SECOND REPORT

STANDING COMMITTEE ON PETROLEUM & CHEMICALS (1993-94)

(TENTH LOK SABHA)

PROPOSED NATIONAL DRUG POLICY

(Ministry of Chemicals and Fertilisers, Deptt. of Chemicals & Petrochemicals)

Presented to Lok Sabha on 6 August, 1993
Laid in Rajya Sabha on 6 August, 1993

LOK SABHA SECRETARIAT
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SECOND REPORT OF STANDING COMMITTEE ON PETROLEUM AND CHEMICALS

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INTRODUCTION

I, the Chairman of Standing Committee on Petroleum and Chemicals (1993-94) having been authorised to submit the Report on their behalf, present this Second Report on the Ministry of Chemicals & Fertilisers (Deptt. of Chemicals & Petrochemicals) relating to Proposed National Drug Policy.

2. The Ministry of Chemicals and Fertilizers (Department of Chemicals and Petrochemicals) had laid on the Table of both Houses of Parliament on 12th August, 1992 a 'Background Note on Review of Drug Policy, 1986' for eliciting the views of the Members on the subject. Taking note of the importance of the subject, the Standing Committee on Petroleum & Chemicals (1993-94) took up the examination of the Proposed National Drug Policy with the approval of Hon'ble Speaker, Lok Sabha.

3. The Committee took evidence of the representatives of Ministries of Chemicals and Fertilizers (Deptt. of Chemicals & Petrochemicals), Commerce and Health on 5th, 21st and 22nd July, 1993. The Committee also heard the views of several manufacturer associations, experts, voluntary health organisations etc. which are concerned with the Drug Policy on 6th, 7th and 20th July, 1993.

4. The Committee also received Memoranda from several other Associations/Experts which were considered by the Committee. The Committee considered the draft Report at their sittings held on 30th July and 2nd August, 1993. The Committee adopted the Report on 3rd August, 1993.

5. The Committee would like to express their thanks to the officers of Ministries of Chemicals and Fertilisers (Deptt. of Chemicals and Petrochemicals), Commerce and Health and also representatives of various other organisations who appeared and placed their considered views before the Committee on the subject.

6. For facility of reference, the recommendations & conclusions of the Committee have been printed in thick type.

NEW DELHI;
3 August, 1993

13 Asadha, 1915 (Saka)

SRIBALLAV PANIGRAHI
Chairman,
Standing Committee on
Petroleum & Chemicals.

PART I—BACKGROUND ANALYSIS

I. OBJECTIVES OF THE DRUG POLICY

The first comprehensive drug policy was announced in 1978 on the basis of the recommendations of the Hathi Committee. After gaining experience over the years the Government reviewed the working of the Drug Policy, 1978 and restructured and replaced it with the "Measures for rationalisation, Quality Control and Growth of drugs and pharmaceuticals Industry in India", known as Drug Policy, 1986. The main objectives of Drug Policy, 1986 are as under:—

a) ensuring abundant availability, at reasonable prices of essential & life saving and prophylactic medicines of good quality;

b) strengthening the system of quality control over drug production and promoting the rational use of drugs in the country;

c) creating an environment conducive to channelising new investment into the pharmaceutical industry to encouraging cost-effective production with economic sizes and to introducing new technologies and new drugs; and

d) strengthening the indigenous capability for production of drugs.

2. After announcement of New Industrial Policy by the Government in July, 1991 and liberalisation of import procedures certain changes became necessary in the Drug Policy relating to industrial licensing, foreign investment etc. Similarly certain changes were sought to be made in the pricing aspects of drugs and pharmaceuticals. With these developments the Government propose to revise the Drug Policy, 1986.

3. A Background Note on Review of Drug Policy, 1986 was placed by the Department of Chemicals & Petrochemicals on the Tables of both Houses of Parliament on 12th August, 1992. The Note indicated the areas of likely changes in the Drug Policy.

4. During the course of examination, on being asked by the Committee whether the Ministry had consulted various experts/manufacturer organisations/consumer organisations etc. before finalising the Background Note, the Secretary, C&PC replied that they had done a very detailed exercise. There was a Standing Committee consisting of representatives of Health Ministry, R&D experts, from R&D organisations. from industries and other experts and then consumer organisations were also called. It was after balancing the various view points that the paper was finalised.

5. The Committee also wanted to know about the objectives of the new drug policy. The Secretary, Chemicals and Petrochemicals stated that there

was no proposal to change the objectives and the Government only proposed to bring certain changes in the implementation aspects so that the key objectives of the policy like ensuring abundant availability of good quality medicines at reasonable prices could be achieved. The witness also stated that the prices of drugs/medicines in the country were the cheapest and were comparable to world standards.

6. Asked about the present status of the Drug Industry, the Committee were informed by the Department of Chemicals and Petrochemicals that present drug policy resulted in growth of the industry and has helped to achieve a broad base in terms of both the range of products and technology to produce them from the basic stage.

7. The Committee were further informed by the Department of Chemicals & Petrochemicals that there were about 250 large units and about 8000 small scale units in the sector. These units are stated to be producing almost the complete range of formulations and about 350 bulk drugs. The present annual production of bulk drugs is of the order of Rs. 1045 crores and that of formulations is estimated to be Rs. 5520 crores. It is estimated that 70 per cent of the indigenous demand for bulk drugs and almost the entire demand for formulation are being met through domestic production. The country also exports drugs and pharmaceuticals worth Rs. 1400 crores annually.

II. NATIONAL HEALTH PROGRAMME

(i) *Health for all by 2000 AD.*

8. During the course of examination of the Deptt. of Chemicals and Petrochemicals the Committee pointed out that the 'Health for all by 2000 AD programme' which had been adopted by the Government would need medicines worth Rs. 15000 crores by the turn of the century as compared to present level of production of about Rs. 6500 crores. Asked as to whether the indigenous availability of medicine of this magnitude would be possible under the proposed drug policy, the Secretary, C&PC replied:—

> "For reaching the target of health care for all, the quantitative productions must roughly go up four times. Therefore, it is important that more and more investment comes up in this Industry. The way growth is going on, it is just impossible unless there is a marked change on the investment pattern and that change will not take place if we keep the drug industry as it is at present. We have to give same kind of liberalisation. We want investment to come in this industry and for that we will have to remove restrictions like licensing and so on. We are not saying to do away with it completely but make it more manageable. This is through our new Drug Policy."

9. During the course of evidence of the Ministry of Health, the Committee wanted to know the steps being taken to achieve the Health for all by 2000 AD programme. A representative of the Ministry stated that Health was a state subject and Drugs were under concurrent list and the role of Central Government was to facilitate the State Governments. The witness also stated that their Health programmes were hit by paucity of funds. As against the WHO guidelines for incurring expenditure on Health care to the extent of 5% of GDP, the actual expenditure in the country (both of Centre and State) was 1% of GDP only.

10. Asked about the likely impact of Dunkel proposals on the National Health Programmes, the witness replied:—

> "Our import bill is only 10% of the total costs. The rest is only domestic formulations. Now with the coming in of the Dunkel draft, we will have to be very clear about these national health programmes which are also internationally funded. We do not have full resources to fund all the entire schemes."

(ii) *Coordination between the Ministries of Chemicals & Petrochemicals and Health*

11. The Deptt. of Chemicals & Petrochemicals is responsible for licensing, overall production aspects of drug and pharmaceutical sector. The Health Ministry is responsible for quality and distribution of drugs. On being asked by the Committee whether one Government Department could look after the entire work, the representatives of the Deptt. of Chemicals & Petrochemicals as also of the Health Ministry stated that the functions of various Govt. Deptts. were inter-linked and the work could be handled by the two Ministries by having proper coordination.

12. On being asked by the Committee whether Ministry of Health was involved in formulation of the drug policy, the Secretary, C&PC stated that the representatives of Health Ministry were being consulted regularly on the matter. The witness agreed to a suggestion of the Committee that coordination between the two needs to be strengthened.

13. Asked about the views of Health Ministry for their involvement in formulation of the drug policy, the Drug Controller stated that they were involved in making the lists of category I & II of medicines. The officials of the Health Ministry were also on certain Committees appointed by Deptt. of Chemicals and Petrochemicals. He further added:—

> "Definitely, I would wish better coordination between different Ministries or different segments which are concerned with the drugs."

14. In the 'Background Note on Review of Drug Policy', laid on the Tables of both Houses of Parliament, the Deptt. of Chemicals & Petrochemicals has indicated to set up a coordination Committee for monitoring the areas of key concern in implementation of the Drug Policy and for taking effective and timely action. This coordination Committee

will consists of representatives of the Ministries of Commerce, Finance, Health, Department of Bio-technology and Industrial Development and BICP under the Chairmanship of Secretary, C&PC.

III. INDUSTRIAL LICENSING

15. Drug Policy 1986 limits the activities of Companies with foreign equity above 40 per cent to 66 bulk drugs/intermediates and their formulations only. Companies with foreign equity upto 40 per cent were on par with Indian Companies. However, in the New Industrial Policy, automatic approvals can be given for equity upto 51 per cent in high priority areas. The Government also propose to declare drug industry as a priority sector.

16. Explaining the need for modification in the Drug Policy after New Industrial Policy, the Secretary, C&PC stated before the Committee during the evidence that after the programme of economic liberalisation was launched in July, 1991 and all industries were removed from the shackles of controls like industrial licensing etc., it was felt that the Drug Policy needed the same treatment. So a review of the Drug Policy became necessary. It was felt that the drug industry is an important industry, where adequate production was so essential for the health care of our people. To bring it in line with the ecconomic liberalisation policy of the Government and to make it free from various licensing controls like all other industries, some changes in the drug policy were considered necessary.

17. In reply to another question the witness stated that licensing would be abolished in the drug industry. The witness also stated that it would help in attracting more investments, including foreign investment in the sector.

18. The Committee further enquired whether some of restrictions/ controls would be retained in the revised policy so that the Government could ensure production and availability of all essential drugs at reasonable price. The Secretary replied that such checks would be there.

19. When asked whether the Ministry was hopeful to attract foreign investments in the drug and pharmaceutical sector, the witness stated:—

> "This is a sector which has got high technological aspect and if, with foreign equity participation, we can have good technical collaborations, it is all the more welcome. We should not be suspicious about the foreign equity participation in this aspect. In any case, all these cases where equity participation is above 51 per cent, it will be decided case by case."

IV. RESERVATION OF ITEMS FOR THE PUBLIC SECTOR

20. As per the Drug Policy 1986, 15 items are reserved for production by Public Sector Undertakings (PSUs). In the New Industrial Policy, Government has reviewed the items reserved for PSUs and has limited such reservation only to a few strategic high-tech and essential items.

21. Several manufacturer associations submitted before the Committee that such items should be dereserved as private sector was in a position to produce all types of drugs at competitive prices.

22. However, some of the experts/voluntary organisations and representatives of Indian Medical Association in their presentation before the Committee pleaded that some of essential drugs which were meant for National Health Programme should be reserved for PSUs so that public at large could get these drugs at reasonable prices. The representatives of Indian Medical Association (IMA) also suggested that Public Sector should continue to have a leading role. However, performance of PSU should be improved by reducing overhead expenditure, improving management and plugging loopholes to control corruption.

23. Asked about the views of the Government in this regard, the Secretary, Chemicals and Petrochemicals replied that list of items reserved for PSUs would be reviewed and pruned.

24. Explaining the role of PSUs in the Drug Sector, CMD, IDPL stated before the Committee that IDPL was providing about 16-20 per cent of bulk drug as input to the organised sector and small scale units. He stated that the share of bulk drugs from PSUs including Hindustan Antibiotics Ltd. would be around 25 per cent. He added that due to lack of remunerative prices for bulk drugs, IDPL was facing financial problems for which a revival plan had been finalised.

Incidentally during the course of examination of the subject it came out that while the private industry in the drug and pharmaceutical was doing well, financial position of several PSUs was not very sound. Besides, the following PSUs have been referred to BIFR:—

(i) Indian Drugs & Pharmaceuticals Ltd.
(ii) Bengal Chemicals & Pharmaceuticals Ltd.
(iii) Bengal Immunity Limited
(iv) Smith Stainstreet & Pharmaceuticals Ltd.

25. Revival plans of these companies are stated to be under consideration of the Government.

V. PRICING MECHANISM

26. The objectives that were enunciated in regard to pricing in the Drug Policy, 1986 are:—

(a) to stimulate production of drugs and formulations which are essential to the needs of large majority of the people of the country;

(b) to make the price control system less cumbersome but more effective by reducing the span of control; and

(c) to ensure a reasonable return to the producers of essential drugs while at the same time restricting undue increase in their price.

27. In pursuance of the provisions of Drug Policy, 1986 the Drugs (Price Control) Order, 1979 was replaced by a new order called Drugs (Price Control Orders), 1987 in August, 1987. Under this order, the drugs under price control are in two-categories. Drugs under category-I are those required for National Health Programmes and the list was prepared by the Department of Chemicals and Petro-chemicals in consultation with Ministry of Health. There are 21 items in this list.

28. Drugs under category-II *i.e.* other essential drugs were identified by an Expert Committee (Kelkar Committee) from a basket of 418 drugs by applying certain exclusion criteria *viz.* consumption not significant, new drugs for which process developed indigenously, drugs whose availability is far more important than the price, drugs having adequate market competition etc. This list contains 125 items.

29. On the above basis presently there are 143 drugs under price control and about 72 per cent of the turnover of the organised sector is covered under price control.

30. From the submissions made to the Committee by various organisations/experts as also by the administrative Ministry it came out that the drugs/formulations in the country were reasonably priced and were cheaper than many of the advance and developing countries.

31. In regard to pricing policy of drugs and formulations, the manufacturers associations deposed before the Committee that drug industry was the only industry which was having duel control *viz.* product-wise control and profitability control resulting very low profitability in the industry.

32. On being pointed out by the Committee that several companies in the private sector had been declaring very good dividends, the representatives of the industry stated that the profitability of the drug sector was from diversification of their activities like production of agro-chemicals, cosmetics and exports.

33. The Committee further pointed out that free pricing could lead to spurt in prices of medicines. To this the representatives of the industry stated that the Indian drug industry was working in a competitive atmosphere and the medicines which were not under the price control were available at reasonable prices and there had been marginal increase in prices over a period of time.

34. The other difficulties explained by the manufacturers are as under:—

(i) Actual costs are not allowed;

(ii) It takes 10-12 months and even 18 months in revision of price resulting in great loss to the producers;

(iii) Limit of 5-6% in price increase annually whereas cost of input materials increases regularly;

(iv) Unremunerative prices have forced the investors to go into other fields and required investment in the sector is not coming;

(v) Profitability in certain cases is reportedly of the order of 2 to 3 per cent, only; and

(vi) Pricing of 143 drugs and several thousand formulations unmanageable for the Deptt.

35. The representatives of the Druggists and Chemists also submitted before the Committee that wholesale and retail margins were very less in case of essential drugs which discouraged many units to keep such drugs. They also stated that presently different margins were allowed for different set of medicines and it would be better if margins were alike in all cases.

36. During the course of evidence of the representatives of the Deptt. of Chemicals and Petro-chemicals, the Committee enquired about the steps taken or proposed to be taken in this regard. The Secretary C&PC stated that presently items under category I list were allowed 75% post manufacturing expenses (MAPE) and in case of category II list 100% MAPE was allowed. The Govt. was now considering to make one small list of essential drugs where 100% MAPE would be allowed.

37. As regards simplyfying the price revision producers the Secretary informed the Committee that presently the price increase was based on BICP studies and it was not possible for BICP to study several thousand formulations. At times there was delay in revision in prices resulting in shortages of essential drugs. To remove the deficiencies, the Govt. proposed to streamline and simplify the procedures for price revision.

38. When asked to explain the steps proposed for simplification of the procedures, the witness elaborated the following steps:—

(i) for fixing the drugs under price control some limit of turnover would be fixed;

(ii) if a particular drug has monopoly and 90% of it is manufactured by a single company it would be under price control;

(iii) if there is enough competition and if more than 60% of market of that drug is not controlled by a single manufacturer and there are 5 bulk or 10 formulation manufacturers then it could be beyond price control;

(iv) popular packs of medicines would have same ceiling price on the basis leading manufacturers cost which will also be applicable to small scale industries manufacturing such packs; and

(v) price increase to the extent of 70% of the wholesale index could be automatic and for further increase cost-cum-technical study would be required.

VI. IMPACT OF DUNKEL'S PROPOSAL

39. Another area having bearing on the drug industry is the likely impact of Dunkel's proposal, if accepted. Under the (Dunkel Draft Final Act) there is provision of Trade-Related Intellectual Property Rights (TRIPs). Patent rights under TRIPs are entirely different from the present provisions contained in the Indian Patent Act, 1970. While the Patent Act, 1970 provides for process patent, the TRIPs proposals seek product patent.

40. The Dunkel package has the following features that are distinctly different from the present provisions of the Indian Patents Act:

(i) Product patents' will have to be given in all areas of technology.

(ii) The duration of a patent will be 20 years from the date of patent application uniformly for all sectors.

(iii) It permits compulsory licensing on the merits of individual case, but the patent holder will have to be heard before such a licence is given.

(iv) In the case of process patents, a provision for reversal of burden of proof is included subject to certain conditions.

(v) It requires that in the matter of enjoyment of patent rights, there shall be no discrimination as between imported products and locally produced products. This means that a compulsory license cannot be given solely on the ground of non-working of the patent.

41. Different manufacturer Associations/Experts/Voluntary Health Organisations/Common Cause forums in their submissions brought to the notice of the Committee that the process patent system under the Indian Patent Act, 1970 has helped the indigenous industry to grow and it has enabled the country to be almost self-reliant in the field of drugs and medicines. The increasing exports of various formulations were also the result of the process patent system. Similarly the price level was also reasonable.

42. The above associations have also brought to the notice of the Committee that in case Dunkel proposals regarding TRIPs were accepted, the likely impact in future would be as under:—

(i) Prices of drugs/medicines will go up several times;

(ii) Exports will go down and imports will increase resulting in out-go of Foreign Exchange;

(iii) The period of patent right will be 20 years which is very long period. Further after expiry of this period, patent holder can also seek process patent.

(iv) Research and development activities will come to stand-still;

(v) Essential drugs which are required for national health programmes and for common use by the poor people may disappear from the market;

(vi) Multi-national companies will have monopoly over the market and they will dictate the market in terms of prices and availability.

43. However, one manufacturer association representing large number of Indian and multinational companies in their submission to the Committee has welcomed the Dunkel's proposals. According to them, there will be real competition and more R&D will take place. Regarding prices, they have argued that price increase could be marginal as life of most of the present patents had expired.

44. As regards the share of internationally patented drugs presently marketed in the country, the views of different organisations/experts were varying between 15% to as high as 40-45%.

45. During the course of examination of the Deptt. of Chemicals and Petrochemicals the Committee wanted to know about the assessment of the Deptt. in regard to likely impact of Dunkel's proposals on the Indian Drug & Pharmaceutical sector. The Secretary, C&PC stated:—

"The movement all our various drugs and formulations to the extent of 10 to 15 per cent only are covered by patents. The rest of the common medicines are outside the patent. There patent has expired. In any case they are not affected."

46. He added that the medicines which were being manufactured for the common-man in the country would continue to be manufactured. The patent provisions would be applicable only to the discoveries made after signing the agreement. Besides 10 years time would be allowed as a transitional period subject to introduction of new drugs under the provisions of exclusive marketing rights.

47. The Department of Chemicals and Petrochemicals further stated in a written note that the following number of drugs are marketed in India which are covered by product patent abroad:—

Patent Expiring Year	*No. of Patent*
1993	13
1994	11
1995	4
After 1995	10

48. On being pointed out that the product patent system could affect the

prices of new drugs and their availability like anti-cancer, anti-AIDS etc. the Secretary C&PC agreed that such drugs could be affected.

49. When asked as to whether the Government could refuse signing the Dunkel's proposals, the witness stated that many advanced and developing countries had already signed and many others were falling in the line. The real view had to be taken by the Government as a whole as to whether our country wanted to remain a member of GATT or they could afford to be outside the GATT.

It also came out that by remaining outside the GATT it would not be conducive for export performance of the country as also for inflow of much needed investment.

50. The Committee also wanted to know the impact of Dunkel's proposals on the prices of medicines. The Secretary C&PC replied that the prices of items patented after the signing of the agreement would be certainly higher as there would not be competition from domestic market, but at the moment the exact quantum of increase could not be assessed.

51. He, however, added that some alternatives could be available in the market of off patented items. Besides multinational companies might set up more units in the country in the context of big market and low labour cost. Besides almost all the drugs in the list of essential drugs drawn by the World Health Organisation are outside the purview of patent laws as their patents have expired. The few drugs under the patents will also not be affected.

52. Taking note of the fact that the Commerce Ministry was the nodal Ministry of the Government for signing the Dunkel proposals the Committee took evidence of the representatives of the Ministry of Commerce. The Committee wanted to know the views of the Government in regard to likely impact of Dunkel's proposals on the drug and pharmaceutical sector. The Special Secretary of the Ministry brought out the following points:—

(i) The Ministry of Chemicals has assessed the proportion of drugs patented in foreign countries to be about 10-15%. If the proportion of patented drugs remains the same, the effect of prices would be limited to these drugs. Also the availability of previous generation drugs would exercise a downward pull on prices;

(ii) Some provisions have been provided in the Dunkel proposals for safeguards against abuse of business practices and compulsory licensing for non-commercial use by Government.

(iii) The Govt. can give compulsory licence if it is found to be in conflict with restrictive business principles of the country. Govt. can give compulsory licence for manufacture of drugs used for non-commercial purposes by the Govt. like for distribution in hospital etc.

(iv) The Govt. has retained the power of imposing restriction on import of materials; and

(v) the Indian Patents Act, 1970 will have to be changed substantially.

53. Regarding investment policy, the Spl. Commerce Secretary informed that Dunkel's Text did not add anything to what was therein GATT agreement of 1947 and did not affect the investment. The Govt. had all the policy authority to allow or refuse anybody to invest in the country. At the time of allowing a foreign investor to set up a Company, the Govt. could impose any sort of conditions. However, once the investor had set up a manufacturing establishment it would have to be treated at par with the domestic investors.

54. Asked about the impact on price of drugs etc. the Special Secretary stated:—

"It will be totally unaffected because the Dunkel text will apply, if it has to be accepted only to the patent applications to the medicines which are based on patent applications which are filed after the Dunkel text takes effect. As of today the expectation is that in 1993 December, the negotiations will end and it will take effect in 1995. So, anything that has happened upto 1994, any medicine that has come into market upto 1994 based on patent that have been sold in other countries upto that time will not be affected, neither the price level nor the capacity to manufacture it. It will be totally unchanged."

In reply to another question, the witness stated:—

"If the Dunkel text is to be accepted then it cannot automatically have applicability in India. It will be first brought into the Indian law and then only it will apply here. If a complaint is to be made, it cannot be made on the basis of patent obtained in United States or the law of the United States. It will have to be made in accordance with the law that we would indicate if we are to accept this."

VII. RESEARCH AND DEVELOPMENT

55. The Drug industry is highly research oriented. To develop a new drug it requires 10-12 years time as also the large sum of money to the tune of 200 to 300 million dollars. During the year 1992 not more than 20 new molecules were discovered all over the world. The representatives of manufacturer associations brought to the notice of the Committee that within the present policy frame work the price of drugs/formulations were not remunerative and as such funds were not available for research work. It also came out during evidence that presently about 2-3 percent of sales turnover was being spent on researach and development.

56. In this connection Deptt. of Chemicals and Petro-chemicals have also stated in a note that it is estimated that about 2% of sales is spent on R&D. There are about a dozen companies who spend more than Rs. 1 crore per annum on R & D in pharamaceutical sector. However, the pharmaceutical industry's R & D expenditure is quite low when compared with average world wide expenditure of 10-15% of sales.

57. During the course of evidence of the representatives of Ministry of Health, the Committee wanted to know about R&D programmes of the Govt. Institutions. A representative of the Ministry replied:—

> "That (budget) is very meagre amount for meeting health care needs. On the non-plan side cost have gone up, we are not also to spend on equipment and medicines because our expenditure being more in service side".

58. In a written note furnished to the Committee, the Deptt. of Chemicals and Petro-chemicals has stated that the investment in R&D were inadequate and to attract more investment in R&D, the Government was considering several concessions to the industries such as keeping the new discoveries outside the price control for a number of years. Similarly one inter-Ministrial Group would consider the suggestions for giving tax benefits, reduction in excise on new products, availability of soft loans etc.

59. About the capability of Indian Institutions to discover new drugs, representatives of the industry stated that they were capable of discovering new drugs by spending Rs. 30 crores to 50 crores.

60. In this connection, Director, Indian Institute of Chemical Technology (Dr. A. V. Rama Rao) in his submission before the Committee stated that Govt. should give more incentive to R&D. He also stated that encouragement should be given to set up more R&D centres particularly keeping in view the country's needs as other advanced countries might not be interested about diseases which were only in India.

61. During the course of evidence of the Deptt. of C&PC the Committee pointed out that R&D area was very important and needed Govt. attention. To this Secretary, C&PC replied:—

> "We want to encourage more and more R&D work in this area which is very technology oriented and a lot of incentives have been suggested."

VIII. QUALITY CONTROL

(i) *Spurious/Sub-standard Durgs*

62. One of the objectives of the Drug Policy, 1986 is to make available quality drugs at reasonable prices. While the licensing and production aspects of drug industry are under the administrative control of Department of Chemicals and Petro-chemicals the quality aspects of drugs formulations are governed by Drugs and Cosmetic Act. The others of the

Drug Controller at Centre under the Health Ministry and similar authorities at State level are responsible for supervising the operations of manufacturing units as also the sales network.

63. Asked about the quality control system, several manufacturer associations deposed before the Committee that Indian Companies were manufacturing quality drugs/formulations which were comparable to standard of advanced countries and the industry was exporting various formulations to several countries.

64. However, some of the voluntary health organisations as also common cause forums brought to the notice of the Committee that spurious and sub-standard drugs find place in the market.

65. During the course of evidence of the representatives of All India Druggists and Chemists Association, the Committee wanted to know the quantum of spurious drugs. A representative of the Association deposed before the Committee that it was less in West and South but was more in northern parts, particularly U.P. and Bihar. He added that spurious drug was less but the sub-standard drugs were more.

66. In reply to another question the witness clarified that sub-standard drugs were found in Government Hospitals, Municipal Corporation Dispensaries etc. where tenders were called on competitive basis. In this connection they suggested that besides the regular inspection by the drug inspectors, some separate machinery should be created in each State which could stop the production and marketing of spurious/sub-standard drugs.

67. The Director, Indian Institute of Chemical Technology (Dr. A. V. Rama Rao) while stressing the need for following the good manufacturing practices (GMPs) stated that the Government should weed out the industries which were not following GMPs.

68. During the course of examination of Deptt. of C&PC, the Committee wanted to know the steps taken to ensure proper quality control in the manufacture and distribution of drugs. In a written note furnished to the Committee, Department of C&PC stated that for effective implementation of Drugs and Cosmetic (D&C) Act in the country and to combat the problems of sub-standard and spurious drugs and to achieve the purpose of quality control of drugs, the following steps have been taken:—

(i) The requirement for every drug manufacturer to have their own testing Laboratory has been made mandatory in the Drugs and Cosmetics Rules;

(ii) The requirement of GMP (Good Manufacturing Practice) has been incorporated in the D&C Rules for the quality assurance of drugs manufactured by the firms;

(iii) Approved testing Labs. (Pvt.) have been introduced in the Drugs and Cosmetic rules for independent testing of drug samples sent by the companies; and

(iv) Qualification of licensing authorities, controlling authorities have been notified in the Drugs & Cosmetics Rules. Most of the States are having full time drugs controllers. However, legal-cum-intelligent cell, sufficient number of Drugs Inspectors, testing facilities, mobile squads and strengthening of Central Drugs Control Department and State Drug Control Organisation are yet to be provided.

69. The Department of Chemicals & Petro-chemicals also stated in a note that to combat the menace of spurious drugs, necessary amendments were made during 1982 in the Drugs & Cosmetics Act for enhancement of punishment to the spurious drug manufacturers/dealers. The Government was also taking steps to open new laboratories.

70. During the evidence of the Drug Controller the Committee wanted to know the steps taken to ensure that only quality drugs/formulations were produced and marketed in the country. In his reply, Drug Controller explained that there were regular checking at production as also sales units. The small scale units were also covered under their programme.

71. In reply to a further question about the machinery available to ensure proper checking, the Deptt. of C&PC informed the Committee that there were about 20,000 manufacturing units and 2,00,000 sales premises in the country. To look after the quality control aspects there should be minimum 2000 Drug Inspectors. However, there were only 700 Drug Inspectors. Similarly, at least 1,00,000 samples should be tested by Govt. testing laboratories, however, presently samples tested were only 28,000 samples per annum.

72. In this connection, the representative of the Health Ministry stated during his evidence that due to lack of funds at Centre as also at State levels adequate machinery/equipments etc. were not available to test the required number of samples.

(ii) *Irrational Drugs*

73. Some of the Experts/Voluntary Health Organisations common cause groups in their memoranda presented to the Committee as also during course of their evidence deposed before the Committee that several irrational and non-sensical drugs/formulations were being manufactured and marketed in the country simply in commercial considerations. Such drugs are reportedly more harmful and could lead to tragedies.

74. A representative of the Voluntary Health Organisation deposed before the Committee that Bangladesh Government had taken a lead in this direction where the Government has permitted manufacture and sale of essential drugs only.

75. During the course of the examination of the Health Ministry the Committee wanted to know the steps taken by the concerned authorities to check the menace of irrational drugs/formulations. Drug Controller of India replied that they were aware of this problem and there was regular

checking of different formulations. The Committee were informed that based on analysis of various formulations 42 categories of various formulations were found irrational and had been banned. These formulations covered approximately 3000 branded products.

76. On being enquired by the Committee about the side effects of various drugs/formulations, the witness replied that there had not been any indepth evaluation about the side effects of various medicines, however, all medicines cause side effects and it could vary from medicine to medicine.

(iii) Use of Generic Names

77. Based on the recommendations of Hathi Committee Report, Drug Policy 1986 also mentions about the use of generic names. Various voluntary organisations/Indian Medical Association Experts brought to the notice of the Committee that similar drugs manufactured by different companies were being marketed at different prices under brand names.

IX. INDIAN MEDICINE SYSTEM

78. From the times immemorial Ayurveda and other Indian systems of medicines have been practiced in our country. There are still some diseases for which Ayurveda/Homoepathy medicines have better cure. Also due to reasons for faith and lack of access to the modern medicines; Ayurveda, Unani and Siddha systems of medicines have been practised in the country since long. The Drug Policy 1986 emphasised the need to encourage and improve upon the traditional system of medicines with a view to widening the coverage of health care schemes of the Government. Some of the experts/scientists/voluntary organisations also deposed before the Committee that Indian medicine system should be strengthened.

79. During course of evidence of the Health Ministry, the Committee wanted to know the steps taken to encourage the Indian Medicine System. The Drug Controller replied:—

> "The Indian System of medicine is encouraging and now under the Drug and Cosmetic Act, in order to control the quality of Ayurveda, Unani, herbal and Siddha also they have been brought under its purview".

80. When asked whether manufacturing of Ayurveda Medicines etc. needed industrial licence the witness stated that they needed manufacturing license. For sale licensing suggestion could be put to Drugs Technical Advisory Body.

PART II

RECOMMENDATIONS/CONCLUSIONS OF THE COMMITTEE

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.

2. The Secretary, Chemicals and Petro-chemicals has informed the Committee that there is no proposal to change the objectives of the Drug Policy of 1986 and the Government only proposed to bring certain changes in the implementation aspects so that the key objectives of the policy like ensuring abundant availability of good quality medicines at reasonable prices could be achieved. The Committee are also informed during evidence that the Ministry had consulted various experts, manufacturer organisations/consumer organisations, etc. before finalising the background note. 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 prophylectic medicines of good quality at reasonable price and strengthening the quality control and the indigenous capabilities for production of drugs are achieved.

3. The Committee find that under the Health for all by 2000 A.D. Programme which the Government has taken up for implementation medicines worth Rs. 15000 crores would be required as against the present production of around Rs. 6500 crores. It is a stupendious task which have to be accomplished within a short time of 7 years. The Committee therefore would like the Health Ministry and Deptt. of Chemicals and Petro-chemicals 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 Chemicals and Petro-chemicals 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.

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 representatives of the Health Ministry deposed before the Committee that there were constraints of funds to meet the national health programme. The Committee would like to urge upon the Government to raise the Health budget appropriately both at the Centre and at State levels.

5. The Committee were informed that as a consequence of economic liberalisation programme enunciated in the new Industrial Policy, 1991 it was felt necessary that in the important industry like the drug industry where adequate production was very essential for the health care, was kept free from various licensing controls and it was envisaged that automatic approval could be given upto 51% equity participation by foreign companies by declaring drug industry a priority sector. The Government thought that this measure would help in attracting more foreign investment in this sector in the country. At the same time some restrictions/control were allowed to be retained in the revised policy so that the Government could ensure adequate production and availability of all essential drugs at reasonable prices. 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.

6. As per the Drug Policy, 1986, 15 items of drugs are reserved for production by Public Sector Undertakings. In this context, the Secretary, Deptt. of Chemicals and Petro-chemicals 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.

7. Another area where the Government propose to bring changes in the drug policy is the pricing of drugs and medicines. Presently about 143 drugs and thousands of formulations are under the price control. Several organisations of the manufacturers of the bulk drugs and formulations pleaded before the Committee that the profitability of the industry was very low and investors were shying away to invest more funds in the industry. The Committee also note that sometimes there were delays in revision of prices which results in loss to the industry and the industry was surviving because of resorting to diversification of production to Agro-Chemicals, Cosmetics by the manufacturers and to a great extent on exports. The Committee find that the Ministry are aware of these problems and they propose to review the position. Besides, 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 counection, 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 Programme do not go beyond common man's reach.

8. Yet another area which the Committee view with concern is the likely impact of Dunkel proposals on the drug and pharmaceutical sector. The Dunkel proposals provide for product patent under the Trade Related Intellecutal Property 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 manufacturer associations/experts/voluntary health organisations that the TRIPs provisions would adversely 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 views about the share of internationally patented medicines in the country which vary from 10—15% to as high as 40—45%. According to the Deptt. of Chemicals and Petro-chemicals share of patented items was 10—15% only.

9. 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 and 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 Commerce Secretary.

10. As regards the assessment of the Ministry of Commerce with regard to likely impact of Dunkel Proposals on the Indian drug and pharmaceuticals sector, the Special Secretary of the Ministry deposed before the Committee that some safeguards have been provided in the Dunkel Proposals against the abuse of business practices and compulsory licensing for non-commercial use by the Government. Besides the Government have retained the power of imposing restrictions on import of materials. The Committee also note that Dunkel Proposals could only be implemented in the country after the relevant provisions of the Indian Patents Act, 1970 were suitably modified. The Committee were also, informed that several developed and developing countries have already signed the Dunkel text and more countries were falling in the line. It was also pointed out that by remaining outside the GATT, it would not be conducive for export performance of the country as also for inflow of much needed investment. The Government was still interacting with various groups in this regard. In this connection suggestions given by some of the experts for shortening the patent period and manufacture of patent drugs within the country merit consideration.

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 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.

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 Govt. such as improvement in the pricing mechanisam 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 Govt. regarding giving incentives 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 purchase 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 & Development programmes and special incentives be given for undertaking R&D in tropical diseases.

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 Houses of Parliament on 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 phamaceuticals 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.

13. The Committee were informed by several manufacturer 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 smaples 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 Govt. should find ways and means to stengthen the quality control machinery in terms of man power and requisite equipments.

14. It came out during the examination that several irrational and non-sensical drugs/formulations were being manufactured and marketed in the

country on commerical 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 Govt. should take urgent steps to totally weed out the manufacture and sale of irrational and non-sensical drugs.

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. Govt. should consider the use of generic names in the drug industry.

16. The Committee find that Indian medicine system like Ayurveda, Unani and Siddha 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 dircetion, the Committee would like the Govt. 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.

NEW DELHI;
August 3, 1993

Sravana 12, 1915 (Saka)

SRIBALLAV PANIGRAHI
Chairman,
Standing Committee on
Petroleum and Chemicals.

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