secretary replied :

> "I don't think we have. I don't think we are taking any concrete action in this regard. But I do feel that legally we should be in a position to control the standrads."

B. Licensing

3.20 In the area of coordination between the Centre and the States the Hathi Committee (1975) had recommended that licencing of drug producing firms in each State should be done through a licencing board consisting of (1) drug controlling authority of a State concerned; (2) drug controlling authority of States in the region; (3) a senior representative of the Drug Controller of India; and (4) if possible one drug control authority from the State of Maharashtra. They said that all licencing should be done by a board composed in this manner. The Secretaty, Health informed the Committee during evidence that this recommendation was not accepted by the Government of India as it was considered that there would be considerable delay in issuing licences instead of a single State's administration doing it. As it is, the industry had been complaining that there was a lot of delay and if a board was set up it would cause further delays.

3.21 As regards the suggestion that licencing of the firms should be done by a team of Central and State Drug Control bodies the Secretary, Health informed the Committee that it was said that such a procedure would be followed in case the States were agreeable. Further, this would require considerable strengthening of the zonal offices of the Central Drug Control Organisation.

3.22 The Hathi Committee suggested that whenever the Central Drug Control Organisation felth that drug manufacturers who had been licenced were unfit to carry on the manufacture, it should be incumbent on the Central Government to take up the matter with the State authorities (at a high level) and get the licences cancelled.

3.23 Asked to state the existing practice in this regard the Secretary, Health Ministry informed the Committee that whenever an officer of the Central Drug Control Organisation, during the course of inspection, finds that the manufacturer is unfit to carry on that activity, the Deputy Drug Controller in that State takes up the matter. The Zonal Offices are divided in such a manner that certain states come in their jurisdiction. The Drug Controller concerned takes up the matter with the State Government. The Secretary observed that by and large, the State Drug Control Authority had taken action on such reports received from the Central offices.

3.24 The Committee enquired whether after having rejected the Hathi Committee recommendation (1975) for setting up of technical Committee and this policy having stayed for some time, what had been the experience and whether a revision of the policy was now considered necessary and whether the fear that such a Committee would hamper licencing procedure was genuine or imaginary.

3.25 Drug Controller was of the view that composition as suggested by Hathi Committee for licencing Board that would create administrative problem as one drug controller might not like his counterpart from another State to be on the Board. Secondly, it would be difficult to get a team of all such persons together to carry out the inspection prior to licencing firm will be difficult. Apart from the fact that all the States had to agree even to get four officers from the four different organisations every time inspection had to be carried out would delay the procedure considerably.

3.26 The Drug controller informed the Committee that about 800 new licences had to be issued every year.

3.27 When asked if it would help if atleast one officer from the Central Drug Controller's Organisation was also inveloved in this process the Secretary, Health remarked that at one stage even joint inspection before licensing was objected to by some States.

3.28 He added :

> "It is desirable that at least somebody from outside, ensures that there is a proper check. But I think, it will not be free from problem. Any way, we will pursue it with the States before the issue of licence, that there should be a general inspection along with the representatives of the Central Government ..... We have accepted the suggestion. We will do something about it."

3.29 As far as the Committee can see the main reason for laxity in strict implementation of The Drugs and Cosmetics Act, uniformally in the country is the weakness of the Drug Control Administrations. Some of the States *viz.* Assam, Bihar, Haryana, Jammu & Kashmir, Madhya Pradesh, Rajasthan and U.P. do not have the necessary infrastructure which is essential to tackle the problems of sub-standard and spurious drugs. Other reasons are that (i) Drug Control organisations in the States are not adequately staffed and provided with necessary resources, (ii) drug testing facilities in the country are inadequate and (ii) the number of trained and experienced Drug Inspectors is not adequate. The manufacturers of and traders in sub-standard and spurious Drugs obviously take advantage of this situation. The Committee recommend that the Ministry should take up the matter with the States concered at the highest level with a view to removing the deficiencies with in a time-frame.

3.30 The Committee agree that it will not be a feasible proposal for the Central Government assuming the responsibility for statutory control over manufacture and sale of drugs all over the country. They are, however, inclined to agree to the view expressed in a non-official memorandum to the Committee that the Central Drug Control Authority had failed to achieve an effective coordinating role. The Committee desire that Central Government might examine what further powers for the Central Authority are necessary to achieve the desirable degree of coordination.

3.31 In this connection, the Committee note that the Hathi Committee had suggested a machanism of a board consisting

of Drug Controlling Authorities of States concerned and senior representatives of the Drug Controller of India to secure Central participation in the issue of drug manufacturing licences. This recommendation was not accepted on the ground that such a system would add to further delays in issuing licences which are already being delayed. However, in the Estimates Committee's view the minimum that can be done is that there should be a general inspection of the unit applying for licence before the issue of licence in which a representative of the Drug Control Authority should be involved. This suggestion of the Committee was accepted by the Health Secretary in evidence and the Committee hope it will be pursued further.

3.32 The Committee note further in this connection that each of the existing four zonal offices of the Central Drug Control Organisation, which are essentially coordinating agencies, have to cover several States with the result that they are unable to maintain effective rapport with the State Drug Control Organisations. Apart from a very meagre force of 34 Inspectors in all the Zones put together, they are reported to be suffering from financial constraints. The Committee urge that the zonal offices should be suitably strengthened to enable them to maintain effective rapport with the State Drug Control Organisations, and render them all possible assistance to discharge their funtions meaningfully.

Multiplicity of Licences

3.33 A non-official organisation has represented to the Committee that there are presently various licences required to be taken by one dealing in drugs. For example, poison licence is superfluous in viev of the drug licence. Yet at present it has to be obtained from the police. Certificate for Medicinal and Toilet Preparations is to be got from the Board of Revenue for dealing in formulations containing alcohol. This again is said to be superfluous in view of the drug licence. Now even under the Drugs and Cosmetics Act, separate licences are required for biological drugs, non-biological drugs and now psychotropic drugs; again for dealing in retail and for dealing in wholesale, etc., licence can be one with due endorsements. It has been pointed out in this connection that even Borkar Committee had suggested redutcion in the number of licences. It has

been suggested that all these licences must be brought under the Drugs and Cosmetics Act and even under the Drugs Act, number of licences must be minimised.

3.34. When asked whether the prevailing multiplicity of licences for dealing in drugs could not be substantially minimised the Drug Controller stated in evidence that there were three different authorities to issue licence and that all the three Acts were Central Acts but all licences were to be issued at the State level only. It could be considered whether one authority could issue the licence.

3.35 The Health Secretary assured the Committee that :—

> "These are areas, which I must admit where there is scope for improvement. We will constitute a Committee of inter-Ministerial Officers and see whether this work can be rationalised in terms of the licence."

3.36 The Committee note that those dealing in Drugs have to obtain besides the licence from the Daug Controlling Authority, licences from many other authorities. In this connection, the Health Secretary assured the Committee in evidence that a Committee of inter-ministerial officers will be constituted to see if the work relating to issue of licences under the Drugs and Cosmetics Act and other Acts could be rationalised. The Committee would like to be apprised of the outcome.

C. *Drug Inspectors*

3.37 The Task Force (1982) in its Report had pointed out that :—

> "The Drug and Cosmetics Rules require that every manufacture and sale establishment shall be inspected by a Drug Inspector act less than twice a year. From the replies received to the Questionnarie it is observed that only the States of Gujarat, Haryana and West Bengal and the Union Territory of Pondicherry have indicated that they carry out inspections twice a year as required under the Rules. The remaining States and Union Territories have replied in the negative. It has been assessed that if effective control over manufacture and sale has to be exercised, there should be one Drugs Inspector for every 25 manufacturing premises and one Drugs Inspector for every

100 sale premises. The number of licensed premises for manufacture of Allopathic, Ayurvedi/Unani Drugs and cosmetics is 12,000. The number of sale premises is about about 1,70,000.. The total number of Drug Inspectors that would be required according to the above norms would be about 2,200. Against this figure, the total number of Drugs Inspector is at present 576. Even in State like Maharashtra and Gujarat where the drug industry is concentrated the number of Drug Iuspectors in inadequate."

3.38 The Task Force (1982) had accordingly suggested that :—

"The number of Drug Inspectors in the States should be increased in keeping with the number of manufacturing and selling premises licensed on the basis of one drug inspector for very 25 manufacturing premises and one inspector for 100 sale premises. For this purpose the drug control organisations in the States would have to be augmented. Such strengthening of Drug control machinery should be considered developmental and expenditure for this purpose should be classified as Plan expenditure and adequate provision made in the State Plan."

3.39. The Health Secretary stated during evidence in this connection that :—

"Now every manufacturing premises is required to be inspected not less then twice a year by the State Drug Inspcetor. However, it is to be admitted that in most States this periodic inspection is not being carried out. I must admit that the paucity of Drug Inspectors is the main constraint for carrying out more frequent inspections of the manufacturers' premises. As I have already submitted, there are 600 Drug Inspectors throughout the country as against the requirement of 2000. Here we have already accepted the suggestion of the hon. Member without waiting for the report of the Committee and also we are going to determine some time-bound action by which each State is expected to increase its drug inspectorate, provide for their training etc., in consultation with the States. We will call a meeting and we will determine 3 to 4 watersheds progress to which the States must take and we can then point out that so and so State has not done that much vis-a-vis such and such State."

Qualifications/Experience of Inspector

3.40 Under Rule 49 of the Drug and Cosmetic rules, a person who is appointed an Inspector shall be a person who :—

(a) has a degree in Pharmacy or Pharmaceutical Chemistry or a post graduate degree in Chemistry with pharmaceutics as a special subject of a University recognised for this purpose by the appointing authority or the Asscciateship Diploma of the Institution of Chemists (India) obtained by passing the examination with "Analysis of Drugs and Pharmaceuticals" as one of the subject; or

(b) holds the Pharnaceutical Chemists diploma granted by the Pharmaceutical Society of Great Britain; or

(c) is a graduate in medicine or science of a University recognised for this purpose by the appointing authority and has at least one year's postgraduate training in a laboratory under (i) a Govt Analyst appointed under the Act or (ii) a Chemical Examiner, or (iii) a Fellow of the Royal Institute of Chemistry of Great Britain (Branch E), or (iv) the head of an institution specially approved for the purpose by the appointing authority.

Provided that only those Inspectors who have had not less than three years' experience in the manufacture or testing of substances specified in Schedule C in a laboratory approved for this purpose by the licensing authority, shall be authorised to inspect the manufacture of items mentioned in Schedule C."

3.41 A non-official organisation has represented to the Committee that the drug industry has acquired a high reputation among doctors and it is manned by highly qualified and experienced staff. The sophisticated nature of operations require an intimate knowledge of the process involved and of the means of standardisation. One would expect that the inspectors appointed to inspect manufacturing units would possess qualification and experience to atleast to match those who man the industry in order to inspire confidence and to be able to guide the industry where such guidence is needed. It has however, been pointed out to the Committee that

although the inspectors are required to possess a degree in pharmacy or pharamaceutical chemistry etc. it is not necessary that they should possess experience in the manufacture or testing of drugs except in some cases. While the rules therefor permit the appointment of a fresh and new graduate without any manufacturing or testing experience the manufacture of drugs has to be conducted under the personal spervision of a person who must possess in addition to the academic qualification prescribed atleast 18 months drug experience after graduation in manufacture of drugs.

3.42 Asked if it would be not be rational that the qualifications of an inspector should atleast match the qualifications of those conducting manufaeture of drugs, the Health Secretary opined during evidence that :

> "It is true that for appoinment of drug inspector, experience in manufacturing or testing of drug is not required in all cases. Only in cases of inspectors inspecting the manufacturing premises which are manufacturing Schedule C drugs, i.e. biological products, an experience of not less than three years in manufacturing and testing is required. We agree in principle also that the qualifications of drug inspector should at least match the qualifications of those required for a person in charge of manufacture of drugs."

He however pointed out that

> "However, it may be pointed out that the salary structure of the Drug Inspectors is such that it can hardly attract persons having experience of two or three years in the manufacture or testing of drugs. He is in a Class II post carrying the scale of Rs. 650-1200. The drug inspectors in the State Governments are still worse. Those persons who have these qualifications and experience would rather go to the industry and work in the industry where they will get much more. As the availability of persons with experience increases, it should be possible that we will have to upgrade the pay scale. As more and more qualified people are coming up, we will have to increase the emoluments. Only then the persons who are well qualified will come for these jobs."

3.43 The Drug Controller added that in most States there was generally a training programme and training programmes were also being conducted at the Centre for the new drug inspectors for 5 weeks where they are exposed to all the different manufacturing techniques and they are also shown the factory. Mostly a new Inspector is put to an experienced inspector. He, however, ageed that "the ideal thing is that we get an experienced inspector."

3.44 Drug Inspector is supposed to be the kingpin of whole mechanism of the Drug Control in the country. The Drugs ond Cosmetics Rules require that every manufacture and sale establishment should be inspected by a drug inspector not less than twice a year. The Task Force had found that except for the States of Gujarat, Haryana and West Bengal and the Union Territory of Pondicherry no other State of Union Territory was adhering to this requirement. As against the requirement of 2,000 drug inspectors in the country, the number available today is only about 600. Government should take necessary steps to ensure that the inspectorates of the State Drug Central Organisations are Strengthened adequately in accordance with a time bound programme.

3.45 Sophisticated nature of operations in drug manufacturing today requires intimate knowledge of the processes involved. The drug industry is therefore manned today by highly qualified and experienced staff. It is therefore necessary that the inspectors appointed to inspect the drug manufacturing units should also possess qualifications and experience atleast to match the qualifications and experience of those engaged in the manufacture not only to inspect the processes with a view to ensuring standards but to inspire confidence and be able to guide the industry. If need be, salary structure of Inspectors be improved so as to attract qualified and experienced personnal.

D. *Drug Technical Advisory Board*

3.46 The constitution of the Drug Technical Advisory Board is laid down In Section 5 of the Drugs and Cosmetics Act as follows :—

The Drugs Technical Advisory Board—(1) The Central Government shall, as soon may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administrations of this Act and to carry out the other functions assigned to it by this Act.

The Board shall consist of the following members, namely :—

(i) the Director General of Health Services, ex-officio, who shall be Chairman ;

(ii) the Drug Controller, India, ex-officio;

(iii) the Director of the Central Drugs Laboratory, Calcutta, ex-offico;

(iv) the Director of the Central Research Institute, Kasauli, ex-officio ;

(v) the Director of the Indian Veterinary Research Institute, Izatnagar, ex-officio ;

(vi) the President of the Medical Council of India, ex-officio;

(vii) the President of the Pharmacy Council of India, ex-officio;

(viii) the Director of the Central Drug Research Institute, Lucknow, ex-officio ;

(ix) two persons to be nominated by the Central Government from among persons who are in-charge of drugs control in the States;

(x) one person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian University or a college affiliated thereto ;

(xi) one person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian University or a college affiliated thereto ;

(xii) one person to be nominated by the Central Government from the pharmaceutical industry ;

(xiii) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research ;

(xiv) one person to be elected by the Central Council of the Indian Medical Association ;

(xv) one person to be elected by the Council of the Indian Pharmaceuticals Association ;

(xvi) two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government."

3.47 It has been represented to the Committee that the Drugs Technical Advisory Board which lays down standards for the drug industry and on which the industry is very poorly represented should draw on the expertise and experience of the industry by having more representatives on it. The Hathi Committee was of the opinion that the Drugs Control Organisation also had a role as "advisor to the industry to strive for constant improvement of its per formance" ; this role can be played more effectively if the Board were to be in greater contact with the industry than at present.

3.48 Asked if the Board could not be made more representative by strengthening the representation of various interest on the Board, the Secretary, Health stated in evidence that :—

> "The Drug Technical Advisory Board is a very important body under the Act itself and its composition is given in Section 5 of the Act. Though the pharmaceutical industry has a representative on it, yet most of the other representatives are technical people like ICMR, President of the Medical Council of India. President of the Pharmacy Council of India. The Trade has no representative and we cannot have one, unless we amend the Act. Any amendment of the rules under the Act has to be published in the gazette for comments of the public. In other words, trade and other public get adequate opportunity to present their points of view."

3.49 There is force in the representation made on behalf of the drug industry that the industay is poorly represented on the Drug Technical Advisory Board which lays down the drug standards. While the Board does have a representative of the Pharmaceutical industry, it does not have a trade representative. There are about 2 lakh traders dealing in drugs in the country at present. The Committee desire that the need to have a trade representative on the Drugs Technical Advisory Board should be examined to make the Board more broad based.

CHAPTER IV

PHARMACOPOEIAS

A. *Pharmacopoeias for Allopathic Drugs*

4.1 The Drugs and Cosmeties Act exercises a control over the manufacture and sale of Allopathic, Homoeopathic, Ayurvedic and Unani Drugs. So far as Allopathic and Homoeopathic drugs are concerned there are official pharmacopoeias and these drugs are required to comply with the standards laid down in these pharmacopoeias. As regards Ayurvedic and Unani drugs the Committee have been informed that there is at present no official pharmacopoeia and consequently no standards have been prescribed for these drugs in the Drugs and Cosmetics Act and the Rules. The Committee have been informed that the Ayurvedic pharmacopoeias Committee is engaged in the compilation of the Ayurvedic pharmacopoeia and when this pharmacopoeia is published the question of prescribing standards for Ayurvedic products would be considered.

4.2 For Allopathic Drugs the Indian pharmacopoeia is compiled by the Indian Pharmacopoeia Committee constituted by the Ministry of Health and Family welfare. The Committee have been informed that two editions of the Indian pharmacopoeia and two Supplements ehereto have so far been published The Third Edition of the Indian tpharmacopoeia has also been compiled and is being sent for printing. The Indian Pharmacopoeia Committee lays down standards for drugs taking into consideration the standards laid down in other pharmacopoeias and the standards that are capable of being achieved by the indigenous drug industry.

4.3 It has been stated by a non-oficial in a memorandum that:—

> "The Indian pharmacopoeia being the sole recognised book of standards for drugs included in it, it is necessary, that these standards are kept upto date. Factually the last edition of Indian pharmacopoeia was published in 1966 the previous one being of 1955 and the standards laid down therein still constitute the official standards. A supplement to the 1966 edition was published in 1975 containing monographs on some newer drugs. In order to keep abreast of times it is necesary that the revision of the pharmacopoeia is undertaken more frequently."

4.4 The Secretary, Health stated during evidence in this connection that :—

> "It has to be admitted that the Indian pharmacopoeia has not been published as regularly as it should be. Although pharmacopoeia of developed countries is published every 5 years, I think, at least in India if we are able to ensure that it is published every 10 years and new edition of pharmacpoeia every 5 years in supplement, it will be better. If we follow even this arrangement, it should be adequate for the purpose. It has to be admitted that the present arrangement is not at all satisfactory and therefore we will ensure that it is at least published every 10 years. We in the Ministry intend to do this. After 1966, nothing has come in-between, I wanted to submit that this matter is under consideration."

Publication of revised edition of the Pharmacopoeia

4.5 It has been stated by a non-official in a memorandum to the Committee that :-

> "According to information although the latest compilation of the pharmacopoeia is ready for publication, it will not be possible to publish it in less than 2 years on account of other commitments of the Controller of Printing. We feel that in the interests of keeping the standards of drugs upto date it is necessary that Pharmacopoeia should be published with the least possible delay. If the Government Press does not have spare capacity permission should be given for printing the Pharmacopoeia elsewhere. Such delays make a mockery of Drug Standards."

4.6 The Commitee wanted to know whether it would not be possible to have it printed early. The Secretary, Health stated during evidence :-

> "The Ministry of Health have agreed to the printing of the third edition of the Indian Pharmacopoeia through the aegis of the Publication and Information Directorates of the Council of Scientific and Industrial Research. They have been able to complete the job within a period of one year. In fact, we are providing Rs.6 lakhs in the current year's budget for this purpose."

4.7 It has been stated that at present the Drug Controller [India] acts as the Secretary - of the Indian Pharmacopoeia Committee and that of the National Formulatory Committee in addition to his own duties which are quite onerous. Moreover, the Drugs Controller (India) is also the Secretary of Drugs Technical Advisory Board constituted under the Drugs and Cosmetics Act, 1940. The functions of each of these Committee and of the Board are such that to do full justice to the subjects dealt a seperate officer for each of these function would be justified.

4.8 Commenting on this suggestion, the Secretary, Health observed during evidence as follows:--

> ".....at the moment, the Drug Controller of India is the Secretary to the Indian Pharmacopoeia Committee. I think, this arrangement not satisfactory, as we in the Ministry feel. Once we tried to get a whole-time person but the Ministry of Finance did not agree. Now we try to pursue again. Unless there is a wholetime officer for this Committee, it will not be possible to deal with the matter appropriately. We will again take up the matter with the Ministry of Finance to have a full time officer."

Organisation for Compilation of Pharmacopoeia

4.9 A non-official organisation has suggested that there should a separate cell in the Ministry of Health and Family Welfare for the compilation of the Indian Pharamacopoeia and keeping the standards of the drugs upto date.

4.10 In this connection, the Secretary, Health expressed the following views:--

> "it is necessary that compilation of Indian Pharmacopoeia should be entrusted to an autonomous organisation which should be independent of the Department. Our idea is that this should be done separately by a full-time officer. We would like to pursue this matter in this manner.
>
> The Secretary added that:--
>
> "We are now again going to pursue the matter with the Ministry of Finance. We had already taken a decision 4 or 5 years back. At that time, the Finance did not agree. We intend to pursue this and make them agree because this is an important aspect.

B. *Standards regarding Ayurvedic, Unani Sidha and Homoeopathic Drugs*

4.11 As stated earlier, there is at present no official pharmacopoeia for Ayurvedic Unani and Sidha drugs and consequently no standards have been prescribed for these drugs in the Drugs and Cosmetics Act and the Rules. The Committee were informed that considering the importance of laying down standards for these drugs, the Government of India has constituted Pharmacopoeia Committees for all the three India system with the following objectives:--

1. To prepare an official formulary of Single and compound preparation which are frequently used;
2. To provide standards for drugs and medicines of therapeutic usefulness or pharmaceutical necessity; and
3. To lay down tests for identity, purity and quality.

4.12 The Committee have been informed that all these Committees are engaged in bringing out their respective pharmacopoeias. So far only the first part of the Formulary of Ayurveda, has been published. The first parts of the Unani and Sidha Formularly are under print.

4.13 When asked how control over Drug Standards was being exercised on Ayurvedic and Unani drugs in the absence of any standards having been laid down, the representatives of the Ministry of Health stated during evidence that Chapter IVA of the Drugs & Cosmetics Act exercises limited control over Ayurvedic and Unani Drugs. The main points to observed in the preparation of the drug were that the medicine should be prepared under hygenic conditions and under the supervision of a person having prescribed qualifications, the raw materials used in the preparation of such drugs should be genuine and properly identified and list of all the ingredients contained in the drugs sould be indicated. He informed the Committee that after the enactment, modern and perliminary standards had been worked out and the medicines were being prepared accordingly.

4.14 The Secretary, Health informed the Committee during evidence that the first part of the Ayurvedic Formulary of India consisting of 444 formulations had been published in 1978. The second part of the formulatry had been drafted and was awaiting the final appaoval of Ayurvedic pharmacopoeia Committee. As soon as it was

approved it would also be published. Preliminary work on the third part of Ayurvedic Formulary had been undertaken and it had been decided to prepare monographs of 100 single drugs in the first instance. He stated that monographs of 100 single drugs were ready and monograps of 30 drugs had been completed and the remaining work was to be completed by 1984. 'This work', he said, "had been seriously taken up."

4.15 The Secretary informed the Committee further: "I cannot qu ite say that it is not enough, at this stage. But a major beginning has been made."

4.16 The Committee were informed further that for the first time the ministry had set up a Public Sector Corporation called the India Pharmaceutical Corporatin of India, in Ram Nagar, U.P. based in 15 acre herbal garden. This Corporation intended to produce medicines worth Rs. 25 lakhs and the idea was to raise the production to the tune of Rs. 1 crore which could be standard Ayurvedic Madicines. It was also the intention to use them in CGHS dispensaries. It was also contemplated to set up similar units elsewhere.

4.17 As regards Unani and Sidha drugs, the Committee were informed during evidence that Unani Pharmacopoeia Committee had brought out a formulary of 440 formulations which had been sent to the Press for publication.

4.18 Similarly first part of the Sidha formulary was said to be ready and under print in Coimbatore. The second was said to be in hand. Some of the formulations of 100 single drug monographs were stated to be applicable in the case of all the three system *viz.* Unani, Ayurvedic and Sidha Drugs.

4.19 Attention of the representatives of the Ministry of Health was drawn to the practice of sale of drugs and herbals by some unauthorised persons along the road side. The Committee wanted to know the action taken against such people. The representative of the Ministry informed the Committee that under section 17 of the IMCCA framed in 1970 no body can practice without a licence.

Homoeopathic Drugs

4.20 The Committee have been informed that the Homoeopathic Pharmacopoeia Committee set up in 1965 had so for published three volumes of the Homoeopathic Pharmacopoeia. The first list of the

Homoeopathic remedies consisted of 2600 such remedies and since some of them were not used so frequently the same was pruned to 1600. This Committee's task was to make monographs of 1600 single remedies.

4.21 It was pointed out during evidence that most of the Homoeopathic practitioners were unqualified persons. The representative stated that "we would not like an unqualified person to practice in the field."

He added that there were 126 colleges in the country which were producing as many as 4000 to 5000 graduates every year.

4.22 India Pharmacopoeia which is the sole basis for maintenance of standards of drugs is not being pubished regularly. The last edition of the pharmacopoeia was published 17 years ago i. e. in 1966. Whereas in the developed countries Pharmacopoeia are being published every 5 years, in India it would be about 20 years by the time new edition is published. This is not at all a satisfactory situation and calls for immediate attention. The Committee recommend that arrangements should be made to ensure that henceforward the new edition is published at least every 10 years and a supplementary edition is brought out every 5 years. This will go a longway in keeping the indigenous drug idustry abreast of the latest developments in the field of drugs.

4.23 The Committee are not at all satisfied with the existing arrangements to look after the work relating to compilation and publication of the India Pharmacopoeias. At present the Drugs controller [India] acts as the Secretary of the India Pharmacopoeia Committee as well as of the National Formulary Committee, in addition to his own duties which are quite onerous. Considering the importance of the matter the Committee recommend that the work of the India Pharmrcopoeia Committee should be looked after by a separate organisation under a whole time officer.

4.24 What has surprised the Commitee more is the fact that no official pharmacopoeia for Ayurvedic, Unani and Sidha systems of medicines exists at present. Consequently no standards have so for been prescribed for these drugs under the Drugs and Cosemtics Act and Rules. The Committee cannot

but deplore this attitude towards the indigenous systems of medicines which, the Committee are told, are more economical to the people and more popular among them. It is only now that some belated attempts are being made to compile formulations of drugs of these systems.

4.25 The Committee were given to understand during evidence that with the setting up of the India Pharmaceutical Corporation of India where Rs. 1 crore worth of medicines are intended to be produced in the course of four years the Ayurvedic system of medicines will receive a greater fillip, and based on this experience similar work will be taken in hand in Unani-system as well as in due course. The Committee hope that there will be no let up in efforts in this direction.

NEW DELHI :
December 21, 1983
Agrahayana 30, 1905 [*S*]

BANSI LAL
Chairman,
Estimates Committee.

APPENDIX

Summary of Observations/Recommendations

S. No.	Para No. of Report	Recommendations/Obseavations
1	2	3
1.	1.15	The drug industry in India has registered a phenomenal growth in recent years. The output of the industry has touched Rs. 1550 crores enabling India to become the 12th largest drug producing country in the world. The total value of import of drugs and formulations into the country is at present only of the order of Rs. 150 cores per annum as aginst the export of drugs of the value of Rs. 65 crores. It is in this context that the Committee examined the quality of the drugs and the quality control measures.
2.	1.16	The manufacture, sale and distribution of drugs is governed by the Drugs and Cosmetics Act, 1940 and the rules framed thereunder, as amended from time to time. Since under the Constitution, 'Drugs' is a Concurrent subject the administration of this Act is the responsibility of both the Central Government as well as the State Governments. There are said to be about 8000 manufacturers of allopathic drugs in the country who have been licenced under this Act. Out of them 130 are in the organised sector i.e. medium and large sector and the remaining are in the small scale sector. There are as many as 1.7 lakh traders in the drug trade. The Act stipulates, inter-alia, that no person himself or by any other person on his behalf shall manufacture for sale, or distribute any drug which is not of standard

1	2	3

quality, or any misbranded or adulterated drug, etc. If a person does so, he is liable for imprisonment which may in certain cases extend to life imprisonment. A non-official organisation has expressed the view that despite progressively enhanced punishments provided in the Act from 1955 to 1982, these have not had a visible impact on the high incidence of substandard drugs in the market. According to the statistics made available to the Committee by the Ministry of Health and Family Welfare, of the drug samples tested during the period 1977-78 to 1981-82 the percentage of samples found sub-standard ranged between 14.5 to 21.6. The percentage of samples found sub-standard in 1981-82 was 18.3.

The Health Secretary pointed out in evidence that the percentage of drugs found sub-standard should not be viewed as unduly high for two reasons. Firstly, the production of drugs in the country had gone up substantially, Seconly, the large number of samples tested were from the small scale sector numbering 7000 units which contributed only 20 per cent to the total drug production. As much as 80 per cent of the total drug production was accounted for by the large and medium scale sector. The Health Secretary also pointed out that the fact that 18 per cent of the samples tested were found to be sub-standard. in a year did not mean that 10% of the drugs moving in the market were all sub-standard This displays a complacent attitude. Any complacency or laxity in the maintenance of drug standards can pose grave danger to the health of the people. The Committee, therefore, desire that a stricter vigil should be kept in this regard, particularly on the drugs and formulations produced and distributed by multinationals and Government Undertakings.

1	2	3
3.	1.17	The Committee find that under the Drug and Cosmetics Act every manufacturer of drugs is required to test every batch of the finished product before its release for sale. In fact this is a part of the condition of the drug licence under which the manufacturer produces drugs. The quality of drugs has also to be ensured by the Drug Control Authorities. The Committee are however, surprised that no indication is at present available as to what percentage of drugs produced in the country is being subjected to testing either by the Drug Controller of India or by the State Drug Control Authorities. The Ministry of Health and Family Welfare have, on the basis of information received by the Drug Controller, India in respect of two Central Government Laboratories viz. Central Drug Laboratory, Calcutta, and Central Indian Pharmacopoeia Laboratory Ghaziabad, which act as Government analysts for a number of States-Union Territories, intimated that during the years 1978-79, 1979-80 and 1980-81, the drugs of as many as 857 manufacturers [including 29 large scale units] were found substandard. The Committee strongly feel that it is incumbent upon Government to test check on a regular basis a minimum percentage of production of each unit engaged in the production of drugs under licence from Government, be they multinationals or Government Undertakings. The sample testing should not be confined only to cases where as a result of complaint or otherwise there is *prima facie* suspicion. Maintenance of drug standards is the responsibility both of Central Government and the State Governments and cannot be left to the manufacturers.
4.	1.27	The Committee understand that in developed countries qulity control of drugs is carried out at all stages of manufacture. In our country it is

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