TENTH REPORT

STANDING COMMITTEE ON PETROLEUM & CHEMICALS (1994-95)

(TENTH LOK SABHA)

PROPOSED NATIONAL DRUG POLICY

[MINISTRY OF CHEMICALS & FERTILISERS (DEPTT. OF CHEMICALS & PETROCHEMICALS]

(Action taken by Government on the recommendations contained in the 2nd Report of the Standing Committee on Petroleum & Chemicals)

Presented to Lok Sabha on.....
Laid in Rajya Sabha on.....2.1

LOK SABHA SECRETARIAT
NEW DELHI
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CORRIGENDA TO TENTH REPORT OF STANDING COMMITTEE ON PETROLEUM & CHEMICALS ON 'PROPOSED NATIONAL DRUG POLICY'.

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e Ceased to be Member of the Committee consequent upon retirement from Rajya Sabha *w.e.f.* 1st July, 1994. Renominated to the Committee *w.e.f.* 12th July, 1994.

** Nominated to the Committee *w.e.f.* 21st April, 1994.

*** Nominated to the Committee *w.e.f.* 18th April, 1994. Expired on 21st September, 1994.

38. Shri Jagdish Prasad Mathur
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1. Shri G.R. Juneja — *Deputy Secretary*
2. Shri Brahm Dutt — *Under Secretary*

$ Nominated to the Committee *w.e.f.* 11th April, 1994.
$$ Nominated to the Committee *w.e.f.* 16th November, 1994.

INTRODUCTION

I, the Chairman, Standing Committee on Petroleum and Chemicals (1994-95) having been authorised by the Committee to submit the Report on their behalf present this Tenth Report on Ministry of Chemicals & Fertilisers, Deptt. of Chemicals & Petrochemicals on Action Taken by Government on the recommendations contained in the Second Report of the Standing Committee on Petroleum and Chemicals (1994-94) (Tenth Lok Sabha) on 'Proposed National Drug Policy'.

2. The Second Report of the Committee was presented to Lok Sabha on 6th August, 1993. Replies of Government to all the recommendations contained in the Report were received on 1st December, 1994.

3. The Committee considered and adopted the Report at their sitting held on 20th December, 1994.

4. An analysis of action taken by Government on the recommendations contained in the Second Report (1993-94) of the Committee is given in Appendix II.

NEW DELHI;
7 January, 1995

17 Pausa, 1916 (Saka)

SRIBALLAV PANIGRAHI,
Chairman,
Standing Committee on
Petroleum & Chemicals.

CHAPTER I

REPORT

The Report of the Committee deals with the action taken by the Government on the recommendations contained in the Second Report (Tenth Lok Sabha) of the Standing Committee on Petroleum & Chemicals (1993-94) on 'Proposed National Drug Policy' which was presented to Lok Sabha on 6th August, 1993.

2. Action Taken notes have been received from the Government in respect of all the 16 recommendations contained in the Report. These have been categorised as follows:—

(i) *Recommendations/observations that have been accepted by the Government:—*
Sl. Nos. 1 to 7, 11 to 14 and 16

(ii) *Recommendations/observations which the Committee do not desire to pursue in view of the Government's replies:—*
Sl. Nos. 8 and 9

(iii) *Recommendation/observation in respect of which reply of the Government has not been accepted by the Committee:—*
Sl. No. 10

(iv) *Recommendations/observation in respect of which final reply of the Government is still awaited:—*
Sl. No. 15

3. The Committee desire that the final replies in respect of the recommendations for which only interim replies have been given by the Government should be furnished to the Committee expeditiously.

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

A. Funds for National Health Programme
(Recommendation S.No. 4)

5. The Committee were dismayed to note that as against the WHO guidelines for spending 5% of GDP outlay on health care, actual expenditure in the country was 1% of GDP only. The Committee had urged upon the Govt. to raise the health budget appropriately both at the Centre and at State levels.

6. The Ministry in their reply have stated *inter-alia* that an aditional demand for Rs. 117 crores from Social Safety Net for Six National Health Programmes has been sent to the Planning Commission by the

Ministry of Health and Family Welfare. Further, during the Mid-term Appraisal of the 8th Five Year Plan further enhancement, in the outlays of National Health Programmes have been proposed.

7. The Committee find that the question of providing additional funds for the National Health Programmes is still at the proposal stage. They reiterate their recommendation and would like to be informed of the additional funds actually provided by the Planning Commission and Central as well as State Government for health programmes.

B. Sickness in Public Sector Undertakings

(Recommendation S.No. 6)

8. While deploring the sickness of PSU's in drugs and pharmaceutical sector, the Committee had recommended that Government should formulate suitable packages for their revival.

9. The Ministry in their detailed reply has given PSU-wise position in regard to formulation of revival packages for the PSUs.

From the reply the following position emerges:—

	Central PSUs	Latest position about revival package
1	2	3
(i)	Indian Drugs & Pharmaceuticals Ltd. (IPPL)	Revival package approved by BIFR on 10.2.1994. Revival plan put into operation *w.e.f.* 1.4.1994.
(ii)	Bengal Immunity Ltd. (BIL)	Declared non-viable in June 1993. Operating Agency *viz.* IRBI has submitted revival plan to BIFR in Dec. 1994.
(iii)	Bengal Chemicals & Pharmaceuticals Ltd.	Declared as sick company *w.e.f.* 14.1.93. Operating Agency *viz.* IRBI has submitted recently a revised revival plan to BIFR.

1	2	3
(iv)	Smith Stanistreet Pharmaceuticals Ltd. (SSPL)	Declared as sick company on 21.12.92. Revival Plan sanctioned by BIFR on 31st August, 1994.
	Joint Sector Units	
(i)	UP Drugs & Pharmaceuticals Ltd.	Declared as sick company on 31.12.92. Case under consideration by BIFR.
(ii)	Orissa Drugs & Chemicals Ltd.	Declared as sick company on 26.10.92. Revival plan sanctioned on 18th Aug., 1994 and put into operation.

10. The Committee are happy to note that the Government has taken necessary steps for revival of sick PSUs in drugs and pharmaceuticals sector. The Committee would however, like the Government to get the finalisation of revival packages for BCPL, BIL and UPDPI expedited. Needless to emphasise that the Government should closely monitor the implementation of revival packages of all PSUs so that these organisations are able to stand on their own at the earliest. Since IDPL being the first PSU in Drug Sector to be cleared by BIFR for revival, the Committee would also like to be apprised of the progress and impact of implementation of the revival package.

C. Effect of Dunkel Proposals

(Recommendations S.No. 10)

11. In the context of GATT agreement, the Committee had inter-alia observed:—

> "The Committee feel that if the Dunkel Proposals relating to drug industry are accepted as they are at present, this could adversely affect the indigenous drug industry. The Committee, therefore, would like to see the Government to further negotiate the matter with GATT and to leave no avenues unexplored before finalising the proposal so as to bring maximum benefit of the proposal to the people and to safeguard the interests of the country's drug industry which was providing drugs/medicines at reasonable prices to the public at large."

12. In their reply the Ministry has stated that the Government had proposed amendments to the Agreements on TRIPs in order to obtain a clean transition period by doing away with pipeline protection and to obtain greater flexibility in the use of compulsory licensing. However, against the proposals of the Government of India, there were proposals from certain developed countries for the elimination of the transition period and for other amendments. However, none of the proposals found

any support among the participants. Therefore, the text of the Agrement on TRIPs has remained substantially unaltered. The Uruguay Round Negotiations have been concluded and there can be no further negotiations in this area.

13. The Committee find that the Government has been unable to get any proposed concessions in the agreements on TRIPs as far as drug industry is concerned. The Committee, however, would like the Government to make all out efforts to safeguard the interests of Indian drug industry as also the public at large within the existing provisions in the agreement and to ensure that the prices of medicines remain within reasonable limits.

D. Funds for R&D and quality control machinery

(Recommendation S.Nos. 11 and 13)

14. The Committee had noted that as against the world average outlay of 10-15% of sales in R&D, Indian companies were hardly spending 2-3% on R&D. In this context the Committee had recommended that to improve the health standards of the people at large, appropriate budget provisions should be made to carry out necessary R&D programmes. In the context of quality control, the Committee had also recommended that to ensure quality control of drugs and medicines, the Governments should find ways and means to strengthen the quality control machinery in terms of man power and requisite equipments.

15. The Ministry in their reply has detailed several measures for strengthening the R&D activities as also the measures for monitoring the quality of the drugs and medicines. An inter-Ministrial group under the Chairmanship of Secretary, Deptt. of Chemicals & Petrochemicals and comprising Secretaries of other concerned Deptts. has been constituted on 26th October, 1994 to decide within a set time frame on measures to give further impetus to R&D in the drug sector. The Group has been asked to finalise its recommendations within a period of three months.

16. The Committee would like the inter-Ministerial Group to complete its task within the stipulated time frame. They would also like to be informed of the measures suggested by the Group and the action taken by Govternments to implement them.

17. As regards the funds required for R&D and activities relating to quality control machinery, the Ministry has stated that the required funds are to be mobilised by levying a cess of 1% on production of drugs and pharmaceuticals by a special legislation to be piloted by the Ministry of Health & Family Welfare. The funds mobilised through the cess would be utilised also for encouraging Research and Development in the drug sector.

18. The Committee would like the Government to ensure that the funds collected through cess on production of drugs and pharmaceuticals are actually utilised for R&D. They have found that in the case imposed on production of crude oil and gas under the provisions of OIDB Act, 1974 out of Rs. 20941 crores collected upto March, 1994 only Rs. 902 crores were

provided in the Oil Industry Development Fund. The Committee would therefore like the Government to ensure that in the proposed legislation for imposing cess on drug and pharmaceuticals clear and unambiguous provisions should be made so that the cess collected under this head is solely utilised for the R&D and activities relating to drugs and pharmaceutical sector.

E. Use of Generic Names

(Recommendation S.No. 15)

19. The Committee had noted that similar drugs were being manufactured and marketed under different brand names at different prices. In this context the Committee had recommended that for the benefit of large number of consumers, Government should consider the use of generic names in the drug industry.

20. In their reply the Ministry has stated that the question of generic selling of drugs was one of the recommendations of the Hathi Committee, so that doctors and retail pharmacists are not swayed by the heavy pressure marketing tactics adopted by different companies for popular multiple brand names for the same drug. As an experimental approach, as early as in 1981, 5 drugs, namely, Analgin, Aspirin, Chlorpromazine, Ferrous, Sulphate and Piperazine were recommended to be sold only under generic name and also the single new drugs that were to be approved in future. Some of the companies had moved the Hon'ble High Court of Delhi against the relevant provisions stipulated under the Drugs and Cosmetics Rules. The Hon'ble Court struck down the provisions relating to 5 drugs under generic name on the ground that selection of brand name is a proprietary right of the company and such right cannot be taken away. The Govt. had filed a Special Leave Petition (SLP) against the judgement in the Hon'ble Supreme Court of India. The SLP was admitted, but no stay was granted. The case has not come up for hearing as such, the matter is subjudice at present.

21. The Comittee would like the Government to take measures for early decision by the Supreme Court and to apprise them of the outcome.

F. Follow-up Action on the recommendations of the Committee

22. The Committee are happy to note that most of the recommendations/suggestions made by them have been accepted by the Government and taken into consideration while making modifications in the Drug Policy, 1976. They however, find that many important policy decisions are yet to be implemented. These include setting up of a National Drug Authority, setting up of an National Pharmaceutical Pricing Authority for fixation of prices of drugs, tax incentives for R&D activities, provision of cess for development of drug industry etc. The Committee desire that the Government should implement these decisions expeditiously so that the desired results are achieved at the earliest.

CHAPTER II

RECOMMENDATIONS THAT HAVE BEEN ACCEPTED BY GOVERNMENT

Recommendation (Serial No.1)

On the basis of the experience gained over the years, the Government reviewed the working of the Drug Policy, 1978 and restructured and replaced it by Drug Policy, 1986 containing the "measures for rationalisation, quality control and growth of Drugs and pharmaceuticals industry in India." After announcement of new industrial policy by the Government in July, 1971 and liberalisation of import procedures certain changes became necessary in the Drug Policy of 1986 relating to industrial licensing, foreign investments, pricing of drugs and pharmaceuticals and other related matters. In this background a background note on review of Drug Policy 1986 was placed by the Department of Chemicals and Petrochemicals on the Tables of both the Houses of Parliament on 12 August, 1992. The main objectives of the Drug Policy 1986 are ensuring abundant availability at reasonable prices of essential and life saving and prophylactic medicines of good quality, strengthening the quality control and the indigenous capabilities for production of drugs.

Reply of the Government

No comments.

Recommendation (Serial No.2)

The Committee would like the Government to see that the main objectives of the Drug Policy, 1986 with regard to ensuring abundant availability of essential and life saving and prophyletic medicines of good quality at reasonable prices and strengthening the quality control and indigenous capabilities for production of drugs are achieved.

Reply of the Government

The modifications in the Drug Policy, 1986 announced in September, 1994 after the review of Drug Policy, 1986 have spelt out measures to achieve the objectives of ensuring abundant availability at reasonable prices of good quality medicines. Since Industrial Policy, Import Export Policy and other Economic Policies of the Government have undergone major changes and been liberalised, it was felt that the production of life saving drugs would get the necessary impetus to meet any future demands as well as of ensuring adequate availability of drugs at reasonable prices, if a more liberalised regime is operated in the Drugs sector in granting

industrial approvals. Therefore, keeping in view these considerations as well as the need to encourage more investments in this important sector to achieve the future production requirements to meet the growing needs of the country, industrial licensing for all bulk drugs cleared by the Drug Controller (India) and all their intermediates have since been abolished, except in the case of (i) five bulk drugs namely Tetracycline, Oxytetracycline, Folic Acid, Vitamin Bl and Vitamin B2 which will continue to be exclusively reserved for public sector, and (ii) the bulk drugs produced by the use of recombinant DNA technology, and/or requiring in vivo use of nucleaic acid as the active principles.

For achieving quality production in drugs, various provisions incorporated in the Drugs & Cosmetics Act and Rules stipulate action to be taken to maintain the quality of drugs. However, modifications in Drug Policy, 1986 announced in September, 1994 *inter-alia* include the decision to set up a National Drug Authority, by a separate Act of Parliament, to look after the quality control aspects, particularly in respect of strengthening of the enforcement machinery to ensure stricter quality control of drugs and pharmaceuticals both by the Centre and in the States, the rational use of drugs and all other related matters. Necessary action is to be taken by the Ministry of Health and Family Welfare in this regard.

[Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5(2)/90-PI.II Dated:1.12.1994]

Recommendation (Serial No.3)

The Committee therefore would like the Health Ministry and Department of Chemicals & Petrochemicals to work together so that necessary infrastructure to make available the required quantum of drugs and medicines is developed in the country. Similarly, the National Health Policy and National Drug Policy should be synchronised so as to achieve the programme of Health for all by 2000 A.D. The Committee also desire that the proposed Coordination Committee comprising the representatives of Ministries of Health and Chemcials and Petrochemicals and other concerned Departments of the Government should not remain on paper only and all out efforts should be made to take care of the health needs of all citizens of the country.

Reply of the Government

The Department of Health in the Ministry of Health & Family Welfare and the Department of Chemicals & Petrochemicals in the Ministry of Chemicals & Fertilizers already work in close coordiantion with each other and in consultation with other concerned Departments to ensure adequate availability of quality drugs in the country. As a part of the modifications in the Drug. Policy, 1986, announced in September, 1994 an inter-Ministerial

Co-ordination Committee has been set up afresh under the Chairmanship of Secretary (C&PC) and comprising Secretaries of the Ministries/Departments of Commerce, Revenue, Health, Bio-technology and Industrial Development & the Chairman, BICP for monitoring the areas of key concern, every quarter and for taking effective and timely action. All out efforts will be made to make the Committee effective, so that it may address itself to the problems and hinderances coming in the way of further growth and development of the drug industry. The major areas of specific focus of this Committee would be production and availability of drugs, quality control, good manufacturing practices (GMP) in drugs, availability of foreign technology, R&D, introduction of new molecules in the country, prices of drugs and exports.

Under the modifications in Drug Policy, 1986, announced in September, 1994 a National Drug Authority (NDA) with a particular focus on aspects relating to quality control and rational use of drugs and strengthening drug control administration at the Centre and the States is to be set up by the Ministry of Health and Family Welfare. For meeting the requirements of medicines for the health needs of the people at reasonable prices and strengthening the indigenous base so as to achieve the goal of "Health for All by 2000 A.D." Government has, under the modifications in Drug Policy, 1986, taken several steps *viz.*, abolishing of industrial licensing for all bulk drugs intermediates and formulations except for the five bulk drugs reserved for production by the Public Sector, allowing automatic approval of investment of foreign equity upto 51% for production of all bulk drugs, intermediates and formulations and simplifying the mechanism for pricing of bulk drugs and formulations.

[Ministry of Chemicals & Fertilizers (Department of Chemical & Petrochemicals) O.M. No. 5(2)90-PI.II Dated: 1.12.1994]

Recommendation (Serial No. 4)

The Committee are dismayed to note that as against the WHO guidelines for spending 5% of GDP outlay on health care, actual expenditure in the country was 1% of GDP only. The Committee would like to urge upon the Government to raise the Health budget appropriately both at the Centre and at State levels.

Reply of the Government

Under the Central Sector Health Programme, Government of India in the Ministry of Health & Family Welfare, have been implementing the following National Health Programmes throughout the country:—

1. National Malaria Eradication Programme (50:50)
2. National Leprosy Eradication Programme (100%)
3. National Tuberculosis Control Programme (50:50)
4. National Programme for Control of Blindness (100%)

5. National AIDS Control Programme with Blood Safety Measures & S.T.D. Control Programme (100%)
6. National Guinea-Worm Eradication Programme (50:50)
7. National Cancer Control Programme (Purely Central)
8. National Iodine Deficiency Disorders Control Programme (Purely Central)
9. National Mental Health Programme (Purely Central)

The Ministry of Health & Family Welfare is in touch with the Planning Commission and other Internal and External Agencies for increase in outlays of these important programmes so that they could be appropriately funded and implemnted through the country so as to have a significant bearing on reduction of mortality and morbidity and also have a salutory effect on the efforts to improve the quality of the life of the common man. Due to the constant efforts of the Ministry of Health & Family Welfare over the years substantial increase in the outlays of various National Health Programmes has been possible. This has been done not only by raising the internal funding through the Planning Commissioin, but also by having additional funds for various disease control programmes made available by the World Bank for the Social Safety Net during 1992-93 and 1993-94. Substantial funds have also been mobilised from the World Bank for control of AIDS, Leprosy and Blindness and the same is also expected during 1995-96 for the Tuberculosis Control Programme. The following Table shows the progressive increase in outlays for major national health programmes:

APPROVED OUTLAYS (Rs. IN CRORE)

	1992-93	1993-94	1994-95
Major (Nine) National Health Programmes	282.90	304.68	392.15

An additional demand for Rs. 117 crores from Social Safety Net for Six National Health Programmes has been sent to the Planning Commissioin by the Ministry of Health and Family Welfare.

During the Mid-Term Appraisal of the 8th Five Year Plan, further enhancement in the outlays of National Health Programmes have been proposed. Due to continual efforts made by the Ministry of Health & Family Welfare, the total Central Sector's outlay for Health Programmes have also been progressively increased as shown in the following Table:—

Years	Rs. in crores
1991-92	301.90
1992-93	44.00
1993-94	483.30
1994-95	578.00

[Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5(2)/90-PI.II Dated 1.12.11994]

Comments of the Committee

Please see para 7 of Chapter I of the Report.

Recommendation (Serial No. 5)

The Committee would like the Government to watch the effect of working of new Industrial Policy which permits 51% foreign investment in equity in the drug industry closely and carefully especially where equity participation is more than 50% for taking appropriate measures necessary to ensure inflow of investment, production and supply of all essential drugs in required quantity at reasonable prices. The Committee would also like the Government to ensure that growth of indigenous industry is not adversely affected by new Industrial Policy.

Reply of the Government

This measure would bring the Drugs & Pharmaceuticals sector in line with the other sectors of the industry. By removing crubs on foreign companies wanting to invest upto 51% foreign equity, the endeavour is to encourage the introduction of newer and more efficient technologies. However, as a safeguard so as to protect the interest of the indigenous industry, it has been decided to consider proposals involving foreign equity participation above 51% on merits of each case. The observations of the committee that growth of the indigenous industry is not adversely affected will be kept in view for future guidance.

[Ministry of Chemicals & Fertilizers
(Department of Chemicals & Petrochemicals)
O.M. No. 5(2)90-PI.II Dated 1.12.1994]

Recommendation (Serial No. 6)

As per the Drug Policy, 1986, 15 items of drugs are reserved for production by Public Sector Undertakings. In this context, the Secretary, Department of Chemicals & Petrochemicals stated that list of items reserved for Public Sector Undertakings could be reviewed and pruned. While the Committee note the views of different manufacturer associations to do away with such reservation policy, they desire the Government to take due care while reviewing these items to ensure that items of drugs and pharmaceuticals of essential nature and required to meet the "Health for All By 2000 A.D Programme" should be allowed to be reserved for production by Public Sector Undertakings so that production and supply in large quantity (*i.e.* drugs for hospitals and primary medical centres and health care areas) remain unhindered and at the same time it gives fair return to the heavy investments made by PSUs. The Committee while deploring the sickness of PSUs, recommend that Government should formulate suitable package for their revival.

Reply of the Government

After careful examination, it was found that many of the drugs reserved for public sector undertakings had lost relevance *vis-a-vis* production programmes of these units. Therefore, it was thought proper to prune the list of items reserved for the public sector to only a few select items, where capacity in public sector is adequate to meet the country's demand and where heavy public investment has been made. Based on this approach,

only 5 drugs have been kept reserved for production in the public sector which are as follows:—

1. Tetracycline
2. Oxytetracycline
3. Folic Acid
4. Vitamin B1
5. Vitamin B2

The position will be further reviewed after a period of 3 years. It is expected that this will not hinder the availability of essential drugs to meet the goals of the 'Health for all by 2000 A.D'

In regard to formulating suitable packages for the revival for sick public sector undertakings, the position is as under:—

1. *Indian Drugs & Pharmaceuticals Limited (IDPL)*

A revival package had been under consideration of the Government since August, 1992 and the Revival Package has been approved by the BIFR in the last hearing held on 10.2.94. The revival period is for 10 years beginning from 1994-95. The Revival Plan has been put into operation from Ist of April, 1994.

2. *Bengal Immunity Limited (BIL)*

BIL was a sick company in the private sector in the name and style of Bengal Immunity Company Limited. The management of the company was taken over by the Government w.e.f. 18th May, 1978. It was nationalised w.e.f. 1.10.84. A new company in the name and style of the Bengal Immunity Limited was set up on 1.10.84. The company has been incurring heavy cash as well as net losses over the years. In compliance with the provisions of Sick Industrial Companies (Special Provisions) Act, 1985, the Board of Directors of the company made a reference to the BIFR. The BIFR formally declared BIL as sick on 9.3.93. A Revival Package prepared jointly by the management of the representatives of the company, was submitted to the BIFR on 19.7.93. The BIFR appointed IRBI, Calcutta as the Operating Agency to make a techno-economic analysis for possibilities of revival of BIL. The BIFR also directed the Department of Chemicals & Petrochemicals to make such a study. The study was made by the Department of Chemicals & Petrochemicals and report forwarded to the Operating Agency. The report of the Operating Agency *i.e* IRBI, Calcutta was received on 31.1.94. the BIFR in a hearing held on 24.2.94 decided to publish a draft scheme giving a stipulated time to all parties including the existing promoters (Government of India) to communicate firm views with regard to financial assistance and other assistance envisaged in the Revival Package. The matter relating to the Revival Package of BIL was also discussed in a meeting in the Ministry of Finance (Department of Expenditure) on 26.4.94. United Bank of India, the Banker of BIL, was requested to furnish comments in writing. The BIFR has on the basis of the report of the Operating Agency notified the draft scheme for revival of BIL on 11.5.94 stipulating time upto 11.7.94 for written submissions. On the basis of the report of Operating Agency

and the support and fresh funds proposed to be extended by the existing promoters namely, Central Government, the BIFR in a hearing held on the 19th July, 1994, directed the Operating Agency namely, IRBI to prepare a final scheme for consideration and sanction by the BIFR. The IRBI, Calcutta took a meeting on the 9th Novemebr, 1994 in order to finalise the scheme. The Scheme is to be submitted by IRBI now to the BIFR.

3. Bengal Chemicals & Pharmaceutical Limited (BCPL)

This was sick company in the private sector in the name and style of Bengal Chemicals & Pharmaceutical Works Ltd. (BCPW). The management of the company was taken over by the Central Goverment w.e.f. 15.12.1977. It was nationalised from 15.12.1980. A new company in the name and style of Bengal Chemicals & Pharmaceuticals Limited (BCPL) was set up in March, 1981.

The company has been incurring heavy cash losses as well as net losses over the years. In compliance with the provisions of the Sick Industrial companies (Special Provisions) Act, 1985, the Board of Directors of the company made a reference to the BIFR in the prescribed manner. The BIFR formally declared the BCPL as a sick company on 14-1-93. The BIFR appointed IRBI, Calcutta as the Operating Agency to look into the techno-economic viability of BCPL.

The Operating Agency (IRBI, Calcutta) in its June, 1993 report found the company as nonviable. Based on the report of the Operating Agency, the BIFR decided in a hearing held on 24-6-93 to give the management some time to submit additional data. The management prepared a fresh plan jointly with the representatives of the employees. This plan was found non-workable by the Government. At the same time, BIFR decided to go ahead with a change in the management. At the initiative of the Department of Chemicals & Petrochemicals, a last opportunity for preparation of a workable Revival Plan was obtained from the BIFR. On the basis of the input given by the Department of Chemical & Petrochemicals namely, IRBI prepared a revised report on BCPL. The report of the Operating Agency and the support, the fresh financial assistance agreed to by the existing promoters namely, the Central Government was considered by the BIFR in a hearing held on the 16th September, 1994. The BIFR directed the Operating Agency to prepare the final scheme for further consideration and approval. Operating Agency has since forwarded the revised report to the BIFR*.

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*. At the time of factual verification of the Report the Ministry intimated that 'BIFR appointed IRBI Calcutta as the Operating Agency (O.A.). On the basis of the report of the O.A. and support of the Govt. the BIFR directed on 19.7.1994 the O.A to prepare a final scheme. O.A. has since submitted the final scheme in Dec. 1994.'

4. *Smith Stanistreet Pharamceuticals Limited (SSPL)*

It was a sick company in the private sector. The management of the company was taken over by the Central Government w.e.f. 4th May, 1972. It was nationalised w.e.f. 1.10.1977. A new company in the name and style of Smith Stanistreet Pharmaceuticals Limited (SSPL) was incorporated on 19.7.1978.

The company has been incurring cash and net losses since 1985-86. In compliance with the provisions of Sick Industrial Companies (Special Provisions) Act, 1985, the Board of Directors of the company made a reference in the prescribed manner to the BIFR. The BIFR formally declared SSPL a sick company on 21.12.1992.

In the second hearing held on 22.6.93, the BIFR appointed IRBI, Calcutta as the Operating Agency to look into the Revival Plan prepared by the management and also give a report of the techno-economic viability of the company. The Revival Package was further modified. The Operating Agency was directed to prepare a revised report taking the cut off date as 1.4.94.The draft scheme for revival of SSPL was published by the BIFR and in a hearing held on the 31st August, 1994, the scheme has been sanctioned by the BIFR.

JOINT SECTOR UNITS

1. *Uttar Pradesh Drugs & Pharmaceuticals Ltd. (UPDPL)*

UPDPL was promoted by the IDPL, a Central PSU, and Pradeshiya Industrial Investment Corporation of Uttar Pradesh (PIICUP), a Government of U.P. Organisation. The company was incorporated on 28.1.1978.

The company has been incurring losses since 1987-88. In compliance with the provisions of Sick Industrial Companies (Special Provisions) Act, 1985, the Board of Directors of UPDPL made a reference to the BIFR in the prescribed manner. The BIFR declared UPDPL as sick on 30.12.92. IDBI was appointed as the Operating Agency by the BIFR. On the basis of the techno-economic analysis made by the Operating Agency (IDBI, Bombay) and the stand taken by PIICUP, one of the two promoters of the company. BIFR in a hearing held on 6.4.94 decided that it would be necessary to effect a change in the promoters of the company. The BIFR directed IDBI, Bombay (OA) to prepare necessary notifications. Simultaneously, the BIFR observed that any fresh scheme of the existing promoters would be given preference. The BIFR considered the case of UPDPL in a hearing held on the 28th September, 1994 and directed the Operating Agency (OA) of the two promoters namely, IDBL and PIICUP to take action *inter-alia* with regard to the possibilities of giving a loan by PIICUP against the surplus assets of the company. Further development in the matter will depend upon the support of the PIICUP.

2. *Orissa Drugs & Chemicals Limited (ODCL)*

ODCL was promoted by IDPL, a Central PSU and Industrial Promotion & Investment Corporation of Orissa Limited (IPICOL), a State Government of Orissa organisation. The Company was incorporated on 1.5.1979. The commercial production was established on 16.9.82.

The company has been incurring cash as well as net losses over the years. In compliance with the provisions of Sick Industrial Companies (Special Provisions) Act, 1985, the Board of Directors of the company made a reference in the prescribed manner to the BIFR. The company was formally declared sick by the BIFR on 26.10.1992.

On the basis of the report of the Operating Agency and the support extended by the State Government of Orissa, the BIFR has sanctioned the Revival Scheme in a hearing held on the 18th August, 1994. The Revival Plan has been put into operation.

[Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M.No. 5(2)/90-PI. II Dated : 1.12.1994]

Comments of the Committee

Please see para 10 of Chapter I of the Report.

Recommendation (Serial No. 7)

The Government also propose to simplify the pricing procedures to ensure transparency in deciding what are the drugs to remain under price control and their pricing mechanism. In this connection, the Committee feel that some experts may be associated to achieve better results. The Committee would like the Government to expedite finalisation of the proposals and take suitable steps to achieve the 'Health for all by 2000 A.D.' goal. The Committee also desire that there should be timely revision of prices. At the same time, the Committee would like the Government to ensure, if necessary, by providing tax relief that prices of essential drugs including drugs required for National Health Programmes do not go beyond common man's reach.

Reply of the Government

The Government has further simplified and rationalised the price control system operating in the drug sector to make it more manageable, simple to operate and to create an environment conducive to channelising of new investments into the pharmaceutical industry. It has been the endeavour of the Government to make the pricing mechanism more transparent and objective, particularly, in regard to exclusion/inclusion of drugs for the purpose of price control. In the modifications in the Drug Policy announced in September 1994, clear cut criteria has been laid down in this regard.

It has been decided to keep the drugs, having an annual turnover of Rs. 400 lakhs or more, under price control. However to take care of the monopoly situation, if for any bulk drug having an annual turnover of Rs. 100 lakhs or more, there is a single formulator having 90% or more

market share in the retail trade (as per ORG) a monopoly situation would be considered as existing and the drug would be kept under price control. Drugs in which there is sufficient market competition viz., at least 5 bulk drug producers and at least 10 formulators and none having more than the 40% market share in the retail trade (as per ORG), would be kept outside price control.

The Government would set up an independent body of experts, to be called the National Pharmaceutical Pricing Authority (NPPA), to do the work of price fixation. NPPA would take decisions on the applications of price approvals, within a set time limit of two months for formulations and four months for bulk drugs.

The above measures are expected to bring in more transparency and objectivity in the matter of price fixation of bulk drugs and formulations and also safeguard the interests of the consumers.

As for providing of tax relief to contain the prices of essential drugs including drugs for the National Health Programme, Government have been giving fiscal concessions to the drug sector from time to time.

Drugs required for National Health Programmes are fully exempt from Excise Duty. Full exemption from Excise Duty is also available on specified raw materials required for the manufacture of drugs for National Health Programmes. There is no excise duty on drugs like Insulin for treatment of diabeties and Zidovudine for AIDS.

There is no excise duty on medicines of allopathic, Ayurvedic, Unani, Sidda or Homoeopathic system, if these are prepared in accordance with standard text books or pharmacopeia and sold under generic description.

[Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) S.O. NO. 5(2)/90-PI.II Dated: 1.12.1994]

Recommendation (Serial No. 11)

The Committee's examination has revealed that Research & Development which is very crucial for the growth and Development of drug industry has been a neglected area so far. As against the world average outlay of 10.15% of sales in R&D, Indian companies are hardly spending 2.3%. The representatives of the industry have attributed this sorry state of affairs to less profit margins in the industry. With the various measures under consideration of the Government such as improvement in the pricing mechanism, delicensing of the drug industry, free inflow of investment, the Committee trust that industry would improve its profitability and in turn would enhance the quantum of R&D expenditure. The Committee also recommend that the various proposals of the Government regarding giving incentive to R&D like keeping the new discoveries outside the price control for a period of 10 years, giving some tax benefits and providing soft loans for R&D purposes should be expedited and finalised without further loss of time.

The Committee were informed by the representatives of the Health Ministry that due to lack of funds enough money could not be made available for undertaking enough R&D and purpose of new modern machines and equipments and their budgets were mainly for service heads. The Committee desire that to improve the health standards of the people at large, appropriate budget provisions should be made to carry out necessary Research and Development programmes and special incentives be given for undertaking R&D in tropical diseases.

Reply of the Government

In the modifications in Drug Policy 1986 announced in September, 1994, in order to give encouragement to Research and Development (R&D) efforts, the following measures have been announced and follow up action taken:—

That a new drug which has not been produced elsewhere, if developed through indigenous R&D would be put outside price control for a period of 10 years from the date of commercial production in favour of the company who undertook the R&D.

Government has constituted on the 26th October, 1994 an inter-Ministerial group under the Chairmanship of Secretary, Department of Chemicals and Petrochemicals and comprising Secretaries of other concerned Departments to decide, within a set time frame on measures to give further impetus to R&D in the drug sector. The above Committee will examine the measures and finalise its recommendations within a period of 3 months.

There is no specific budget at present for Research & Development for the Central Drugs Standard Control Organisation in the Ministry of Health & Family Welfare excepting the budgetary provision for Drug Testing Laboratories etc., set up for testing samples of drugs under the Drugs & Cosmetics Act, 1940. The basic research and development on drugs and pharmaceuticals are monitored by the Council of Scientific and Industrial Research (CSIR) under the Ministry of Science & Technology and the clinical research is monitored by the Indian Council of Medical Research (ICMR) an autonomous research organisation under Ministry of Health & Family Welfare. Government has approved a proposal of levying a cess @ 1% on production of drugs and pharmaceuticals by a special legislation to be piloted by the Ministry of Health and Family Welfare. The funds mobilised through the cess would be utilised towards implementation of the activities proposed for the National Drug Authority (NDA) to be set up by the Ministry of Health & Family Welfare and the balance funds would be utilised for encouraging R&D in the drug sector.

[Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. NO. 5(2)90-PI.II Dated: 1.12.1994]

Comments of the Committee

Please see para. 16 of Chapter I of the Report

Recommendation (Serial No. 12)

The Committee regret to note that in the 'Background Note on Review of Drug Policy', which was laid by the Government on the Tables of both the Houses of Parliament on the 12th August, 1992, does not spell out any proposal or scheme to give incentives to increase the exports. Out of annual production of drugs and pharmaceuticals worth Rs 5700 crores in the country, drugs and pharmaceuticals worth Rs 1400 crores only are exported. During evidence some representatives of the industry submitted that the export of drugs and pharmaceuticals was very profitable to the industry and the Indian drug industry as a whole has a great export potentialities provided due opportunities and necessary incentives are given to it. The Committee recommend that Government should give suitable incentives to the manufacturers of drug industry so as to enable them to augment their export in a big way.

Reply of the Government

The following are the incentives made available and export promotion measures taken to augment exports of drugs and pharmaceuticals:-

(i) Total flexibility has been provided for export production of drugs and formulations within the existing facilities.

(ii) Bulk drugs have been included in Group 'B' of EXIM Bank's commodity credit scheme for deferred payment facility for 3 years.

(iii) Extreme Focus Groups have been set up for drugs and pharmaceuticals to achieve an export growth of atleast 30% in dollar terms during the next couple of years.

(iv) With the loss of erstwhile USSR market, efforts are being made by manufacturers-exporters to locate new markets and diversify their products.

[Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5(2)/90-PI. II Dated: 1.12.1994]

Recommendation (Serial No. 13)

The Committee were informed by several manufacturer's associations that the Indian medicines are of international standards and are being exported to several countries. The Committee, however, regret to note that at times spurious medicines find place in the market. Similarly, certain irrational drugs are produced and marketed which could cause health hazards. The Committee's examination has revealed startling features in regard to functioning of Government machinery at the Centre and State levels. As against the required strength of about 3000 drug inspectors, the actual strength was 700 only. Similarly about one third standard norms of

the samples were being tested. The representatives of the Health Ministry also brought out that due to lack of funds adequate machines and equipments were not there to handle more samples. To ensure quality control of drugs and medicines, the Committee recommend that Government should find ways and means to strengthen the quality control machinery in terms of man power and requisite equipments.

Reply of the Government

The existing machinery for drug testing and inspection of manufacturing units and their premises is far from adequate. However, the Ministry of Health and Family Welfare have been taking steps to strengthen the quality control machinery both at the Centre and in States/UTs. Steps have been taken to fill up as many vacant posts as is possible in the Central Drugs Standard Control Organisation (CDSCO).

The Ministry of Health and Family Welfare have prepared a project to provide for adequate testing facilities as well as enforcement machinery to ensure stricter quality control of drugs and pharmaceuticals, both at the Centre and in State. Central licensing of drugs and pharmaceuticals moving in inter-state commerce has also been proposed. In order to implement the proposals, the establishment of more drug testing laboratories, expansion of zonal and sub-zonal offices, augmentation of Drug Inspectorate Staff and greater financial assistance to States by the Centre have been envisaged.

The implementation of these proposals would require additional funds. Therefore, it has been decided by the Government that these funds are to be mobilised by levying a cess of 1% on production of drugs and pharmaceuticals by a special legislation to be piloted by the Ministry of Health and Family Welfare. The funds mobilised through the cess would be utilised also for encouraging Research and Development in the drug sector.

Further, in order to provide a more efficient mechanism for ensuring quality control and rational use of medicines, a National Drug Authority (NDA) would be set up by a separate Act of Parliament. NDA, in addition to the work related to effective implementation of the provisions of Drugs and Cosmetics Act and of Rules made thereunder, would also be responsible for monitoring standard practices in drug promotion and use and for clearly identify those which are acceptable and prohibiting those which are unethical and against the consumer's interest.

[Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M.No. 5(2)/90-PI. II Dated: 1.12.1994]

Comments of the Committee

Please see para 18 of Chapter I of the Report.

Recommendation (Serial No. 14)

It came out during the examination that several irrational and non-sensical drugs/formulations were being manufactured and marketed in the country on commercial considerations. The Committee feel that these drugs besides being harmful, the country could hardly afford the production of such irrational and non-sensical drugs. The Committee, therefore, recommend that the Government should take urgent steps to totally weed out the manufacture and sale of irrational and non-sensical drugs.

Reply of the Government

The Central Government has acquired power under Section 26(A) of the Drugs & Cosmetics Act for prohibiting manufacture and sale of drugs/formulations considered ineffective/harmful/irrational in the context of present knowledge. The Drugs Consultative Committee, a statutory body under the Drugs & Cosmetics Act, has constituted a Committee of experts which examines every year suggestions received from various forums on drugs having questionable efficacy/safety/rationality and forwards its recommendations to the Drugs Technical Advisory Board (DTAB), the highest technical body under the Drugs & Cosmetics Act. Based on the recommendations of DTAB, Government, in exercise of the powers vested in the Act from time to time, through Notifications, prohibit manufacture and sale of such formulations. Since drug registration is not centralised in India and the Central Government does not have a centralised list of all formulations licensed by State Licensing Authorities, notifications for ban issued by the Central Drug control authorities lists out combination preparations under pharmacological classifications, so that any manufacturing units engaged in the manufacture of formulations falling under such pharmacological classifications, stop manufacturing the same. The ban notification list is widely circulated to the State Drugs Controllers and to the Zonal offices of CDSCO for follow up action. Government have so far prohibited manufacture and sale of 45 categories of formulations through various notifications. Based on the recommendations of DTAB, some formulations, (the safety and rationality of which were questioned) are being subjected to controlled clinical trials and generation of retrospective as well as perspective date on adverse drug reaction (A.D.R.) are being collected, which will be put up before Drugs Technical Advisory Board for taking final action in the matter. The examination of formulations moving in the market from the angle of safety/efficacy/rationality is a continuous process.

Screening of irrational or harmful drugs is also an on going exercise and the definition of new drugs has been widened and guidelines issued on clinical trials. With a view to ensuring proper dispensing and rational use of drugs, packagings have been standardised. Five leading hospitals at Pondicherry, Chandigarh, New Delhi, Bombay and Lucknow have been identified as Adverse Drug Reaction Monitoring Centres (ADRMC).

While the Ministry of Health & Family Welfare are taking some action on these matters, the general perception unfortunately is that this area is presently not being given the due attention it requires. Under the Modification in Drug Policy, 1986 announced in September 1994, Government has decided to set up a National Drug Authority (NDA) by a separate Act of parliament to look to quality control aspects and rational use of drugs.

[Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5(2)90-PI. II, Dated 1.12.1994.]

Recommendation (Serial No. 16)

The Committee find that Indian medicine system like Ayurveda, Unani and Sidda systems have been practised in the country since long and some of the medicines are very efficient for health care. The Committee learn that as a measure for giving some recognition to Ayurveda, Unani and Siddha systems of medicines, these have been included in the Drugs and Cosmetics Rules. While this is a step in right direction, the Committee would like the Government to fully recognise and encourage the Indian Medicine Systems to cover the Health care of the People and for which proper plans should be formulated and implemented. They also desire that more R&D work should be undertaken for the development of Indian medicine system.

Reply of the Government

The Indian Systems of Medicines (ISM), namely Ayurveda, Unani and Siddha have been brought within the purview of the Drugs & Cosmetics Act. The other steps taken include setting up of parallel institutions, on the lines of modern system of medicine, for regulating education, practice research and laying of standards of drugs of ISM. Besides, assistance is being provided for upgrading the standards of ISM Colleges for development and cultivation of medicinal plants.

Further, Government has decided as part of the decision taken on review of the Drug Policy' 86, that various aspects relating to development and promotion of Ayurveda, Unani, Siddha, Homeopathic and Traditional system of medicines would be actively pursued and the machinery for carrying out these tasks would be adequately strengthened. To provide better focus to this important work, it is proposed to create a separate Department by the Government to look after all matters relating to development and promotion of these systems of medicines under the Ministry of Health and Family Welfare, who are to initiate the necessary process towards creating the separate Department for Indian System of Medicines.

[Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5(2)90-PI. II, Dated 1.12.1994.]

CHAPTER III

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

Recommendation (Serial Nos. 8 & 9)

Yet another area which the Committee view with concern is the likely impact of Dunkel Proposals on the Drugs and Pharmaceutical Sector. The Dunkel proposals provide for product patent under the Trade Related Intellectual Propriety Rights (TRIPS) Scheme. The Committee note that the process patent scheme under the provisions of the Indian Patent Act, 1970 has helped the Indian drug industry to grow to its present level. Presently the industry produces about Rs. 6500 crores worth products annually and it exports about Rs. 1400 crores worth drugs and formulations. It is almost self reliant in the matter of formulations and upto 70% of requirements of bulk drugs. In this connection, the Committee have been informed by various manufacturers' associations/experts/voluntary health organisations that the TRIPs provisions would adeversely affect the Indian drug industry. According to these associations, prices of medicines will go higher several times and multinational companies would capture the market. Besides, there are divergent view about the share of internationally patented medicines in the country which vary from 10—15% to as high as 40—45%. According to the Department of Chemicals & Petrochemicals, share of patented items was 10—15% only.

One manufacturer association representing large number of Indian and multinational companies in their submission to the Committee has, however, welcomed the Dunkel Proposals. In their opinion with the acceptance of the Dunkel Proposals, there will be real competition in the market, there will be more R&D and there may be a marginal increase in the prices of drugs. The Secretary, Department of Chemicals & Petrochemicals informed the Committee that medicines which were being manufactured for the common man in the country would remain unaffected and the provisions contained in the Dunkel Proposals would be applicable only to the discoveries made after signing the agreement. Besides, ten years' time would be allowed as transitional period. The same view was also expressed by the Committee Secretary.

Reply of the Government

Organisation of Pharmaceuticals' Producers of India (OPPI) had indicated that the number of new drugs introduced into the market globally per year is in the region of 10—15. This number remains almost a constant. As and when new drugs are patented and introduced, old

patented drugs go off patent. According to the ORG survey of June, 1993, only 7 drugs listed in the WHO list of essential drugs would be patented if India has product patent for pharmaceuticals. Of these seven drugs, the patents of three expire in 1994, two in 1995 and one each in 1997 and 1998. Of these 7 drugs, only 3 drugs have brands in India. Patented drugs as a percentage of the total value of drugs in the WHO list are 0.78%.

The TRIPs Agreement would affect only those products which are patented after the entry into force of the Agreement which is expected to be by around January, 1995. However, there are safequard provisions in the TRIPs Agreement to meet exigencies like provision of compulsory licensing, powers to use the subject matter of a patent without authorisation of the right holder in case of national emergency and for public non-commercial use as well as for controlling abuse of Intellectual Propriety Rights.

[Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5(2)/90-PI. II Dated 1.12.1994.]

CHAPTER IV

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

Recommendation (Serial No. 10)

Since the Dunkel Proposals relating to drugs & pharmaceuticals industry are an involved area, the Committee feel that they did not have enough time to discuss this subject in depth. However, the Committee feel that if the Dunkel Proposals relating to drug industry are accepted as they are at present, this could adversely affect the indigenous drug industry. The Committee, therefore, would like to see the Government to further negotiate the matter with GATT and to leve no avenues unexplored before finalising the proposal so as to bring maximum benefit of the proposal to the people and to safeguard the interests of the country's drug industry which was providing drugs/medicines at reasonable prices to the public at large.

Reply of the Government

Government had proposed amendments to the Agreements on TRIPs in order to obtain a clean transition period by doing away with pipeline protection and to obtain greater flexibility in the use of compulsory licensing. However, against the proposals of the Government of India, there were proposals from certain developed countries for the elimination of the transition period and for other amendments. However, none of the proposals found any support among the participants. Therefore, the text of the Agreement on TRIPs has remained substantially unaltered. The Uruguay Round Negotiations have been concluded and there can be no further negotiations in this area.

[Ministry of Chemicals & Fertilizers (Department of Chemcials & Petrochemicals) O.M. No. 5(2)/90-PI. II Dated 1.12.1994.]

Comments of the Committee

Please see para 13 of Chapter I of the Report.

CHAPTER V

RECOMMENDATIONS IN RESPECT OF WHICH FINAL REPLIES OF GOVERNMENT ARE STILL AWAITED

Recommendation (Serial No. 15)

The Committee also note that similar drugs were being manufactured and marketed under different brand names at different prices. The Committee recommend that for the benefit of large number of consumers, Government should consider the use of generic names of the drug industry.

Reply of the Government

The question of generic selling of drugs was one of the recommendations of the Hathi Committee, so that doctors and retail pharmacists are not swayed by the heavy pressure marketing tactics adopted by different companies for popularing multiple brand names for the same drug. As an experimental approach, as early as in 1981, 5 drugs, namely, Analgin, Aspirin, Chlorpromazine, Ferrous Sulphate and Piperazine were recommended to be sold only under generic name and also the single new drugs that were to be approved in future. Some of the companies had moved the Hon'ble High Court of Delhi against the relevant provisions stipulated under the Drugs & Cosmetics Rules. The Hon'ble Court struck down the provisions relating to 5 drugs under generic name on the ground that selection of brand name is a proprietary right of the company and such right cannot be taken away. The Government had filed a Special Leave Petition (SLP) against the judgement in the Hon'ble Supreme Court of India. The SLP was admitted, but no stay was granted. The case has not come up for hearing as such, the matter is subjudice at present.

[Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) O.M. No. 5(2)/90-PI. II Dated 1.12.1994].

Comments of the Committee

Please see para 21 of Chapter I of the Report.

NEW DELHI;
January 7, 1995

Pausa 17, 1916 (Saka)

SRIBALLAV PANIGRAHI
Chairman,
Standing Committee on
Petroleum & Chemicals.

APPENDIX I

MINUTES

STANDING COMMITTEE ON PETROLEUM & CHEMICALS (1994-95)

Sixteenth Sitting
20.12.1994

The Committee sat from 1500 hrs. to 1530 hrs.

PRESENT

Shri Sriballav Panigrahi —*Chairman*

MEMBERS

Lok Sabha

2. Shri Sant Ram Singla
3. Shri V.S. Vijayaraghavan
4. Shri M. Krishnaswamy
5. Shri Gopi Nath Gajapathi
6. Shri K. Ramamurthee Tindivanam
7. Shri Janardan Prasad Misra
8. Shri Rameshwar Patidar
9. Shri Ramnihore Rai
10. Shri Uddhab Barman
11. Shri Muhiram Saikia

Rajya Sabha

12. Shri E. Balanandan
13. Shri Mohd. Masud Khan
14. Shri Pasumpon Tha. Kiruttinan
15. Shri Ramji Lal
16. Shri Dineshbhai Trivedi

SECRETARIAT

1. Shri G.R. Juneja — *Deputy Secretary*
2. Shri Brahm Dutt — *Asstt. Director*

The Committee considered the draft Report on action taken by the Government on the recommendations contained in the Second Report of the Committee on 'Proposed National Drug Policy'. After some discussion the Committee adopted the report subject to modifications/amendments shown in Annexure.

2. The Committee also authorised the Chairman to finalise the report after factual verification by the Department of Chemicals and Petrochemicals and present the same to Parliament.

The Committee then adjourned.

ANNEXURE

Modifications/Amendments made in Action Taken Report

At the end of Para 10 (at page 3) the following may be added:

"Since IDPL being the first PSU in Drug Sector to be cleared by BIFR for revival, the Committee would also like to be apprised of the progress and impact of implementation of the revival package."

APPENDIX II

(Vide Para 4 of the Introduction)

Analysis of the Action Taken by Government on the recommendations contained in the 2nd Report of the Standing Committee on Petroleum & Chemicals (Tenth Lok Sabha) on proposed National Drug Policy.

I	Total number of recommendations	16
II	Recommendations that have been accepted by the Government (*Vide* Recommendation at Sl. Nos. 1 to 7, 11 to 14 and 16).	12
	Percentage to total	75%
III	Recommendation which the Committee do not desire to pursue in view of Government's reply (*Vide* Recommendation at Sl. No. 8 and 9)	2
	Percentage to total	12.5%
IV	Recommendations in respect of which reply of Government has not been accepted by the Committee (*Vide* Recommendation at Sl. No. 10)	1
	Percentage to total	6.25%
V	Recommendation in respect of which final reply of Government is still awaited (*Vide* Recommendation at Sl. No. 15)	1
	Percentage to total	6.25%