SIXTEENTH REPORT

ESTIMATES COMMITTEE
(1985-86)

(EIGHTH LOK SABHA)

MINISTRY OF HEALTH & FAMILY WELFARE

DRUG STANDARDS

Action Taken by Government on the Recommendation contained in the Sixtieth Report of Estimates Committee (Seventh Lok Sabha)

Presented to Lok Sabha on.....2.....1985

LOK SABHA SECRETARIAT
NEW DELHI

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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 16th Report on Action Taken by Government on the recommendations contained in the Sixtieth Report of Estimates Committee (7th Lok Sabha) on the Ministry of Health and Family Welfare—Drug Standards.

2. The Sixtieth Report was presented to Lok Sabha on 22nd December, 1983. Government furnished their replies indicating action taken on the recommendations contained in that Report by 1st July, 1985. The replies were examined by the Committee at their sitting held on 17th October, 1985 and draft Report was adopoted by the Committee on the same date.

3. The Report has been divided into the following Chapters:—

(i) Report.

(ii) Recommendations that have been accepted by Government.

(iii) Recommendations which the Committee do not desire to pursue in view of Government's replies.

(iv) Recommendations in respect of which replies of Government have not been accepted by the Committee.

(v) Recommendations in respect of which replies of Government are awaited.

4. An analysis of action taken by Government on the recommendations contained in the Sixtieth Report of Estimates Committee is given in Appendix. It would be observed therefrom that out of 22 recommendations made in the Report 14 recommendations, i.e., about 64 per cent have been accepted by the Government and the Committee do not desire to pursue 2 recommendations, i.e., about 9 per cent in view of Government's replies. Replies of Government in respect of 5 recommendations, i.e., about 22 per cent have not been accepted by the Committee. Final reply in respect of one recommendations, i.e., 5 per cent is still awaited.

NEW DELHI;
November 6, 1985
Kartika 16, 1907 (S)

CHINTAMANI PANIGRAHI,
Chairman,
Estimates Committee.

CHAPTER I

REPORT

1.1 This Report of the Estimates Committee deals with Action Taken by Government on the recommendations contained in their Sixtieth Report (7th Lok Sabha) on Drug Standards, which was presented to Lok Sabha on 22nd December, 1983.

1.2 Action Taken Notes have been received in respect of all the 22 recommendations contained in the Report.

1.3 Action Taken Notes on the recommendations of the Committee have been categorised as follows:

(i) Recommendations|Observations which have been accepted by the Government:—

Sl. Nos. 1, 2, 4, 5, 7, 9, 11, 14, 15, 16, 19, 20, 21, 22.

(TOTAL 14, CHAPTER II)

(ii) Recommendations|Observations which the Committee do not desire to pursue in view of Government replies:—

Sl. Nos. 12, 13.

(TOTAL 2, CHAPTER III)

(iii) Recommendations|Observations in respect of which Government's replies have not been accepted by the Committee:—

Sl. Nos. 3, 6, 8, 10, 18.

(TOTAL 5, CHAPTER IV)

(iv) Recommendations|Observations in respect of which final replies are still awaited:—

Sl. No. 17.

(TOTAL 1, CHAPTER V)

1.4 The Committee will now deal with action taken by Government on some of the recommendations.

Testing of Drugs

Recommendation S. No. 3, (Para 1.17)

1.5 Despite the provision under the Drugs & Cosmetics Act requiring the manufacturers to test every batch of finished product before sale, the Committee were surprised to find that no indication was at present available regarding the percentage of Drugs produced in the country being subjected to testing either by the Drug Controller of India or by the State Drug Controlling Authorities. The Committee strongly felt it necessary on the part of the Government to carry test checks on a regular basis a minimum percentage of production of each unit engaged in the production of drugs under licence from Government.

1.6 In their reply, the Ministry have, while accepting this recommendation in principle, stated that "State Health Departments have indicated that regular sampling programmes exist in order to maintain drug standards. While States like Rajasthan, Orissa and Dadra & Nagar Haveli and Punjab propose augmentation of staff, Arunachal Pradesh and Goa, Daman & Diu propose to establish drug testing laboratories for this purpose. Punjab and Maharashtra have expressed the impracticability of test checking every batch of drugs manufactured. In view of the large number of manufacturers and the increased rate of production, Tamil Nadu has issued instructions for sampling of a minimum percentage of production."

1.7 The Committee reiterate that it is incumbent upon the Government to test-check on a regular basis a minimum percentage of the production of each drug production unit as it would in the Committee's opinion, have a salutory effect on the maintenance of drug standards by the producers. Production of quality drugs being vital for public health needs no emphasis and the Committee hope that the Central and State Govts. will devise ways and means to impliment the recommendation of the Committee in right earnest.

Publicity of manufacturers of sub-standard drugs

Recommendation (Sl. No. 6, Para No. 1.29)

1.8 During his evidence before the Committee when it was pointed out to the Health Secretary that the fact that a particular sample was seized and found substandard should be given out to the Press, Television and Radio to forewarn the public against the use of such drugs, he had said that he would look into the legal aspects and take a decision in consultation with the State authorities. The Committee had, thereupon, recommended that an early deci-

sion should be taken in this regard and that the law should be changed if necessary.

1.9 In their interim reply, the Ministry had stated that a reference had been made to the Ministry of Law for comments and that the views of the State Governments had also been sought for.

1.10 In their final reply the Ministry have stated that majority of the State Health Departments have expressed their reservations regarding publicity of sub-standard drugs on the ground that in most cases drugs are found to be sub-standard due to minor reasons like defective labelling, disparity in quantity etc. A blanket procedure of routine publicity would cause undue apprehension in the minds of the public and would jeopardise trade and invite legal complications, Publicity, they feel should be given only in case of conviction due to production of spurious drugs which are potential health hazards. While some states are already publicising seizures, prosecutions and convictions in case of drugs found sub-standard, no publicity is given about drugs being sub-standard before cases are finalised in courts of Law as the manufacturer can claim re-analysis of samples.

1.11 In their interim reply Ministry of Health had stated that a reference had been made by them to the Ministry of Law to comment on the legal aspects and that the State Governments had also been asked to give their views on the Committee's recommendation. In their final reply, the Ministry of Health have only conveyed that majority of State Health Departments have expressed their reservation on the publicity of sub-standard drugs on the ground that in most cases drugs are found to be sub-standard due to minor reasons like defective labelling, disparity in quantity etc. The Ministry of Health have not informed the Committee as to what were the comments of the Ministry of Law in the matter. Since there is considerable time lag between test findings and conviction of producer/dealer by court, postponement of publicity till conviction will make it nugatory as meanwhile the sub-standard/spurious drug would have been mostly consumed and the mischief would have been done. While the Committee agree that adverse publicity need not be given to the drugs found sub-standard on account of minor reasons like defective labelling, they strongly feel that where there is a prima facie case regarding the drugs being spurious or even sub-standard quality-wise, prompt action should be taken to prevent the particular lot reaching the market and in case the lot or any part thereof has already reached the market, wide publicity

should be given at the earliest stage so as to forewarn the public against the use of such drugs. The relevent law should be amended, if necessary, in consultation with the Ministry of Law, after studying similar laws in other countries known for their high standards in the maintenance of drug standards, especially life-saving drugs, to enable action being taken as suggested by the Committee.

Drug Testing Faccilities

Recommendation (Sl. No. 8, Para No. 2.7 & 2.8)

1.12 The Committee had found that the existing drug testing facilities in the country were woefully inadequate and that in the absence of adequate facilities enforcement of drug standards could not be said to be satisfactory. The Committee recommended that as suggested by the task force appointed by Government in 1982, a 100 per cent Centrally Sponsored Scheme to create adequate facilities for drug testing in the country should be drawn up and launched without delay.

1.13 In their reply the Ministry have stated that the recommendation of the Task Force that a 100 per cent Centrally Sponsored Scheme should be formulated for assisting the states in strengthening the drug testing facilities had not earlier been accepted by the Ministry of Health. However the possibility of incorporating such a scheme in the Seventh Five Year Plan is under consideration of Government.

1.14 The Committee reiterate that a 100 per cent Centrally Sponsored Scheme as suggested by the Task Force (1982) to create adequate facilities for drug testing in the country should be drawn up for implementation early in the Seventh Five Year Plan period.

Incentives to Drug Manufacturers

Recommendation (Sl. No. 10, Para No. 2.20)

1.15 The Committee recommended 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 purpose of income-tax calculations etc. should be made available to the drug manufacturing units to facilitate the creation of in-house testing facilities.

1.16 In their reply the Ministry have stated that they had earlier forwarded these recommendation to the Ministry of Finance for necessary action. The Ministry of Finance had not agreed with their recommendation that testing equipments imported by drug manufacturers or commercial testing laboratories should be exempted from customs duty. The Ministry of Finance has also not agreed that capital investment in purchase of sophisticated equipments should be treated as revenue expenditure.

1.17 Due to paucity of resources it may not be possible for the Govt. to establish drug testing facilities on the scale it is urgently needed to maintain drug standards. Therefore the efforts of the private sector to come in the field should be welcome and deserve encouragement. The Committee desire that the Ministry of Health should again take up with the Ministry of Finance the question of exemption from customs duty the testing equipment imported by the drug manufacturers and treatment of capital investment in the purchase of sophisticated drug testing equipment as revenue expenditure.

1.18 The Committee regret the Ministry of Health have not intimated the action taken by them on the suggestion of the Task Force commended by the Committee regarding easy availability of bank loans at concessional rates and procurement of drug testing equipment by drug manufacturers under hire-purchase system. The Committee recommend that these two matters should also be taken up by the Ministry of Health with the authorities concerned and the Committe informed of the outcome of their fresh efforts in this direction.

Trade representative in the Drug Technical Advisory Board

Recommendation (Sl. No. 18, Para No. 3.49)

1.19 In the representation made on behalf of the drug industry, Committee was informed that the industry was poorly represented on the Drug Technical Advisory Board which laid down the drug standards. The number of traders dealing in drugs in the country being about 2 lakh, Committee desired that the necessity of having a trade representative on the Drugs Technical Advisory Board should be examined to make the Board more broad-based.

1.20 In their reply the Ministry have stated, the Government is of the view that it is not necessary to have a trade representative on the Drugs Technical Advisory Board as suggested by the Committee.

1.21 The Committee would have appreciated if the Ministry of Health had cared to give convincing reasons for arriving at the decision not to accept the recommendation of the Committee to make the Drugs Technical Advisory Board more broad-based by including a representative of the Trade which has substantial interest in the activities of the Board. The Committee have therefore, no choice but to reiterate their recommendation. After re-examination of the Committee's recommendation, if the Government still do not consider it desirable to have a representative of Trade on the Board, they should apprise the Committee of their decision along with the reasons therefor.

.. .... Implementation of the Recommendations

1.22 The Committee would like to emphasise that they attach the greatest importance to the implementation of the recommendations accepted by Government. They would, therefore, urge that Government should ensure expeditious implementation of recommendations accepted by them. In case it is not possible to implement a recommendation in letter and spirit for any reason, the matter should be reported to the Committee in time with reasons for non-implementation.

1.23 The Committee also desire that the final reply in respect of the recommendation contained in Chapter V of this Report may be furnished to the Committee expeditiously.

CHAPTER II

RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY GOVERNMENT

Recommendation (Sl. No. 1, Para 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.

Reply of Government

No Comments.

Recommendation (Sl. No. 2, Para 1.17)

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 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 available 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 10 per cent of the drug 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 multinational and Government Undertaings.

Reply of Government

The Government accept the recommendation that a strict vigil over the drugs and formulations produced by multinational and Government undertakings would be maintained.

The recommendations were forwarded to the State Health Authorities. The State Health Departments have now indicated that vigilance is maintained and regular sampling programmes are carried out over the drugs and formulations produced by the multinationals and Government undertakings as well as those produced by manufacturers in the small scale industries sector in the States. The Drugs Controller (India) has devised a proforma and circulated to State Drugs Controllers for furnishing quarterly report giving the details of action taken on drugs found to be not of standard quality. The State Drugs Controllers have started furnishing the information.

Recommendation (Sl. No. 4, Para 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.

Reply of Government

Government accepts the recommendation that their should be quality control at all stages of manufacture. With this object in view a document on "Good Manufacturing practices" has been prepared which will be scrutinised by the Drugs Technical Advisory Board. After approval by the Board action will be taken to incorporate "Good Manufacturing practices" in the Drugs and Cosmetics Rules.

Recommendation (Sl. No. 5, Para 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 manufacturers 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 drugs 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.

Reply of Government

The Committee's recommendation that information regarding the action taken for destruction of drugs where samples have been found to be sub-standard and action taken against the manufacturers should be available has been accepted. Accordingly, a suitable proforma has been devised, and sent to the State Drug Control Organisations for furnishing information quarterly. The information has started coming and will be compiled in the Directorate General of Health Services.

Recommendation (Sl. No. 7, Para 1.30)

As regards drugs imported into the country the Committee note that 78 out of 3183 samples were found sub-standard in 1980-81. In 1981-82, 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 wider-scale 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.

Reply of Government

Government accept this recommendation. Instructions are issued to the Assistant Drugs Controllers at the Ports to carry out extensive sampling of imported drugs.

The Assistant Drugs Controllers at the Ports have now started increased sampling of imported drugs to ensure that no sub-standard or spurious drugs are imported in the country.

Recommendation (Sl. No. 9, Para 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 manufacturers 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/ U.Ts 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 Committee would urge that the statutory provision in this regard should strictly be adhered to and no further leniency should be shown.

Reply of Government

Government agree with the Committee. The Drugs Controller has addressed the State Drug Controllers in October, 83 requesting them that the statutory provision requiring each drug manufacturing unit to have its own testing facilities should be strictly enforced.

Recommendation (Sl. No. 11, Para 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 (iii) 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 Staes concerned at the highest level with a view to removing deficiencies within a time-frame.

Reply of Government

This Ministry has been, from time to time writing to the State Government at various levels regarding the urgent need for strengthening of Drug Control Machineries in the States. The State Governments were also impressed upon to give priority to Drug Administration and provide adequate funds in the Seventh-Five-Year Plan for strengthening and development of the Drug Control Machinery.

In the Meeting of State Health Ministers held on 1st September, 1984, to consider matters relating to Drugs and Prevention of Food Adulteration, it was recommended "that the State Governments take immediate action for including appropriate proposals in the State Sector of the 7th Five-Year-Plan for strengthening the State machinery incharge of control of Drugs and Prevention of Food Adulteration, particularly the Inspecting testing, intelligence and legal wings according to the guidelines laid down in this regard by expert bodies."

The State Health Departments have now indicated that proposals for strengthening the Drugs Control Machinery, provisions of necessary funds, etc. have been included in the Seventh Five-Year-Plan, wherever necessary.

Recommendation (Sl. No. 14, Para 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 functions meaningfully.

Reply of Government

The Committee's recommendation that the Zonal offices should be suitably strengthened is accepted by the Government and necessary proposals for this purpose are being included in the Seventh-Five Year-Plan.

Recommendation (Sl. No. 15, Para 3.36)

The Committee note that those dealing in Drugs have to obtain besides the licence from the Drug 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.

Reply of Government

The Government is of the view that it would not be possible for one authority to issue licences under the Drugs and Cosmetics Act, Medicinal and Toilet preparations (Excise Duties) Act and the Poisons Act in all States. It is understood that in some States the Poisons Act is being administered by the Drug Control Organisation and in other States this Act continues to be administered by the State Home Ministry. However, as the licences have to be issued by the State Authorities, the views of various State Governments on the recommendations were called for.

The suggestion has been welcomed by most States|Union Territories. They are also of the opinion that views of Departments concerned with the issue of the various relevant licences would also have to be sought before the proposal is finalised by the State Governments.

Recommendation (Sl. No. 16, Para 3.44)

Drug Inspector is supposed to be the kingpin of whole mechanism of the Drug Control in the country.. The Drugs and 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 or 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 Control Organisations are strengthened adequately in accordance with a time bound programme.

Reply of Government

The Government while appreciating the concern of the Committee about the improvement of the inspections as per Drugs and Cosmetics Rules, is of the view that it is not possible to implement it immediately. However, the State Governments were, advised to strengthen the Drug Inspectorates on a time bound programme.

Majority of States have now intimated that augmentation of the inspectorates staff are already under their conideration on a time bound basis during 1985-86. Only Punjab has indicated that the proposal was not acceptable due to the ban on creation of posts. While the existing machinery is adequate in the Union Territory of Dadra & Nagar Haveli, the situation has already improved in Gujarat, Goa, Daman & Diu, Chandigarh and Haryana.

Recommendations (Sl. No. 19, Para 4.22 and Sl. No. 20, Para 4.23)

Indian Pharmacopoeia which is the sole basis for maintenance of standards of drugs is not being published 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 atleast every 10 years and a supplementary edition is brought out every 5 years. This will go a longway in keeping the indigenous drug industry abreast of the latest Developments in the field of drugs.

The Committee are not at all satisfied with the existing arrangements to look after the work relating to compilation and publication

of the Indian 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 Indian Pharmocopoeia Committee should be looked after by a separate organisation under a whole time officer.

Reply of Government

The Government accepts the above recommendations of the Committee. A proposal for establishment of a separate organisation under a whole-time officer for compiling the India Pharmocopoeia and National Formulary of India is being included in the Seventh Five Year Plan.

Recommendation (Sl. No. 21, Para 4.24)

What has surprised the Committee more is the fact that no official pharmacopoeia for Ayurvedic, Unani and Siddha systems of medicines exists at present. Consequently no standards have so for been prescribed for these drugs under the Drugs and Cosmetics 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.

Reply of Government

The first Ayurvedic Pharmacopoeia Committee was constituted on the 20th September, 1962, with the following functions:—

(i) To prepare an official Formulary in two part dealing with (a) single drugs of whose identity and therapeutic value there is no doubt and (b) compound preparations which are frequently used in Ayurvedic practice throughout the country;

(ii) to provide standards for drugs and medicines of therapeutic usefulness or pharmaceutical necessity used in the Ayurvedic practice;

(iii) to lay down tests for identity, quality and purity;

(iv) to ensure, as far as possible, uniformity in physical properties and active constituents; and

(v) to provide all other information regarding the distinct characteristics, methods of preparation, doses, method of administration with various anupanas or vehicles and their toxicity.

2. The Ayurvedic Pharhacopoeia Committee prepared the 1st Part of Ayurvedic Formulary of India containing 444 preparations iu the year 1976 and it was published in the year 1978. The second part containing 192 compound preparations has been finalised for the approval of the Ayurvedic Pharmacopoeia Committee and is likely to be published very shortly. These are steps in the direction of standardisation of Ayurvedic drugs. Similarly, the Unani and Siddha Pharmacopoeia Committee have also finalised the first part of the Formularly and are on way to early release having 440 formulations of Unani and 248 of Siddha systems.

3. The single drugs of plant mineral and animal origin appearing in these respective Formularies are also being standardised and the work is in progress. The Central Council for Research in Ayurveda and Siddha has developed preliminary standards of compound preparations of the First Part of the Ayurvedic Formulary of India. The Council has also prepared monographs of more than 100 single drugs. These are being further improved upon in consultation with the Pharmacopoeial Laboratory of Indian Medicine, Ghaziabad, before further consideration by the Ayurvedic Pharmacopoeia Committee.

4. Developing pharmacopoeial standards of Ayurvedic drug is a time consuming process, involving considerable basic work being undertaken in regard to various discipline of modern science, such as Chemistry, Bio-Chemistry, Pharmacology, Pharmacognosy, clinical and experimental medicine, after obtaining documented material from acient classical as well as modern literature. Priority is being given for preparation of Ayurvedic Phrmacopoeial standards. It is proposed to strengthen the Pharmacopoeial Laboratory for Indian Medicine Ghaziabad and also the technical and non-technical staff support in the Ministry of Health & Family Welfare for the Ayurvedic Pharmacopoeia Committee during the Seventh Five Year Plan. It is also proposed that the Central Council for Research in Ayurvedic and Siddha and the Central Council for Research in Unani Medicine will intensify their Pharmacopoeial research work for the evaluation of Pharmacopoeal standards during the Seventh Five Year Plan.

Recommendation (Sl. No. 22, Para 4.25)

The Committee were given to understand during evidence that with the setting up of the Indian 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 up for production. In the third year, production would Committee hope that there will be no let up in efforts in this direction.

The Indian Medicine Pharmaceutical Corporation Limited (IMPCL), Mohan, Almora District, Uttar Pradesh, an Undertaking under the Ministry of Health and Family Welfare, Government of India and set up with the collaboration of the Government of Uttar Pradesh (through the Kumaon Mandal Vikas Nigam, an Undertaking of the Government of Uttar Pradesh) has already started commercial production since September, 1983. The Corporation, whose authorised capital is Rs. 50.00 lakhs and equity paid up capital Rs. 32.75 lakhs, is presently producing 120 varieties of Ayurvedic medicine and supplying to the Central Government Health Scheme. The production of drugs during 1983-84 was worth about Rs. 11.00 lakhs. During the last year, Unani Medicines were also intended to be taken up for production, but there being an initial difficulty in the recruitment of technical personnel in the field of Unani and also there being some technical difficulties, the production of Unani medicines could not start in 1983-84. Due to remoteness of the Factory, difficulties were experienced in attracting suitable staff to the Corporation and as a result, there had been some slippage in the time schedule also arose as a result of delay in release of industrial power by the State Government for a couple of months.

2. It has been projected that in the second year, i.e. 1984-85, about 210 items of medicine (Ayurvedic and Unani) worth Rs. 50.00 lakhs will be taken in hand in Unani system as well as in due course. The be increased to Rs. 75.00 lakhs (about 306 items) and in the fourth year, the production would touch a level of Rs. 100.00 lakhs (above 321 items), covering almost the full range of medicines required by the Central Government Health Scheme Dispensaries and the Central Research Councils.

3. The manufacture of medicines is in accordance with the officially prescribed Formulary of Indian System of Medicine, published by the Ministry of Health and Family Welfare. The performance of the Corporation is regularly watched through the meetings of the Board of Directors and periodical reviews.

CHAPTER III

RECOMMENDATIONS WHICH THE COMMITTEE DO NOT DESIRE TO PURSUE IN VIEW OF GOVERNMENT'S REPLIES

Recommendation (Sl. No. 12, Para 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.

Reply of Government

Government are of the view that rather than acquire more power for the Central Government, the State Governments should, through motivation, incentives and encouragement, be persuaded to strengthen the drug set-up in the states and improve their working.

Recommendation (Sl. No. 13, Para 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.

Reply of Government

The recommendations of the Estimates Committee were sent to State Governments. A majority of States are of the opinion that since joint inspection is already being carried out after grant of licence, the Central Government possessing the power to inspect and prosecute, the present practice may continue as the mechanism of inspection prior to grant of licence will cause undue delay. It may also be stated that the Central Drugs Standard Control Organisation does not have the necessary inspectorate staff for carrying out such inspections.

CHAPTER IV

RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF GOVERNMENT HAVE NOT BEEN ACCEPTED BY THE COMMITTEE

Recommendation (Sl. No. 3, Para 1.17)

The Committee find that under the Drugs & 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. 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 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 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.

Reply of Government

The Govermnent accepts this recommendation in principle.

State Health Departments have indicated that regular sampling programmes exist in order to maintain drug standards. While States like Rajasthan, Orissa and Dadra & Nagar Haveli and Punjab propose augmentation of staff, Arunachal Pradesh and Goa, Daman &

Diu propose to establish Drug testing Laboratories for this purpose. Punjab and Maharashtra have expressed the impracticability of test-checking every batch of drug manufactured in view of the large number of manufacturers and the increased rate of production. Tamil Nadu has issued instructions for sampling of a minimum percentage of production.

Recommendation (Sl. No. 6, Para 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 manufacturer 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 welcome 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.

Interim—Reply of Government

A reference has been made to the Ministry of Law to comment on the legal aspects. The views of the State Govts. have also been sought for.

Final Reply of Government

Majority of the State Health Departments have expressed their reservations regarding publicity of sub-standard drugs on the grounds that in most cases dugs are found to be sub-standard due to minor reasons like defective labelling, disparity in quantity etc. A blanket procedure of routine publicity would cause undue apprehension in the minds of the public and would jeopardise trade and invite legal complications. Publicity, they feel, should be given only in case of conviction due to production of spurious drugs which are potential health hazards. While some States are already publicising seizures, prosecutions and convictions in case of drugs found sub-standard, no publicity is given about drugs being sub-standard before cases are finalised in Courts of Law as the manufacturers can claim re-analysis of samples.

Recommendation (Sl. No. 8, Para 2.7 and 2.8)

The Committee find that so far only 5 States have set up adequate drug 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.

The Committee understand that the Task Force appointed by Government had in 1982 suggested a 100 per cent 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 per cent centrally sponsored scheme as suggested by the Task Force to create adequate facilities for drug testing in the country should be drawn up and launched without delay.

Reply of Government

The recommendation of the Task Force that a 100 percent Centrally sponsored scheme should be formulated for assisting the States in strengthening the drug testing facilities had not earlier been accepted by the Ministy of Health. However, the possibility of incoporating such a scheme in the Seventh Five Year Plan is under consideration.

Recommendation (Sl. No. 10, Para 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.

Reply of Government

The Ministry of Health had earlier forwarded these recommendations to the Ministry of Finance for necessary action. The Ministry of Finance had not agreed with the recommendation that testing equipments imported by drug manufacturers or commercial testing laboratories should be exempted from Customs duty. The Ministry of Finance has also not agreed that capital investment in purchase of sophisticated equipments should be treated as Revenue Expenditure.

Recommendation (Sl. No. 18, Para 3.49)

There is force in the representation made on behalf of the drug industry that the industry 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.

Reply of Government

The Government is of the view that it is not necessary to have a trade representative on the Drugs Technical Advisory Board as suggested by the Committee.

CHAPTER V

RECOMMENDATIONS IN RESPECT OF WHICH FINAL REPLIES ARE STILL AWAITED

Recommendation (Sl. No. 17, Para 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 personnel.

Reply of Government

The recommendations of the Committee for an improved salary structure of Inspectors to attract qualified and experienced personnel is being referred by Government to the Drugs Technical Advisory Board for consideration.

APPENDIX

(*Vide* Introduction)

Analysis of action taken by Government on the 60th Report of the Estimates Committee (7th Lok Sabha)

I.	Total number of Recommendations	22
II.	Recommendations which have been accepted by the Government (Sl. Nos. 1, 2, 4, 5, 7, 9, 11, 14, 15, 16, 19, 20, 21, 22) . . .	14
	Percentage to total	64%
III.	Recommendations which the Committee do not desire to pursue in view of Government's replies (Sl. Nos. 12, 13)	2
	Percentage to total	9%
IV.	Recommendations in respect of which replies of Government have not been accepted by Committee (Sl. Nos. 2, 6, 8, 10, 18) . . .	5
	Percentage to total	22%
V.	Recommendations in respect of which final replies of Government are still awaited (Sl. No. 17)	1
	Percentage to total . . .	5%

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