Measures for Rationalisation, Quality Control and Growth of Drugs & Pharmaceutical Industry In India.

Introductory

1.1 Health is a fundamental human right. The Constitution of India directs the State to regard the improvement of public health as among its primary duties. The Five Year Plants have been providing the framework within which the Centre and States have developed their health services infrastructure and programmes. Since the attainment of Independence considerable progress has been achieved in the promotion of health status of the people – as reflected in the eradication/control of diseases like small-pox, malaria etc., reduction in mortality rate, rise in life expectancy, creation of a fairly extensive network of health care institutions and the availability of a large stocks of medical and health personnel.

1.2 The National Health Policy of 1983 marks a significant step in the national endeavour to improve public health. It reiterates India's commitment to the goal of "Health for all by the year 2000 A.D." through the universal provision of comprehensive primary health care service. The attainment of this goal requires an accelerated development of all inputs to the health care system, including essential and life saving drugs and vaccines of proven quality. Drugs alone are not sufficient to provide health care. However, if rationally used, they do play an important role in protecting, maintaining and restoring the health of the people and in controlling population. The Indian Pharmaceutical Industry has, therefore, a vital role in serving the basic health needs of the people.

1.3 The Report of the Hathi Committee (1975) is an important landmark in the development of the Indian Pharmaceutical Industry. The Hathi Committee emphasized the achievement of self-sufficiency in medicines and of abundant availability at reasonable prices of essential medicines. Since 1975, the Indian Pharmaceutical Industry has grown to be the most diversified and vertically integrated pharmaceutical industry in the entire Third World. The country has achieved self-sufficiency in formulations and also in a large number of bulk drugs. In 1984-85, imports of formulations were only Rs.10.17 crores or about 0.5% of the total formulation production in the country and imports of 49 bulk drugs were negligible. Technologies for the production of several bulk drugs, including antibiotics like Ampicillin, Amoxycillin, Erythromycin, Anti-infectives like Sulphamethaxazole and Trimethoprim., anti-TB drugs like Ethambuto Cardio Vascular drugs like Methyl Dopa; Analgesics like Ibuprofen and Isopropyl antipyrine; anti – amoebics like Metronidazole and Tinidazole, anti-cancer drugs like Vinblastine, Vincristire and Cisplatin were indigenously developed. The trade balance in pharmaceuticals is also improving as a result of increasing exports. In 1984-85, exports of drugs and formulations were Rs.217.49 crores while imports were Rs.215.62 crores. A wide range of bulk drugs and formulations are being exported to several countries, including the U.S. and the West European countries. Some Indian firms have also set up production facilities in other countries and are also engaged in the sale of turnkey plants and technical services. The diverse production and technological capabilities developed by the Indian Pharmaceutical Industry are valuable assets in achieving the goals of the National Health Policy and in fully harnessing the export potential.

1.4 While these achievements are impressive by themselves, there are many areas where the industry has to reorient itself if it has to effectively serve the health needs of the people. The present production pattern does not adequately reflect the genuine requirements of the health care needs of the country. The proliferation of formulations and packs without adequate

therapeutic rationale is a matter of concern. While many firms in the organized as well as small scale sector have excellent internal testing facilities and a good record of quality control and adoption of good manufacturing practices, the same cannot be said of a large number of firms manufacturing formulations. The present institutional and statutory arrangements for enforcing quality control for registration of new formulations, for monitoring adverse reactions and for dissemination of unbiased information about the safety and efficacy of products marketed in the country are far from being adequate.

1.5 Abundant availability on a continuous basis, at reasonable prices, of essential, life saving and prophylactic medicines of good quality, is the corner stone of the new measures. It shall be the endeavour of the Government to ensure that the above objective, which is in consonance with the Government's Policy of reaching Healthcare facilities to the common masses and with that of ensuring Health for all by the year 2000 A.D., is achieved. In order to subserve this objective, changes have been brought about in the system of price control of drugs as well as in the licensing and approval procedures. Experience gained in the implementation of the Drugs (Prices Control) Order, 1979 has clearly shown that the pricing system needs to be simplified and rationalized, if the benefits of the price control are to be effectively realised by the consumer, particularly the weaker sections of the society for safeguarding whose interests the Government is committed. The span of price control at present is impracticably large covering 347 bulk drugs and over 4,000 formulations marketed in about 20,000 packs. It is proposed to reduce to a considerable extent this span of control and to make the price control system less cumbersome but more effective.

1.6 As prices of drugs are also determined by the cost effectiveness of domestic production, it is imperative to impart a technological and productivity thrust to the Indian Pharmaceutical Industry which would also enable it to harness export opportunities. The objective of ensuring abundant availability of medicines at reasonable prices, will be best served by promoting competition and economic scales of production and also by removing unnecessary barriers to growth. To this end, licensing and approval procedures have been simplified and greater flexibility given in order to those of essential and life saving drugs. The validity of this premise has already been established by the experience, in recent years, with the market prices of bulk is produced by a good number of manufacturers. At the same time, FERA companies will continue to be regulated by Government to ensure that their operations are in consonance with the national objectives and priorities.

1.7 It is against this backdrop that the Government has reviewed the functioning of the Drug Policy and now restructured the Policy in the light of the experience gained and keeping in mind the objective of achieving "Health for All by the Year 2000 A.D."

Part II - Objectives

The new measures aim at :

ensuring abundant availability, at reasonable prices, of essential life saving and prophylactic medicines of good quality;
strengthening the system of quality control over drug production and promoting the rational use of drugs in the country;
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 strengthening the indigenous capability for production of dr.

Part III - Rational Use of Drugs

3.1 Registration of new formulations, rationalization of existing formulations and creation of a National Drug Authority.
New formulations based on drugs already approved for use in the country would not be allowed to be manufactured unless their therapeutic efficacy and rationality are adequately tested and proved. A machinery to be called the National Drug & Pharmaceutical Authority would be established at the Central level, with a permanent secretariat.

3.2 Registration of new drugs
With a view to exercise closer scrutiny over the introduction of new drugs in the country, the Drugs and Cosmetic Rules will be amended to define clearly a new drug and to give statutory basis to the detailed guidelines which would be drawn up for the scrutiny and approval of new drugs.

3.3 Standardisation of packaging
With a view to ensuring the proper dispensing and use of drugs, statutory guidelines for packaging instructions would be laid down. Colour coding of packs would be insisted upon to differentiate products according to the degree of hazard. Packs would also be standardised.

3.4 Monitoring of adverse reaction
During the VII Five Year Plan, Central and peripheral units would be set up to monitor adverse drug reactions. It is also proposed to develop a Central Information Bank on the safety, efficacy, prescription and use of all drugs.

3.5 Use of generic name
Pending a final decision by the Supreme Court, permission is being granted for marketing single ingredient formulations of new drugs subject to the following conditions that the generic (Proper) name should be displayed in double the size of the trade (brand) name both in equally bold letters. Generic names will be progressively adopted in the case of all drugs included in the list of essential drugs.

3.6 Apart from the allopathic system of medicine, it is also proposed to encourage and improve upon the traditional system of medicine with a view to widening the coverage of health care schemes of the government. It is a recognized fact that large portions of our population, specially those in the rural areas, prefer to use the traditional Indian system of medicine, both for reasons of faith as also lack of access to the modern medicines; Ayurveda, Unani and Siddha systems of medicines have been practised in this country for several centuries. However, there is no uniformity in the methods of preparation of the Compound drugs in use in these systems, identification of ingredients and their composition. In order to bring about some uniformity and standardisation, Ayurvedic, Siddha and Unani Pharmacopoeial Committee constituted by the Government of India are bringing out "National Formularies". The Formularies indicate the ingredients with their scientific names, the proportions in which these drugs are used and the method of preparation. This is the first phase for the standardisation work before finalising pharmacopoeial standards. The Pharmacopoeial Committees have now simultaneously taken up the work of evolving of standards in respect of single ingredient drugs used in these systems.

3.7 It is proposed to speedily evolve pharmacopoeial standards in respect of the drugs in these systems and also to enlarge and reactivate drugs testing facilities in each State in order to ensure quality control. It is also proposed to take steps for ensuring steady and regular availability of

raw material for the growing pharmaceutical industry in the Indian systems of medicine both to meet internal as well as export demands.

Part IV-Quality Control

4.1 Strengthening infrastructural facilities
It is decided to step up the Central and State infrastructural facilities for quality control in a phased manner during the VII and VIII Five Year Plan periods. The progress made in the provision of these infrastructural facilities and the effect on enforcing quality control would be reviewed at the end of the VII Five Year Plan with a view to make the necessary corrections and to strengthen the machinery for ensuring quality control.

4.2 Internal Testing Facilities
During the VII Five Year Plan period, it will be ensured, through intensive inspection and corrective action, that all manufacturers have internal testing facilities.

4.3 Good Manufacturing Practices
Statutory effect would soon be given to the good manufacturing practices which lay down the minimum requirements to be observed in terms of accommodation, equipment, qualified personnel, testing facilities and hygiene in a manufacturing unit.

4.4 Loan Licensing
It is decided to discontinue the loan licensing system in a phased manner before the end of the VII Five Year Plan.

4.5 Certification Scheme
With a view to promote quality-consciousness in the field of drugs both among the manufacturers and user-agencies and to simultaneously reduce the workload on the statutory Drug Controller Agencies, efforts will be made to introduce a certification system under which recognized institutions with proven expertise and testing facilities can certify the adoption by formulators of good manufacturing practices and the quality of formulations manufactured.

Part V - Pricing

5.1 Basic Approach
The Hathi Committee was of the view that more selectivity in the system of price regulation with a view to ensuring fair prices of drugs and formulations would be desirable. In the case of formulations (other than generic), selectivity could be in terms of (a) size of the units; (b) selection of items, and (c) controlling the prices only of market leaders, in particular, of products for which price control is contemplated. An appropriate combination of these criteria is also feasible. The new pricing regulation - would be in conformity with the principle of selectivity commended by the Hathi Committee.

5.2 Coverage
It is decided to rationalize the present categorization of bulk drugs and formulations keeping in view the following objectives:

To stimulate production of drugs and formulations which are essential to the needs of large majority of the people of the country;
To make the price control system less cumbersome but more effective, by reducing the span of

control;
To ensure a reasonable return to the producers of essential drugs, while at the same time restricting undue increase in their price.
Keeping this objective in view, it is now decided to have 2 categories of formulations and bulk drugs required in place of 3 categories which exist at present. Category 1 would consist of drugs required for the National Health Programme and the MAPE (maximum allowable post manufacturing expense incurred from the stage of manufacturing to retailing and manufacturers' margin) allowed for drugs in this category would be 75%; category II would consist of drugs other than those in category I but which are also considered essential for the health needs and a MAPE of 100% for formulations would be allowed while fixing the prices for this category of drugs.

The list of drugs in Category II on the basis of these guidelines would be drawn up within 3 months, by a committee consisting of representatives of Department of Chemicals & Petro-chemicals, Ministry of Health, Bureau of Industrial Costs and Prices and some State Governments. Till such time as this is finalized the existing Drug Price Control Order will continue to be in operation. In the proposed Drugs (Price Control) Order which would be announced after the list of drugs in each category is finalized, there would be a stipulation to the effect that Government will have the right to bring within the ambit to control any drug in the de-controlled category at any point of time should it be considered necessary to do so.

With a view to encourage production of drugs which are more essential to the needs of the country, incentives, other than the MAPE, would also be considered. Government would at the same time strictly monitor the prices of drugs of de-controlled category and for this purpose an effective monitoring mechanism shall be developed.

5.3 Norms of Pricing
It is decided to have a uniform norm for all bulk drugs falling in the controlled category I and II and the manufacturers will be given the following three options

14% post tax return on net worth; or
22% return on capital employed; or
Long term marginal costing with 12% internal rate of return in the case of new plants.
The maximum retail price of domestically produced items excluding excise duty and local taxes, if any, would not be higher than ex-factory cost by more than 75% in the case of category 1 formulations and by more than 100% in the case of category II formulations. This is to say, MAPE would be 75% and 100% respectively for category I and II formulations, of the ex-factory cost.

In respect of imported formulations, selling and distribution expenses, including interest and importers' margin, shall not exceed 50% of the landed cost.

5.4 Drug Price Equalization Account (DPEA)
The DPEA was set up essentially to encourage domestic production of bulk drugs through a system of retention pricing. However, in actual practice the operation of DPEA is giving rise to intractable administrative problems, with anticipated accruals to the DPEA being thwarted by disputes and claims on the DPEA put forth promptly. It is, therefore, decided to discontinue the system of retention and pooled pricing. Protection for indigenous production of bulk drugs, wherever necessary, would be provided through the tariff mechanism. However, provision would be made in the new Drug Price Control Order to ensure that amounts which have already

accrued to the DPEA and those which are likely to accrue as a result of action in the past, are protected and used for the purpose stipulated in the existing DPCO.

Part VI - Licensing

6.1 FERA Companies

The business operations of FERA companies would have to be in accord with national objectives and priorities. FERA companies would be eligible for entry mainly in those areas where the entry is desirable from the objectives of better health care. The list of bulk drugs open to all sectors has been revised accordingly. FERA companies would be eligible for licenses mainly in respect of these bulk drugs, subject to a phased manufacturing programme, and related formulations in order to encourage higher bulk drug production, the ratio between the value of production of bulk drugs to that of formulations (hereinafter referred to as ratio parameter) would be reduced from 1:5 to 1:4 for FERA companies. The definition of "drugs and pharmaceuticals" listed at Entry 14 of Appendix I of the Industrial Licensing Policy, would now read as in Annexure I.

6.2 Companies other than FERA Companies

These companies would continue to be eligible for industrial approvals in respect of all bulk drugs which are approved for use in the country and related formulations, subject to sectoral reservations for public and small scale sectors.

6.3 Role of Public Sector

Public Sector will continue to have an important role particularly in the production of basic bulk drugs which are central to the needs of the National Health Programme. However, the Government recognize the fact that the public sector units will have to function at optimum levels of efficiency, in production as well as marketing, in order to fulfill the role that has been assigned to them in the new policy, namely, that of making available essential bulk drugs at reasonable prices. Keeping in view the crucial role of the public sector in achieving the objectives of National Health Programme, indepth exercises have already been initiated to prepare an action plan of steps to improve performance of each of the public sector units.

Rehabilitation and restructuring plans for these public sector undertakings are expected to be finalized very shortly. These plans shall include changing management cultures and values, improvement of management system; improvement in product strategy; internal generation of cash; savings in fixed costs; reduction in line wastage and batch rejection; improvement in technology; reduction in expenses on utilities; reduction in inventory levels; better and more sensitive marketing strategy; higher capacity utilization; better utilization of R&D facilities etc.

It is decided to continue, to a substantial extent, the present policy of reservation for manufacture by the public sector of certain important bulk drugs. At present 17 bulk drugs including Pencillins and Polio Vaccines are exclusively reserved for production by the public sector units. Considering the projections of requirement of Penicillins, it is decided to expand the capacity of Penicillin in the existing public sector units along with induction of more advanced technology. However, it is felt that even with these measures the public sector units will by themselves not be in a position to meet the entire requirements of the country of these two basic and essential drugs. The 1989-90 demand of Penicillin is estimated to be as high as 2470 mmu as against the

existing installed capacity of 637 mmu inclusive of 390 mmu in the public sector. Thus the present gap in the demand and production of this crucial drug would further widen by the end of 7th Plan period unless corrective steps are taken to narrow it. At present, in order to meet the requirements of this essential drug, imports are also resorted to which result in an outgo of foreign exchange to a substantial extent, this outgo being of the order of Rs. 24 crores in the year 1985-86. Similarly Polio vaccine which is an extremely important input in the immunization programme of the Government is yet to be produced in the country. A capacity of 10 million doses is being installed by M/s.Halfkine, a Maharashtra Government undertaking. However, the 1989-90 demand is estimated to be 80 million doses taking into account the requirement of the Expanded Immunization Programme. Keeping in view the large gap between the capacities created and the 1989-90 demand for Penicillin and Polio Vaccine, the need to reach self-sufficiency in these two vital products, it is decided to open these two products for production by all sectors. The demand for these essential drugs would continue to be met through imports also till such time as indigenous production has reached a level where imports become unnecessary. However 15 other bulk drugs which are presently reserved for the public sector would continue to be so reserved (Annexure - II).

6.4 DGTD Registration

DGTD registration would continue to be available to non-FERA and non-MRTP companies, in respect of proposals which satisfy the criteria for DGTD registration.

6.5 Delicensing

The scheme of de-licensing has already been extended to 94 bulk drugs including all anti-cancer drugs, all new bulk drugs developed through indigenous research, and related formulations as well as two drug intermediates. The scheme, would progressively be extended subject to the following criteria: bulk drugs whose imports are allowed on OGL. bulk drugs, whose production is limited to three producers or less in the organized sector.
bulk drugs whose formulations are of essential and mass consumption nature.
formulations and drug intermediates related to bulk drugs which are delicensed.
The scheme of delicensing would be available for non-FERA and non-MRTP companies only excepting for new drugs which would be cleared for use in the country and would not include bulk drugs reserved for public and small scale sector.

The capacities to be set up under the delicensing scheme will, however, conform to the economic scales of production.

6.6 Encouragement of new drugs

Introduction in the country of formulations based on new bulk drugs require the approval of the Drug Controller (India). In order to establish the safety and efficacy of the new drugs proposed to be introduced detailed information has to be furnished. This information amongst others, should include toxicity data on animals, pharmacological studies and results of clinical trials in Indian conditions, which may extend over several years. Once a firm obtains the approval other firms are not required to obtain approval in respect of that drug again. In order to encourage introduction of new drugs in the country, all new bulk drugs and related formulations would be brought under the scheme of delicensing. If approval for the introduction of the new drug is based on the clinical trials conducted by a MRTP or FERA company, such a company can also

avail the scheme of delicensing in respect of such new bulk drug and related formulations. Exemption under Section 22A of the MRTP Act would also be available in such cases.

6.7 Phased Manufacturing Programme

To encourage cost-effective indigenisation and to ensure that bulk drug production does not remain confined to processing of later intermediates only, it has been decided to introduce system of a phased manufacturing programme (PMP). This will be applicable to all manufacturers and to all types of industrial approvals (licence, registration with the DGTD and registration under the Delicensing Scheme). Where the import content is 20%, or more of the value of production, import licenses for bulk drug manufacturers would be granted only in accordance with the approved PMP which would specify the indigenisation to be achieved annually as a percentage of the value of production. The viability of PMP would be examined in terms of the domestic resources cost of production; with a suitable shadow rate of foreign exchange. All companies manufacturing bulk drugs would be required to submit to the Department of Chemicals and Petro-chemicals their PMP proposals and the existing companies which import drug intermediates or other raw materials from their principals or their associated companies would be required to inform the Government of the details of such transactions within a month of such import.

6.8 Broadbanding

In order to provide greater manufacturing flexibility, broadbanding would be extended to the pharmaceutical industry, taking into account the technical factors like plant design, process and production facilities. To begin with 31 groups of bulk drugs (Annexure III) would be covered by broadbanding. Products, other than bulk drugs, would be broadbanded into the following categories:-

Formulations based on bulk drugs in Annexure IIISurgical ancillaries like sutures, catguts, bandages,
Seras and Vaccines.
Diagnostics of all types.
Allergins.
Transfusion solutions
The facility of broad banding would be available only in respect of products which are approved for use in the country by the Drug Controller (India). For domestic production, companies in the organized sector would be eligible for broad banding only in respect of items open to them.

The procedure to be followed for this is as laid down in the press note No.33 (1986 series) of the Department of Industrial Development dt.26.9.1986. The scheme of broad banding will also be subject to the conditions, laid therein.

6.9 Export Production
For export production, all companies would have total flexibility to produce any product with their existing facilities. They need only inform the government of the details of such production and export.

6.10 Revised Ratio Parameters
In order to encourage higher production of bulk drugs in the country, the ratio parameter between the ex-factory value of bulk drug production to that of formulation has been revised.

The ratio parameter would be related to the size of a company, which in turn has a relationship with its ability to invest in and develop/procure technology for production of bulk drugs. For FERA companies ratio parameter would now be 1:4. For other companies the ratio parameters would be related to the ex-factory value of production of bulk drugs and formulations as follows:

Ex-factory value of production of bulk drugs and formulations Ratio parameter
1. Upto Rs.10 crores 1:10
2. For production in excess of Rs. 10 crores and upto Rs. 25 crores. 1:7
3. For production in excess of Rs. 25 crores. 1:5
The following activities would continue to be excluded in computing the ratio parameters:

Drug Intermediates.
Empty hard gelating capsules
Surgical ancillaries
Seras and Vaccines
Diagnostics of all types
Allergins
Transfusion solutions
The companies in the organized sector are required to submit a production programme, including the production of new drugs, so that they can reach the new ratio parameters within a period of 3 years. As and when a company moved from one category to another, it would be allowed a period of 3 years to reach the new ratio parameter.

In order to encourage production of bulk drugs in the country the formulation turnover of all companies in the organized sector would continue to be based on a ratio of 2:1 between the value of consumption of indigenously produced bulk drugs and that of imported bulk drugs.

6.11 Supply of Bulk Drug to Non-Associated Formulators
FERA and MRTP companies would continue to supply 50% of the bulk drug production to non-associated formulators and other companies, including public sector, 30% of the bulk drug production to non-associated formulators.

6.12 R&D/Import of Know-how
R&D would gain an impetus from the various measures proposed in the policy such as the extension of delicensing to companies which conduct clinical trials and obtain the approval of the Drug Controller (India) for introduction of new drugs. However, wherever necessary, import of know-how would continue to be favourably considered on merits.

6.13 Regularization of production
A very large number of formulations are being produced ranging from one to two decades with industrial approvals which are being questioned. Majority of these drugs are claimed to be covered under registration certificates issued under Section 10 of the Industries (Development and Regulation) (IDR) Act. According to the practice then in vogue, these registration certificates did not mention individual items and capacities but merely permitted production of "drugs and pharmaceuticals". Another major category comprises of items claimed to be covered under notification issued in the 1960s and 1970s, under Section 298 of the IDR Act, announcing exemption from industrial licensing, subject to some conditions. However, COB licences could not be issued in many cases because of non-fulfilment of one or more of the conditions subject to which regard to the fact that the exemptions were granted. Having that the products have

infraction in most cases are technical and been accepted by the medical profession, Government have decided to regularise the production of all such formulations and surgical aids.

6.14 Re-endorsement of capacity
Government's industrial policies in regard to re-endorsement of capacity, and recognition of additional capacities as a result of replacement/modernization/ renovation of equipment, as announced from time to time, would be applicable to the pharmaceutical industry.

Part VII - Duty Rationalization

The measures in the areas of licensing and pricing policies would also be complemented by appropriate fiscal policy measures designed to progressively reduce import and excise duties to the minimum possible levels and to ensure that the cumulative incidence of duty on the bulk drugs is higher than that on the inputs and drug intermediates. Duty rationalization is intended to encourage cost efficient production of bulk drugs and of high quality formulations.

Part VIII - Co-Ordination Between Health and Industry Ministries

With a view to achieve better integration between the Health policies and the industrial policies in the Pharmaceutical sector, an inter-ministerial Standing Committee would be constituted in the Ministry of Industry Department of Chemicals and Petrochemicals with Secretary, Ministry of Health and officials of the other Departments and agencies concerned as members. In the first instance, the Committee would oversee the implementation of the new measures and other related decisions such as revision of the National Formulary, strengthening of the institutional and statutory arrangements for enforcing quality control, dissemination of information regarding safety and efficacy of drugs to medical and paramedical personnel, centralization of drug registration, rationalization of formulations and monitoring of adverse reactions.

Part IX - Review

The implementation and parameters of these measures would be reviewed at the end of the 7th Five Year Plan. Appraisal at short intervals will also be made to ascertain the progress of implementation and the trends emerging from time to time.

Annexure I(Refer to Paragraph 6.1)

Industry Policy-Government Decision
Press Note dated 2nd Dec., 1973.

Drugs & Pharmaceuticals - For FERA Drug Companies

Following bulk drugs subject to a phased manufacture programme, and formulations based thereon with an overall ratio of bulk drug consumption (from own manufacture) to formulations from all sources of 1:4.

1. Streptomycin
2. Tetracycline
3. Oxytetracycline
4. Gentamycin
5. Sulphaguanidine

6. Sulphadimidine
7. Sulphamethoxy-pyridazine
8. Sulphadimethoxine
9. Vitamin B1
10. Vitamin B2
11. Folic Acid
12. Quinine
13. Analgin
14. Phenobarbitone
15. Morphine

Any new drug for which the company conducted clinical trials and obtained Drug Controller's approval.
Polio Vaccine
Measles Vaccine
For non-FERA MRTP companies the existing definition would continue i.e. all bulk drugs and formulations subject to the ratio parameters applicable on the basis of turnover and subject to reservation for the public and small scale sectors.

Annexure - II (Refer to Paragraph 6.3)

List of Bulk Drugs Reserved for Public Sector

1. Streptomycin
2. Tetracycline
3. Oxytetracycline
4. Gentamycin
5. Sulphaguanidine
6. Sulphadimidine
7. Sulphamethoxy-pyridazine
8. Sulphadimethoxine
9. Vitamin B1
10. Vitamin B2
11. Folic Acid
12. Quinine
13. Analgin
14. Phenobarbitone
15. Morphine

N.B. Bulk drugs would include salts, esters and derivatives, if any.

Annexure - III (Refer to Paragraph 6.8)

Group of Bulk Drugs Covered by Broad-Ranging Groups

1. All types of Penicillins
2. Erythromycin, Griseofulvin, Rifampicin
3. Chloramphenicol and its intermediates namely L-Base.
4. 6-APA and 7-ADCA from Potassium Pencillin G
5. Semi-synthetic Penicillins like Ampicillin, Amoxicillin etc.

6. All types of Cephalsporins
7. Sulpha Drugs other than those reserved for Public Sector
8. Steroids & Hormones including the following Prednisolone, Prednisone, Hydrocortisone, Beta-methasone, Ethinyl Oestradiol, Norethisterone, Norgestrel, Testosterone, Progesterons etc.
9. Theophylline, Aminophylline, Hydroxyethyl-Theophylline -Xanthinol Nicotinate and Synthetic Caffeine
10. All Barbiturates other than Phenobabarbitone
11. Analgin , Isopropylantipyrine
12. Chlorpromazine, Prochloroperazine, Promethazine, Trifluoperazine, Triflupromazine
13. Chloroquine, Amodiaquine
14. Oxphenbutazone, Phenylbutazone
15. Diphenydramine, Bromodiphenhydramine
16. Hydrocholorothiazide, Cyclopentazide
17. Chlorophenesin Mephenesin
18. Xylocaine, Procaine, Benzocaine, Prilocaine
19. Metronidazole
    Tinidazole
20. Tobutamide
    Chlorpramamide
21. Acetazolamide
    Thiacetazone
22. Diazepam, Chlordiazepoxide, Oxazepam, Nitrazepam, Lorazepam
23. Pheniramide, Chlorpheniramine
24. Ibuprofen, Ketoprofen, Flurbiprofen, Naproxen
25. Salbutamol, Terbutaline
26. Furazolidine, Nitrofuratoin, Nitrofurazon, Furaltadone
27. Chlorcyclizine, Cyclizine, Meclozine, Buclizine, Diethyl Carbam Zine Citrate
28. Propranolol, Atenolol, Metroprolol, Oxprerolol, Pindolol
29. Mebendazole, Thiabendazole, Benbendazole
30. Drugs obtained by extraction from plant material such as Belladonna, Hyocymine, Sennosides, Digoxin, Ammalicine, Pesperpine, Vincristine, Vinblastine, Quinine, Quinidine, Emetine, Strychnine, Brucine etc.
31. Drugs of animal origin other than Insulin, such as Liver extract, Heparin, Pancreatin, Immunoglobulin etc.

N.B. - Bulk drugs would include salts, esters and derivatives if any.