APPENDIX

STATEMENT SHOWING THE PRODUCTION OF THE MONITORED BULK DRUGS DURING 1990-91 AND 1991-92 BY COMPANIES HAVING FOREIGN EQUITY MORE THAN 25% OPERATING IN INDIA

<table>
<thead>
<tr>
<th>Name of the Company/Bulk Drug</th>
<th>A/C Production Unit</th>
<th>1990-91</th>
<th>1991-92</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. M/S. Abbott Labs. Erythromycin stearate I.P</td>
<td>T</td>
<td>22.33</td>
<td>18.00</td>
</tr>
<tr>
<td>2. M/s Bayer(I) Ltd. i) Chloroquine Phosphate</td>
<td>T</td>
<td>32.96</td>
<td>30.19</td>
</tr>
<tr>
<td>ii) Mephylidine</td>
<td>T</td>
<td>21.76</td>
<td>10.52</td>
</tr>
<tr>
<td>3. M/s Boehringer-Mannheim i) Chloramphenicol Powder</td>
<td>T</td>
<td>50.87</td>
<td>66.52</td>
</tr>
<tr>
<td>ii) Glibenclamide</td>
<td>T</td>
<td>0.58</td>
<td>1.23</td>
</tr>
<tr>
<td>ii) DEC Citrate</td>
<td>T</td>
<td>7.82</td>
<td>8.27</td>
</tr>
<tr>
<td>iii) Digoxin</td>
<td>Kg</td>
<td>16.00</td>
<td>13.58</td>
</tr>
<tr>
<td>iv) Pyrimethamine</td>
<td>T</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>v) Isoprenaline</td>
<td>T</td>
<td>5.00</td>
<td>1.00</td>
</tr>
<tr>
<td>vi) Trimethoprim</td>
<td>T</td>
<td>70.89</td>
<td>97.02</td>
</tr>
<tr>
<td>5. M/s Boots Pharmaceuticals i) Ibuprofen</td>
<td>T</td>
<td>178.60</td>
<td>167.77</td>
</tr>
<tr>
<td>ii) Diloxanide Furoate</td>
<td>T</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>iii) Crystalline Insulin</td>
<td>MU</td>
<td>2703.00</td>
<td>3097.00</td>
</tr>
<tr>
<td>6. M/s Cynamid India Ltd. i) Tetracycline</td>
<td>T</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>7. M/s Duphar-Interfran Ltd. i) Cholacalaciferol IP (Vit D3)</td>
<td>Kg</td>
<td>461.00</td>
<td>322.00</td>
</tr>
<tr>
<td>ii) Isoniazide /hydrochloride</td>
<td>T</td>
<td>1.91</td>
<td>1.55</td>
</tr>
<tr>
<td>iii) Paracetamol</td>
<td>T</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>8. M/s Eskayef Limited i) Trimeterene</td>
<td>T</td>
<td>N.A</td>
<td>0.10</td>
</tr>
<tr>
<td>ii) Trifluoperazine</td>
<td>T</td>
<td>0.24</td>
<td>0.10</td>
</tr>
<tr>
<td>9. M/s E Merck (I) Ltd. i) Vitamin E (Acetate)</td>
<td>T</td>
<td>86.26</td>
<td>167.06</td>
</tr>
<tr>
<td>ii) Vitamin P (Rutin)</td>
<td>T</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>ii) Vitamin K</td>
<td>T</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>iv) Chloroquine Phosphate</td>
<td>T</td>
<td>57.08</td>
<td>57.26</td>
</tr>
</tbody>
</table>
10. Ms/ German Remedies Ltd.
   i) Hydroxyethyl Theophylline T 70.47 70.76
   ii) Sulfamoxole T 63.97 49.49
   iii) Theophylline T 86.96 80.88
   iv) Trimyrophopim T 6.17 7.38
   v) Xantinolnicotinate T 15.05 13.33
11. M/s Glaxo India Ltd.
   i) Betamethasone Kg 1141.00 1190.00
   ii) Griseofulvin T Nil 8.50
   iii) Ibuprofen T 0.25 -
   iv) Ranitidine T 25.56 19.55
   v) Triple Vaccine KL 3.84 4.52
   vi) Vitamin A MMU 13.77 7.33
12. M/s Hindustan Ciba-Geigy Ltd.
   i) Dihydralazine T 17.30 11.72
   ii) Hydrochlothiazine T 12.42 6.50
   iii) Sulphaphenazole T 2.91 Nil
   iv) Sulphagomidine T 15.48 2.24
   v) Sulphathiazole T 2.94 NIL
13. M/s Hoechst India Ltd.
   i) Baralgan Ketone T 2.49 2.50
   ii) Frusemide T 7.80 7.59
   iii) Glybenclamide T 2.49 2.80
   iv) Isopropyl Antipyrine T 22.92 22.79
   v) Pheniramime Maleate T 26.06 38.00
   vi) Procaaine T 36.16 48.41
   vii) Procaine T 7.90 5.26
14. M/s Parke-Davis
   i) Metelopramide T 0.24 0.39
15. M/s Parke-Davis
   i) Amodiaquine Hcl T 16.69 3.49
   ii) Chloramphenicol Palmitate T 11.25 12.87
   iii) Chloramphenicol Powder T 24.69 17.65
   iv) Diphenhydramine Hcl T 0.30 0.65
16. Ms. Pfizer Limited
   i) Chlorpropamide T 29.12 44.38
   ii) Isoniazid T 44.93 24.45
   iii) Oxytetracycline & Its Salts T 112.77 107.09
   iv) Pyrental Palmoate T 16.40 19.84
   v) Sodium PAS T NIL NIL
   vi) Tetracycline T N.A. N.A.
17. M/s Procter & Gamble
   Menthol T 28.05 44.09
18. M/s Rallis India Ltd.
   i) Ibuprofen T NIL NIL
   ii) Iron Dextran KL 23.55 22.18
   iii) Loperamide T NIL NIL
<table>
<thead>
<tr>
<th></th>
<th>Company</th>
<th>Product Description</th>
<th>Quantity</th>
<th>Rate</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>19.</td>
<td>M/s Reckitt &amp; Colmn</td>
<td>i) Parachloro Meta Xylenol</td>
<td>T</td>
<td>88.46</td>
<td>110.10</td>
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<tr>
<td></td>
<td></td>
<td>ii) Chlorpromazine</td>
<td>T</td>
<td>0.51</td>
<td>1.62</td>
</tr>
<tr>
<td></td>
<td></td>
<td>iii) Phtholy lsulphathiazole</td>
<td>T</td>
<td>NIL</td>
<td>NIL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>iv) Prochlorperazine</td>
<td>T</td>
<td>NIL</td>
<td>NIL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>v) Sulphathiazole</td>
<td>T</td>
<td>4.07</td>
<td>NIL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>vi) Sulphadimidine</td>
<td>T</td>
<td>NIL</td>
<td>NIL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>vii) Metronidazole</td>
<td>T</td>
<td>33.18</td>
<td>9.66</td>
</tr>
<tr>
<td>20.</td>
<td>M/s Rhone-Poulence (I) Ltd</td>
<td>i) Chlorpromazine</td>
<td>T</td>
<td>0.51</td>
<td>1.62</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ii) Phtholy lsulphathiazole</td>
<td>T</td>
<td>NIL</td>
<td>NIL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>iii) Prochlorperazine</td>
<td>T</td>
<td>NIL</td>
<td>NIL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>iv) Sulphadimidine</td>
<td>T</td>
<td>4.07</td>
<td>NIL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>v) Sulphathiazole</td>
<td>T</td>
<td>NIL</td>
<td>NIL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>vi) Sulphadimidine</td>
<td>T</td>
<td>NIL</td>
<td>NIL</td>
</tr>
<tr>
<td>21.</td>
<td>M/s Roche Products</td>
<td>i) Chlorodiazepoxide</td>
<td>Kg</td>
<td>888.00</td>
<td>363.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ii) Dehydrometine</td>
<td>Kg</td>
<td>182.00</td>
<td>104.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td>iii) Dizepam</td>
<td>T</td>
<td>0.66</td>
<td>0.91</td>
</tr>
<tr>
<td></td>
<td></td>
<td>iv) Sulphamethoxazole</td>
<td>T</td>
<td>18.38</td>
<td>32.69</td>
</tr>
<tr>
<td></td>
<td></td>
<td>v) Vitamin A</td>
<td>MMU</td>
<td>60.25</td>
<td>58.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td>vi) Vitamin E</td>
<td>T</td>
<td>7.71</td>
<td>7.14</td>
</tr>
<tr>
<td>22.</td>
<td>M/s Roussel Pharmaceuticals</td>
<td>i) Framycetin</td>
<td>T</td>
<td>6.36</td>
<td>8.09</td>
</tr>
<tr>
<td>23.</td>
<td>M/s Sandoz (I) Ltd.</td>
<td>i) Atropine</td>
<td>Kg</td>
<td>NIL</td>
<td>NIL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ii) Digoxin</td>
<td>Kg</td>
<td>10.00</td>
<td>4.27</td>
</tr>
<tr>
<td></td>
<td></td>
<td>iii) Sulphamethoxazole</td>
<td>T</td>
<td>N.A.</td>
<td>N.A.</td>
</tr>
<tr>
<td>24.</td>
<td>M/s Searle (I) Ltd.</td>
<td>i) Diphenoxylate Hydrochloride</td>
<td>T</td>
<td>1.93</td>
<td>1.82</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ii) Spironolactone</td>
<td>T</td>
<td>0.52</td>
<td>0.26</td>
</tr>
<tr>
<td>25.</td>
<td>M/s UNI Sankyo Ltd.</td>
<td>i) Pyrazinamide</td>
<td>T</td>
<td>1.50</td>
<td>0.26</td>
</tr>
<tr>
<td>26.</td>
<td>M/s UNI-UCB Ltd.</td>
<td>i) DEC Citrate</td>
<td>T</td>
<td>N.A.</td>
<td>N.A.</td>
</tr>
<tr>
<td>27.</td>
<td>M/s Wander Ltd.</td>
<td>i) Sodium PAS</td>
<td>T</td>
<td>31.82</td>
<td>18.59</td>
</tr>
<tr>
<td>28.</td>
<td>M/s Wyeth Labs</td>
<td>i) Hydrocortisone</td>
<td>Kg</td>
<td>15.00</td>
<td>2.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ii) Prednisolone</td>
<td>Kg</td>
<td>2246.00</td>
<td>1949.00</td>
</tr>
<tr>
<td>29.</td>
<td>M/s Astra-IDL</td>
<td>i) Ibuprofen</td>
<td>T</td>
<td>NIL</td>
<td>0.03</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ii) Terbutaline</td>
<td>Kg</td>
<td>467.00</td>
<td>465.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td>iii) Lignocaine/Xylocaine</td>
<td>T</td>
<td>4.92</td>
<td>4.37</td>
</tr>
<tr>
<td></td>
<td></td>
<td>iv) Clofazimine</td>
<td>T</td>
<td>1.14</td>
<td>1.33</td>
</tr>
</tbody>
</table>

(*Estimated)
(N.A. Not available)
(Source: IDMA Bulletin XXIV (25), July 7, 1993.)
BACKGROUND NOTE\textsuperscript{1} ON REVIEW OF DRUG POLICY, 1986

(GOVERNMENT OF INDIA,
MINISTRY OF CHEMICALS AND FERTILIZERS,
DEPARTMENT OF CHEMICALS & PETROCHEMICALS)

Introduction

1. The Drug Policy of 1986, which was also entitled "Measures for Rationalisation, Quality Control and Growth of Drugs & Pharmaceuticals Industry in India" was evolved after a detailed examination of the various issues having a bearing on availability, quality and prices of medicines. The main objectives of the Drug Policy, 1986 are:

(a) ensuring abundant availability, at reasonable prices of essential and 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 encourag-

\textsuperscript{1} This paper was circulated to members of Parliament in August 1992, regarding proposed changes in the 1986 Drug Policy.
ing 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. For meeting the requirements of medicines for health needs at reasonable prices and strengthening the indigenous base, the Government has, over the years been guided by the above policy. Implementation of the main policy provisions has been through the I (D & R) Act on Industrial Licensing aspects and through Drugs (Prices Control) Orders under the Essential Commodities Act in regard to the pricing mechanism. The Drug Policy has also given the policy framework in regard to Quality Control and Rational Use of Drugs. Enforcement of quality and standards in medicines is done through the provisions contained in the Drugs & Cosmetics Act, which is administered by the Ministry of Health.

PRESENT STATUS OF THE DRUG INDUSTRY

3. Over the last several years, policy inputs have been directed towards promoting growth of the Industry and to help it achieve a broad base in terms of both the range of products, and technologies needed to produce them from as basic a stage as possible. The results have been very en-
couraging. As on date, there are about 250 large units and about 8,000 small scale units in operation, which form the core of the Industry (including 5 Central Public Sector Units). These units produce almost the complete range of formulations (i.e. medicines ready for consumption by patients), and about 350 bulk drugs (i.e. chemicals having therapeutic value used for production of formulations). It is estimated that 70 per cent of the indigenous demand for bulk drugs and almost the entire demand for formulations are being met through domestic production.

The Industry has also achieved commendable export performance and the result is that the trade balance has been positive for the last three consecutive years. During the last decade the growth of production, imports and exports, in terms of value has been as follows:

(Rs. in crores)

<table>
<thead>
<tr>
<th>Details</th>
<th>1980-81</th>
<th>1990-91</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Production</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Bulk Drugs</td>
<td>240</td>
<td>700</td>
</tr>
<tr>
<td>- Formulations</td>
<td>1200</td>
<td>3600</td>
</tr>
<tr>
<td>2. Imports</td>
<td>113</td>
<td>800</td>
</tr>
<tr>
<td>3. Exports</td>
<td>76</td>
<td>951</td>
</tr>
<tr>
<td>4. Trade Balance</td>
<td>(-)37</td>
<td>(+)151</td>
</tr>
</tbody>
</table>
BACKGROUND OF THE PRESENT REVIEW

4. The need for review of the Drug Policy, 1986 and modifications based thereon has arisen mainly because of the following factors:


   b) The categorisation of drugs for the purpose of price control has attracted controversies/criticisms and several Members of Parliament have raised a number of questions in Parliament pointing out anomalies, and assurances had to be given that these will be examined.

   c) The Drug Industry has also been complaining about the stranglehold of price control and wants the control mechanism to be made more realistic and flexible so as to take care of the rising costs of manufacture and for encouraging new investment for meeting the growing requirements of medicines in the country.

NEW INDUSTRIAL POLICY AND DRUG SECTOR

5. The changes in the Industrial Policy have the following
impact on the Pharmaceutical Sector:

(a) Prior to the announcement of the New Industrial Policy, almost the entire pharmaceutical sector (except for an intermediate viz 6-APA) was totally de-licensed through the Delicensed Registration Scheme 1988. With the abolition of these two schemes in the New Industrial Policy, the Pharmaceutical Sector has been temporarily placed under the ambit of compulsory licensing to meet the requirements of the Drug Policy. These requirements relate to manufacture from the prescribed basic stage and supply of a percentage of the bulk drug produced to Non-Associated formulators, in the case of bulk drugs, and compliance of ratio parameters between bulk drug and formulations activity and consumption of imported and indigenous bulk drugs, in the case of formulations.

(b) The Drug Policy 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 up to 40 per cent were on par with Indian company. In the New Industrial policy, automatic approvals can be given for equity up to 51 per cent in high priority areas.
(c) Broadbanding was previously available only in respect of specified group of products. The New Industrial policy extends it to cover all items.

(d) In the New Industrial Policy, Government has reviewed the list of items reserved for public sector and has limited such reservations only to a few strategic, high-tech and essential items. In the Drug Policy also, 15 items were reserved for the public sector which would require to be reviewed.

(e) The system of Phased Manufacturing Programmes will not be applicable to the new projects.

6. Subsequent to announcement of the Industrial Policy, further changes have been given effect to in the country's Trade and Fiscal policies. These changes have a significant impact on the Pharmaceutical Industry.

(a) Except for few items placed under negative list, under the EXIM Policy 1992-97, any item can be imported without any restriction since there is no actual user's condition.

(b) All imports including import of technologies required by the Pharmaceutical Industry for the manufacture of bulk drugs as well as formulations will have to be made with
REVIEW OF INDUSTRIAL LICENSING AND RELATED ASPECTS

7. The framework for giving industrial approvals in the drug sector has to conform to the structure laid down in the Industrial Policy. New investments and technologies have also to be encouraged in the production of drug and pharmaceuticals as production levels have to go up from the present level of Rs.4,000 crores to Rs. 15,000 crores by 2000 A.D (at 1979-80 prices). Since the earlier regime of industrial approvals provided only for a simple procedure of registration, which has now been scrapped in the New Industrial Policy, to place the entire drug sector under compulsory licensing would appear to be a regressive measure and would not give the right signals for encouraging future investments in this sector. There is no reason why the drug sector should be excluded from the liberalisation envisaged in the New Industrial Policy.

Industrial licensing

8. It has, therefore, to be decided what really should be the core concerns which can be monitored within the framework available in the New Industrial Policy without appearing to be regressive. In this approach the following core
concerns have been identified:

(a) Indigenous manufacture of bulk drugs from the basic stage rather than on the basis of imported late stage intermediates.

(b) Greater dependence on use of indigenously produced bulk drugs in the manufacture of formulations.

9. To bring the Drug Policy in consonance with the spirit and philosophy of the New Industrial Policy, the following line of action is being considered in regard to industrial licensing:

(a) Industrial Licensing be abolished except in the cases of those identified bulk drugs and their intermediates where there is danger of regression to manufacture from later stage imported intermediates, large volume parenterals (I.V.fluids) and the formulations containing identified imported bulk drugs. Industrial licensing, however, should ultimately be done away with by appropriate usage of tariff mechanism to give incentive for basic stage manufacture.

(b) Under the circumstances the condition stipulating mandatory supply of a percentage of bulk drug production to Non-Associated formulators might no longer be necessary.
However, the existing stipulation requiring compliance of ratio parameter limiting consumption of imported bulk drugs to 50 per cent might have to be continued but the ratio parameter linking bulk drugs to formulation activity could be done away with.

**Foreign Investment**

10. The Drug Policy limits the activities of companies with foreign equity above 40 per cent whereas in the New Industrial Policy, automatic approvals can be given for equity up to 51 per cent in high priority areas. At present companies with foreign equity up to 40 per cent are on par with other Indian companies.

Accordingly, it is proposed to declare Drug Sector as a priority sector. Foreign investment up to 51 per cent and automatic approval for foreign technologies can, therefore, be made permissible in the cases of all bulk drugs, their intermediates and formulations. Investment above 51 percent could be considered on a case by case basis in areas where investment is otherwise not forthcoming.

**Reservation of Items for the Public Sector**

11. In the New Industrial Policy, Government has reviewed the list of items reserved for Public Sector and has limited
such reservation only to a few strategic, high-tech and essential items. The same approach would have to be made applicable to the drugs reserved for Public Sector.

It is being considered that the list be pruned to only a few select items where capacity in the public Sector is adequate to meet the country's demand and heavy public investment has been made. The position would be reviewed periodically as per demand of the situation.

**Other Related Issues**

12. The provisions in regard to location, COB licenses, broadbanding etc. would have to be in line with the New Industrial Policy.

**Research and Development**

13. The drug industry is a highly R & D oriented sector in which there is a very high rate of obsolescence. This sector has also been identified as one of the thrust areas for exports. There is, therefore, need to ensure that the technologies used in the country are cost effective and efficient. It is also necessary to attract greater channelising of investment into this sector in order to update existing technologies and for bringing into the country technologies
which are not currently available. At the same time it is to be noted that the Indian companies have achieved considerable stature in terms of production as well as in marketing ability, and indigenous technology has also reached a commendable level in many cases.

In addition to the facilities already available for strengthening the R & D base of the Pharmaceutical Industry, the following are being considered:

(a) 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.

(b) A bulk drug introduced in the country for the first time would not be brought under price control for a period of three years from the date of its commercial production.

(c) Ministry of Finance would set up an Inter-Ministerial to consider the following suggestions:

- Incentives and tax benefits offered earlier by the Government on authentic R & D investments and expenditure be reintroduced (e.g. 100 to 133 per cent tax exemption under section 35 (1) (c) of the Income Tax Act).
- All Government approved & recognised laboratories be treated at par with Universities/National Research Centres for the purpose of exemption from customs duty on imports of capital equipment, chemicals and necessary spares. Alternatively, the duty shall be reduced significantly to say 25% and valorem.

- New drugs discovered and produced indigenously be exempted from excise duty.

- For basic manufacturers, the basic imported materials should attract lower customs duty as compared to finished or semi-finished products.

- A scheme of soft loans be evolved by the Government Financial Institutions for capital expenditure for setting up R & D facilities and for running them, as well as for setting up hi-tech manufacturing units based on indigenous development.

(d) The required procedures and steps for quick evaluation and clearance of new drug applications especially those developed through indigenous R & D would be streamlined.
QUALITY CONTROL AND RATIONAL USE OF DRUGS

14. Drug Control Administration at the Central level and in the states would be strengthened expeditiously. Various aspects relating to Rational Use of Drugs and Quality Control of Drugs would be actively pursued and the machinery for carrying out these tasks would be adequately strengthened.

REVIEW OF PRICING ASPECTS

15. 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;

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

The above objectives are relevant even today.

16. In pursuance to the provisions of Drug Policy, 1986,
the Drugs (Price Control) Order, 1979 was replaced by a new order called Drugs (Price Control) Order, 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 & Petrochemicals in consultation with Ministry of Health.

**Drugs under category** - II i.e. other essential drugs were identified by an Expert Committee (Kelkar committee) from a basket 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.

On the above basis, presently there are 143 drugs under price control. At present, 72 percent of the turnover of the organised sector is covered under price control.

17. However, subsequently there were numerous representations from the Members of Parliament as well as from Industry in regard to exclusion/inclusion of drugs and their categorisation under price control. There was also the
paradox of the relatively more important drugs required for the National Health Programme, being given lesser MAPE which acts as a disincentive for manufacture of these drugs. This gave rise to the possibility of shifting of manufacturing activity from these essential drugs to those getting higher MAPE (including even the decontrolled category).

18. The Government constituted a Standing Committee on February 5, 1990 to consider all matters connected with review of Drugs (Prices Control) Order 1987 and the representations made on various policy issues concerning DPCO 1987, including inclusion/exclusion of drugs in the scheduled categories.

[The Standing Committee under the Chairmanship of Secretary (Chemicals & Petrochemicals) had secretary (Biotechnology), Additional Secretary (Health), Director General (Health Services), Member (Finance) BICP, Deputy Director General, Technical Development (Chemicals), Adviser CSIR, Director IICT-Hyderabad, Director CDRI-Lucknow as members. Department of Chemicals & Petrochemicals was represented by Joint Secretary (Pharmaceutical Industry) and Adviser (Chemicals) as members, and Director (Pharmaceutical Industry) as Member/Convener].
The Committee was assisted by three Expert Groups namely (i) on therapeutic Issues, (ii) on Technology Issues and (iii) on Production & Turnover Issues. Experts from related fields were members of these Groups.

19. Also to assess the situation in realistic terms, discussions were held with various interest groups like Consumer Associations, Indian Medical Association, Voluntary Health Organisation, Trade and Industry at the Ministerial levels. The views expressed were further debated in inter-ministerial meetings also.

20. The Standing Committee had 8 sittings. It considered all the issues as analysed by three Expert Groups and also the outcome of dialogue with various interest groups. The findings were further considered by the Committee of Secretaries. Prime Minister directed that the issues regarding pricing and availability of essential medicines at reasonable prices be further looked into by a Committee under the Chairmanship of Secretary (C&PC) including Secretary (Economic Affairs), Secretary (Health), Director General (Health Services), Director, CDRI, Lucknow and Chairman BICP.

21. In the meanwhile the subject matter was also deliberated upon in the two meetings of the Consultative Committee held on May 11, 1992 and July 1, 1992. There was broad
consensus that the policy framework should ensure adequate availability of quality medicines and at the same time prices of the commonly used medicines should be kept at reasonable level.

22. Deliberations in various meetings highlighted the following points:

(a) It is not administratively feasible to put all the drugs under price control to operate the system effectively and, therefore, a degree of selectivity has to be exercised.

(b) Drugs is a highly sensitive matter. The matter has been debated in the Parliament and Press. The selection of drugs for price control has to be done by Experts on the basis of criteria which are transparent and non-controversial.

(c) From the consumers angle, the price of a drug is as important as its quality and its easy availability. Moreover, there is trade off between the prices and the quality of drugs as well as between prices and the availability of drugs.

(d) Pricing structure should be such that adequate incentives are given to the manufacturers to produce drugs
as per demand and also to make fresh investments.

(e) The span of control should be commensurate with the machinery available with the Government to implement the price controls. The system should be flexible enough to give adequate and timely price increases. This has become all the more important since the prices of inputs are increasing continuously and many of them are imported.

(f) The interest of common man should be kept as the focal point while deciding the changes in the policy. The policy framework should ensure adequate availability of quality medicines and reasonable price level of commonly used medicines.

Policy Options on Pricing Structure

23. On the above basis, possible options are outlined below:

(a) The anomalies due to listing of drugs under price control in two categories with different MAPE can be resolved by having a single category.

(b) The span of control could be determined and kept within reasonable limits by adopting suitable turnover limits across the board, including on drugs required for the
National Health Programmes. In case of drugs having monopoly situation, the turnover limit can be lowered to suitable limits to tackle the situation.

(c) The Kelkar Committee has given the criteria of exclusion based on market competition. It has been observed that drugs which are having mass consumption, being mostly prescribed for common diseases, qualify under this criteria for exclusion from price control. Market forces are expected to keep their prices under check. However, these can be kept under strict watch.

(d) There is need to streamline and simplify the procedures involved in price fixation/revision. Further, in order to simplify, the revision of prices of formulations could be made automatically permissible on annual basis if the increase is upto a fixed percentage of the annual increase in the Wholesale Price Index (all commodities), say 70 per cent and the formulator need not to go through the cumbersome procedure of price revision. In case of a bulk drug, the detailed cost-cum-technical study could be done away with if the annual increase, sought by manufacturers accounting at least for more than two-third production of that drug, is upto a fixed percentage of the annual increase in the WPI (all commodities), say 70 per cent. This could be decided
by a high level Committee on case to case basis.

(e) The apprehension that reduction in span of control would lead to spurt in prices of drugs needs to be seen in the background of declining profitability of drug companies, the growing demands of the medicines and the need of further investment. As against the present demand of Rs.4,300 crores, the demand by 2000 AD is estimated to be Rs.15,000 crores (at 1979-80 prices). Price level of commonly used medicines could be regulated by fixing ceiling prices and making it obligatory for all.

**Modifications being Considered**

24. Keeping in view the above, the following modifications in the existing pricing system are being considered:

(a) Single list of price control drugs with Maximum Allowable Post-manufacturing Expenses (MAPE) of 100 per cent.

(b) For selecting drugs for price control, a criteria based on certain minimum Turnover. It could be Rs.3 crores or more or less.

(c) Drugs with even a lesser turnover than the minimum prescribed above and in whose cases there is monopoly situation could also be kept under price control.
(d) Drugs having adequate market competition could be kept out of price control.

(e) To fix ceiling prices for commonly marketed standard pack sizes and make it obligatory for all including small scale units to follow the prices so fixed.

(f) In order to tackle the possible abrupt increase in prices of formulations based on drugs getting decontrolled and possible undue increase in prices of leading brands of formulations enjoying high turnover, the Government may fix a maximum permissible increase as percentage of existing price and keep a strict watch on the situation.

(g) Streamlining and simplifying the procedures involved in price revision of formulations and bulk drugs.

(h) Incentive for basic manufacture by allowing rate of return higher by 4 per cent.

CO-ORDINATION BETWEEN MINISTRIES FOR IMPLEMENTATION OF THE DRUG POLICY

25. A Coordination Committee for monitoring the areas of key concern in implementation of the Drug policy and for taking effective and timely action is proposed to be set up. The Committee will consist of representatives of the Minis-
tries of Commerce, Finance Health, Departments of Biotechnology and Industrial Development and BICP under the Chairmanship of Secretary (C&PC).

CONCLUSIONS

26. Changes are being considered in the Drug Policy, 1986 in regard to licensing, pricing mechanism, R & D etc. The above note gives a background of the issues involved and outline of the changes has been indicated in the paragraphs mentioned below for ready reference:

Para 9       -- Industrial Licensing
Para 10      -- Foreign Investment and Technologies
Para 11      -- Reservation of Items for Public Sector
Para 12      -- Other Related Issues
Para 13      -- Research & Development
Para 24      -- Pricing Mechanism

The modifications being considered are placed for consideration of the Hon'ble Members and their views/suggestions are invited so that the Government could take final decision on all these issues.