Report of the
Expert Committee for Drugs
ON
THE NATIONAL DRUG POLICY OF BANGLADESH
1982

Government of the Peoples' Republic of Bangladesh
Directorate of Drug Administration
Ministry of Health & Population Control
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INTRODUCTION

The per capita consumption of modern drugs in Bangladesh is about US $ 1.00 per year and this is one of the lowest in the world. Millions of our people have little access to the most essential life-saving drugs, and yet before 1982, a large number of wasteful and undesirable medicinal products were manufactured and marketed, mostly under commercial pressure. The market at that time was flooded with various assortment of tonics, vitamin mixtures, cough and cold remedies and many other undesirable combination products, while essential drugs needed for primary and secondary levels of health care were in short supply. In view of the scarce resources and the urgent need to implement health programmes, it was necessary to formulate a new drug policy as part of the national health policy.

Soon after the promulgation of Martial Law in March 1982, the Chief Martial Law Administrator (CMLA) asked to introduce a new national drug policy designed to give priority to the production of selected essential drugs, and to remove from the market all harmful, useless and undesirable products. The Government appointed an eight-membered Expert Committee for drafting the new national drug policy and to re evaluate all the 4,340 drugs licensed at that time for sale in the country, bearing in mind the country's priority health needs.

The Expert Committee working day and night did a very commendable job, and submitted its Report to me on 11 May 1982. Part of this Report (excluding the list of drugs to be banned) is published in this booklet. The list of banned drugs was published earlier in Drug Administration Publication No. 1. Acting on these recommendations of the Expert Committee, Lt. General H. M. Ershad, the Chief Martial Law Administrator, approved and enacted the Drugs (Control) Ordinance, 1982 (Ord. No. VIII of 1982) on 12 June 1982 as a first step in implementing the new national drug policy. Under this Ordinance, the registration of 1656 harmful, unnecessary or otherwise undesirable drugs was cancelled or suspended, and these products were gradually withdrawn from the market in phases. At the same time, the Government adopted the draft national drug policy recommended by the Expert Committee as the new National Drug policy for Bangladesh.

The Expert Committee identified 16 guidelines for the evaluation of medicinal products and for assessing which products should be withdrawn or reformulated. These guidelines have been described as "admirable" and based on "sound therapeutics" by most experts in Bangladesh and abroad. Our Drug Administration follows these guidelines for continuous evaluation and monitoring of all new and existing drugs for the purpose of registration and licensing.

The new policy has helped to increase local production of drugs. Whereas the value of locally produced drugs was only Tk. 175 Crore in 1981, this has reached the level of Tk. 325 Crore in 1985. The local industry has by now adjusted itself with the new policy. The production capacities affected due to banning of some products have been more than compensated by the increased volume of production of essential drugs. This was exactly the underlying objective of withdrawing the fancy and useless products in the first instance. Whereas the share of 45 essential drugs for primary health care in local production was only 30 percent in 1981, this has now increased to 65 percent in 1985. Many raw materials which were imported

earlier at exorbitant prices are now being imported at competitive prices, and this has helped to reduce prices and to keep them more stable. Unani, Ayurvedic and Homoeopathic drugs were brought under the control of current drug legislations as a consequence of the new drug policy, and this has made their further development and modernization possible.

The new drug policy has already yielded good results. With the full implementation of the new National Drug policy, the supply position of essential drugs in the country will improve further in the coming years. However, we have still to go a long way to fulfil our national objective of ensuring availability of good quality essential drugs for all who need them at the various levels of the health care system at the most reasonable prices.

Sd/-

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Minister for Health & Population control,
Government of the people's
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Dated, Dhaka.
10 March 1986

DRUG SITUATION BEFORE THE DRUG POLICY OF 1982

In 1981, the people of Bangladesh spent an estimated amount of 150 crore taka on allopathic drugs of various kinds comprising about 3,500 brands. Nearly one third of this money was spent on unnecessary and useless medicines such as vitamin mixtures, tonics, alkalisers, cough mixtures, digestive enzymes, palliatives, gripe water, and hundreds of other similar products. Whereas, of the 182 drugs which the Government earlier had selected to be essential, not more than 90 were locally manufactured. It is a responsibility of the Government to protect the consumers from being hood-winked into spending their scanty resources on useless, unnecessary and at times harmful drugs.

There were 166 licensed pharmaceutical manufacturers in the country but local production was dominated by eight multinational companies who manufactured about 70% of the products. There were 25 medium-sized national companies who manufactured another 15% of the products. The remaining 15% were produced by 133 small local companies who were capable of producing only simple liquid formulations.

All the pharmaceutical companies were mainly engaged in formulation. They procured their raw materials by import, involving an annual expenditure of taka 60 crores in foreign exchange.

Incomplete transfer of technology, restrictive business practices, and purchase of raw materials by the multinationals at inflated prices from tied sources were detrimental to our national economy. Though the multinationals have all the technologies and know-how to produce sophisticated essential drugs and basic pharmaceutical raw materials, in Bangladesh these companies were engaged mostly in formulation of simple drugs including many useless products such as vitamin mixtures, tonics, gripe water, etc.

In spite of the 166 local pharmaceutical industries, the country was still importing Taka 25 to 30 crore of finished drugs every year. There was a scope to reduce the number of importable items by deleting those which are not essential or the substitutes of which were locally manufactured.

Unani, ayurvedic and homoeopathic drugs were exempted from control under the then drug laws. Consequently, there was a proliferation of unethical, and harmful products of uncertain quality. Most highly misused products of this group were the alcohol containing tonics.

The Drugs Act 1940 which was the basic drug legislation, is outdated and grossly inadequate. The outdated legal procedure hindered rather than helped prompt prosecution and penalties. Much of the unethical practices in manufacture and trade was possible because of the weakness of the existing legislation. Further, the concept of drugs and medicines as an essential component of health care was missing. There was no provision in the drugs Act for the control of prices of pharmaceutical raw materials or finished products.

Maximum retail prices of finished drugs were fixed by the Ministry of Commerce under the essential Commodities Act and Orders. There was no agency for enforcement of prices at retail level; the prices of drugs fluctuated widely in the market according to demand and supply. Further, there was no control over the prices of pharmaceutical raw and packaging material which contribute more than 60% of the prices at trade level. The same materials were imported from different sources by different manufacturers at widely variable prices ranging up to four times.

In the then drug laws, there was no proivison for regulating technology transfer and/or licensing agreement with foreign collaborators. Similarly there was neither provision for protection of consumers against drug hazards nor there was protection of national interest in respect of patent rights of pharmaceutical substances.

Recognising the right of every citizen to enjoy the highest possible level of health care, there was an urgent need to mobilise and make economic and effective use of all available resources for improving the state of health of our people. Drugs being most essential tools for health care, these cannot be treated just as any other commercial product. In 1981, not more than 20% of the population had access even to the most essential drugs for their health needs and yet the market was flooded with hundreds of useless or non-essential medicinal products.

The problem of increasing costs of expenditure on drugs & medicines has become a crucial issue both for the public health and the private sectors. It was, therefore, needed to take urgent steps to build up an economical and efficient drug supply system to meet the priority health needs of the country and to reduce unnecessary wastage on useless or non-essential drugs and medicines.

Drug Administration under the Ministry of Health is the main agency for administration and enforcement of drug legislation. It has only 32 officers of which 20 serve as inspectors. This number is grossly inadequate. There are two government drug testing laboratoties, one in Dhaka and the other in Chittagong. The combined load of these laboratories exceed 5000 samples per year. The staff and equipment of these laboratories are grossly inadequate. In the country there are about 14,000 retail pharmacies and another 1200 wholesalers. The Government utilizes only 10% of the total available drugs; the remaining 90% is utilized by the private sector.

NATIONAL DRUG POLICY OF 1982

1. Need for a National Drug Policy :

The problem in respect of drug supply are multi-sectoral and complex. That there is a need for large quantity of essential, efficacious and economic drugs for both the public and private sectors cannot be disputed. In fact, if the essential drugs are not readily available at reasonable cost, the national objective of health for all by the year 2000 cannot be achieved. In the context of our scarce resources and urgency of implementation of health programme, it is all the more important that a national drug policy be formulated as a part of national health policy. This policy should ensure procurement, local production, quality conrol, distribution and utilization of drugs under unified legislative and administrative control. Only on the basis of such a policy can effective measures be taken to provide widest coverage with the most relevant essential drugs at the minimum cost.

2. Objective :

The objectives of the national drug policy are :-

2.1 to provide administrative and ligislative support for ensuring quality and availability of essential drugs which are of relevance to the health needs of the majority of the population,

2.2 to reduce the prices of drugs and medicines and to ensure procurement of raw materials at the most compatitive prices

2.3 to eliminate useless, non-essential and harmful drugs from the market.

2.4 to promote local production of finished drugs as well as of basic pharmaceutical raw and packaging materials in the country.

2.5 to ensure co-ordination among various administrative branches of the Government in respect of drug control and drug supply system.

2.6 to develop drug monitoring and information system to prevent wasteful misuse of drug to ensure their proper utilization.

2.7 to promote scientific development and application of unani, ayurvedic and homoeopathic medicines and to ensure their standardization and quality by bringing these under the purview of drug lesiglation.

2.8 to improve the standard of hospital pharmacies and private retail pharmacies by improving the facilities for education and training of professional pharmacists.

2.9 to ensure GMP and each manufacturing company employing qualified pharmacists.

ACTION REQUIRED

To achieve the odjective of national drug policy and to provide guidelines for the formulation of programme the following actions are to be taken :

3. Selection and provision of essential drugs :

3.1 The major strategy is to overcome constraint of limited resources for the optimum utilization. This also calls for the elimination of all unnecessary, useless drugs and drugs of doubtful efficacy from the market. A limited list of 150 essential drugs considered adequate for most therapeutic purposes shall be selected. Out of this about 45 essential drugs will be selected for the primary level of health care on the basis of priority health need, cost, safety, and suitability of treatment of common diseases and symptoms by up to Thana level health workers.

Besides, for the protection of the vast majority people in the rural areas from hazards of undue prescriptions and in an attempt to give them relief by basic health workers, it is essential to limit the essential drugs to 12 which are considered safe and adequate for common medical problems. The list of the essential drugs are appended herewith (Appendix-I).

Besides, there may be a list of another about 100 supplementary drugs needed for tertiary level of health care by specialists (Appendx-II). The various brands of drugs in the market shall be evaluated continuoisly on the basis of their usefulness, essentiality and as per guidelines and criteria developed for this purpose (Appendix-III) and cost-effectiveness in the light of up to date available information. In future, only products which are considered essential and relevant to health needs of the country and are consistent with this policy shall be licensed or rigistered. The selected essential drugs shall be given preferential treatment in terms of licensing, import authorization, duties and other financial benefits.

The selected 45 essential drugs for primary health care shall be allowad to be manufactured or sold only under their generic names. As soon as possible and not later than 1983, a National Formulary will be prepared and published, which shall include all the formulations that will be allowed for manufacture, import or sale in this country. Products such as liquid vitamin mixtures, multiple combinations of potent drugs, combination of antibiotics with other active drugs, alkali mixtures,

gripe waters, cough mixtures, tonics, balms, digestive enzyms preparations, habit-forming drugs, vapo orubs and other similar useless and non-essential products will be identified and their licensing/registration shall be cancelled so that such products are completely elimnated from Bangladesh.

DRUG ACT

3.2 The Drugs Act 1940 shall be revised or replaced by a new drug legislation incorporating provisions for—

i. a system of registration of all medicinal products including ayurvedic, unani and homeopathic medicines;

ii. enforcement of good manufacturing practices;

iii. full control of labelling and advertisement;

iv. control of prices of finished drugs and pharmaceutical raw materials;

v. prescription control of toxic, poisonous and habit forming drugs;

vi. summary trial for offences in special drug courts;

vii. heavy penalties including confiscation of equipment and properties for manufacture and or selling of spurious and sub-standard drugs;

viii. departmental adjudiciation for fine of up to taka 10,000/—;

ix. heavy penalty for possessing or selling of drugs stolen from government stores, hospitals and dispensaries;

x. regulation of technology transfer and licensing agreement with foreign collaborators;

xi. restriction of ownership of retail pharmacies to professional pharmacists only;

xii. control of manufacture and sale of unani, ayurvedic and homeopathic drugs;

xiii. the patent laws in respect of pharmaceutical substances shall be revised;

Product patent in respent of pharmaceutical substances shall not be allowed. Process patent may be allowed for a limited period of time if only the basic substance is manufactured within the country. The tariff structure in respect of pharmaceutical raw materials for selected essential drugs, quality control equipment and chemicals shall be revised. A drug technical advisory board consisting of representatives from pharmaceutical profession, industry, phamacy deptt. of the university, representations from the professional organisations and experts from tha profession shall be constituted to review from time to time for the implemantation of drug policy.

DRUG ADMINISTRATION

3.3 The Directoate of Drug Administration will be expanded and adequately staffed with experts in medical and pharmaceutical sciences. In view of the gross inadequacy of drug inspectors, all Thana Health Administrators shall be given special course of training and be empowered to act as drug inspectors for the purpose, so that they can take meaningful sanctions against whole salers, retailers and peddlers of drugs at thana level and below. All the government drug control laboratories should be brought under the control of Drug Administration. A properly staffed and equipped National Drug Control laboratory with appellate facilites will be set up as early as possible, not later than 1985. Besides its function in respect of drug control and administration, the National Drug control

Laboratory will devote itself to develop appropriate standards and specifications for unani and ayurvedic drugs. It will also help develop national formulations for unani and ayurvedic drugs.

The fees for licensing, registration and testing of drugs which are ridiculously low at present shall be enhanced. Licensing or registration fees for new products which are not included in the national list of essential drugs shall be very high (not less than taka 5000/-). The renewable fees of licensing, registration and testing shall be utilised for expansion and development of drug administration and drug testing laboratories. No manufacturer will be allowed to produce drugs without adequate quality control facilities. However, the small national drug manufacturers may be allowed to establish quality control laboratories on a collective basis.

14 Local Production

The existing capacities of local pharmaceutical industries, especially those owned by Bangladeshi nationals, shall be enhanced through liberal licensing for balancing and modernization and by increasing entitlement for the import of raw materials. Government facilities for the economic and efficient production of essential drugs for primary health care, intravenous fluid and vaccines shall be expanded. Multinational companies will not be allowed to manufacture simple products like common analgesics, vitamin, antacids, etc. Such products will be exclusively manufactured by local firms Local production of basic pharmaceuticals in bulk shall be promoted to attain self-reliance. To encourage such production, special benefits and protections will be provided to private investors. The public industrial sector shall also take appropriate measures for the local production of essential basic pharmaceuticals in bulk. including vital antibiotics.

15 Control of Prices

Government shall control the prices of finished drugs as well as those of pharmaceutical raw and packing materials and intermediates. Level prices will be fixed for the 45 essential drugs for primary health care and their corresponding raw materials. It will be ensured that all raw and packaging materials of acceptable quality are procured from international sources at competitive prices only. The retail prices of finished drugs will be fixed on the basis of costing and reasonable profitability. Undue overhead expenditure shall be prevented. A maximum of 100% mark up for fast moving items and 150% for slow moving items over cost of raw materials shall be allowed. In the case of injectable and sterile preparations, the mark-up may go up to 200%. No mark-up will be allowed on the cost of packaging materials. but actual cost on them will be added.

The agency responsible for drug control and administration shall be responsible for the control of pricing and their enforcement.

16 Distribution and Utilization

Retail sale of drugs and medicines shall be allowed only under the supervision of qualified pharmacists. As soon as possible, arrangement must be made to authorise the establishment of private retail pharmacies within the premises of every Government hospital up to the Thana Health Complex, where under the ownership (on lease) and management of qualified pharmacists, and under the supervision of hospital authorities, essential drugs will be made available for sale at fixed prices against prescriptions of qualified physicians.

3.7 Traditional Unani, Ayurvedic and Homeopathic systems of medicine have a long tradition in many countries including Bangladesh, These systems are now exempted from the drug laws. Consequently, unethical and not uncommonly harmful products proliferate and alcohol containing tonics are much abused.

Appropriate action requires to be taken for necessary training of their personnel, screening of the products and wherever possible, identification of their active ingredients, and standardisation.

A National Pharmacopoeia of Traditional Medicine should be prepared.

CONCLUSION

Drug Policy is inseperable from Health Policy. Both aim at offering optimum Health Care for maximum number of people if not the entire population.

Limited trained manpower and resources complicated by population explosion pose a serious challange for implementation of an effective health care programme.

The national drug policy therefore requires to be drawn in the light of prevailing circumstances in the country.

The one outlined here is based on these principles. It is hoped that the implementation of this policy with modification as and when necessary will serve the aim of the Government in offering Health Care FOR ALL.

ANNEXURE—I

LIST OF 150 ESSENTIAL DRUGS

I. List of 12 Essential Drugs for use by the village level Health Workers.

1. Aspirin Tab,
2. Chloroquine phosphate tab/syrup.
3. Aluminium hydroxide gel tab./suspension,
4. Piperazine tab./elixir.
5. Glucose electrolyte powder ORS.
6. Phenoxy methyl penicillin (penicillin V) Tab/dry suspension.
7. Ampicillin cap/syp./(inj.)
8. Ergometrine/Methylergometrine maleate tablet and Inj.
9. Ferrous Sulphate Tab/Syrup.
10. Ephedrine tab./elixir.
11. Vitamin A 200,000 units cap ; 100,000 units inj.
12. Chloramphenicol eye/ear oint/drop.

II. List of Additional 33 Essential Drugs for primary health care upto the Thana Health Complex level.

13. Paracetamol tab /elixir
14. Pethidine hydrochloride Inj.
15. Sulphadoxin with pyrimethamine
16. Levamisole tab/elixir
17. Chlorpheniramine tab elixir/inj.
18. Lidocaine 1%
19. Isoniazid with thiacetazone tab
20. Streptomycin sulphate Inj.
21. Metronidazole tab/elixir/inj.
22. Atropine sulphate Inj.
23. Hyoscine butyl bromide tab./Inj.
24. Chlorhexidine/choloroxylenol sol n/ cream
25. Procaine Penicillin Inj.
26. Tetracycline/oxytetracycline cap/inj./ ointment
27. Phenobarbitone tab/inj.
28. Diazepam tab/Inj.
29. Cholrpromazine tab./inj /syp.
30. I. V. Saline of various strenghts (0. 9%, 0. 25%, 0. 18%) with 4% dextrose./0. 9% saline without dextrose.
31. Dextrose in water (5%, 25%, 50%)
32. Redistilled water (pyrogen free) amps
33. Cholera fluid
34. Oxytocin/inj.
35. Furosemide tab./inj.
36. Prednisolone tab.
37. Propranolol tab./inj.
38. Aminophylline inj./tab.
39. Co-Trimaxazole tab /susp.
40. Homatropine drop.
41. DT/DPT/PLOIO/TT Vaccines
42. Diptheria anti-toxin
43. Tab. vit B Complex/multi vit. drops 15 ml.
44. Ung. salicylic Acid and Benzoic Acid
45. Benzyl Benzoate saponated

III. List of Additional 105 Essential Drugs for use upto tertiary level)

46. Indomethacin cap./suppository
47. Morphine sulphate Inj.
48. Allopurinol
49. Quinine tab/powder/inj.
50. Corticosteroid eye drop/oint.

51. Diethyl carbamazine tab/suspension
52. Chloramphenicol skin ointment
53. Mebendazole tab.
54. Promethazine tab /inj /syrup
55. Ether anaesthetic
56. Procaine hydrochloride
57. Suxamethonium
58. Thiopental sodium
59. Gallamine triethiodide
60. Tubocurarine
61. Halothane
62. Isoniazid tab.
63. Ethambutol tab.
64 Rifampicin
65. Dapsone tab.
66. Glibenclamide
67. Insulin preparations
68. Pilocarpine drop 1%. 2% 4%
69. Emetine Hydrochloride inj.
70. Naloxone hydrochloride
71. Sodium thiosulphate inj.
72. Trifluperazine
73. Pralidoxime tab/inj.
74. Sodium Antimony gluconate inj.
75. Tincture Iodine
76. Lysol/Cresol/Soap solution (surgical)
77. Benzyl penicillin inj.
78. Benzathine penicillin inj.
79. Erythromycin suspension/tab .
80. Gentaymycin inj/drops/ointment
81. Cloxacillin syrup/cap/inj.
82. Ethosuximide cap.
83. Phenytoin tab/cap/elixir
84. Amitryptyline/nortryptyline tab.
85. Haloperidol tab/cap.
86. Prochlorperazine tab./inj .
87. Potasium chloride inj./tab./syr.
88. Mannitol Solution
89. Dialysis fluid
90. Plasma substitute
91. Sodi-bi-carb. infusion 7.5% or 8.4%
92. Bendrofluazide
93. Acetazolamide
94. Spironolactone
95. Barium Sulphate (X-ray grade)
96. Iodipamide, 30%, 50%.
97. Iopanoic Acid/Iobenzamic Acid tab.
98. Acetrizoic Acid/Iodized Oil inj.
99. Sodium Diatrozoate
100. Iron-Dextran complex inj.
101. Folic Acid tab.
102. Hydrocortisone inj./ointment/cream
103. Dexamethasone inj/Tab.
104. Stilboestrol/Diethylstilboestrol
105. Levo thyroxin
106. Progesterone preparations
107. Neomarcazole
108. Digoxin tab./inj.
109. Diazoxide inj.
110. Methyl-Dopa tab.
111. Glyceryl Trinitrate sublingwal tab./oint.
112. Procainamide inj/cap.
113. Heparin inj.
114. Warfarin-Sodium
115. Tetracaine/Novosine
116. Metaraminol inj.
117. Senna tab.
118. Glycerin suppository
119. Sulphadimidin tab.
120. Ibuprofen
121. Sulphanilamide powder
122. Sulphadizine inj.
123. Adrenaline/Epinephrine inj.
124. Neo-stigmine tab/inj.
125. Salbutamol tab./elixir/inhaler/inj
126. ACD Blood pack/double bag/tripple bag
127. TABC

128. Anti-rabies vaccine
129. Polyvalent anti-venom
130. Tetanus anti-toxin (minimum 10-000 unit dose)
131. Diptheria anti toxin
132. Vitamin B_1 inj/tab.
133. Vitamin C. tab/inj.
135. Vitamin B_{12} inj.
135. Vitamin K tab/inj/vit K_3 inj.
136. Cyclophosphamide tab/inj.
137. 5 Fluoro-Uracil inj/Cap/ointment.
138. Methotrexate tab/inj.
139. Busulphan tab.
140. Vincristine inj.
141. Nitrogen mustard inj.
142. Doxorubicin
143. Chlorambucil
144. Fluorescein eye drop 1%
145. Clofazimine tab.
146. Calciferol
147. Grisofulvin
148. Pyrazinamide
149. Plaster of Paris
150 Zinc Oxide adhesive bandage

ANNEXURE– II

SUPPLIMENTARY LIST

(Specialised drugs) 100 items

1. Adriamycin
2. Thioguanine
3. Folinic acid-For use with Methotrexate
4. Mitomycin tablet/inj.
5. Procarbazine
6. Atropine eye drop/ointment 1%
7. Phenyleprine eye drop 10%
8. Tropicamide eye drop 1%
9. Proparacaine hydrochloride eye drop 0.5%
10. Methyl cellulose eye drop 0.35 and 1%
11. Idoxuridine eye drop
12. sulphacetamide eye drop 10%, 20% drop/6% oint.
13. Fluorescein 10%, 20% I.v. injection.
14. Neomycin-bacitracin-polymixin-B combined as well as separate.
15. Phenformin
16. Beclomethasone inhalant
17. Plasma factors
18. Human-gamma globulin/immunoglobin specific for certain illnesses.
19. Anti-D.immunoglobin
20. Intravenous alimentation nutrients; Intralipid; Aminosol
21. Atonolol
22. Sodium Valproate
23. Cocaine
24. Lignocaine 2% with adrenaline 1:200.000
25. Benzocaine tab.
26. BIPP Paste (Bismuih, Iodoform & Paraffin)
27. Neomycin + bacitracin ointment
28. Thiambutacin tablet
29. 8-methoxypsoralen
30. Triamcinolone tablet/cream
31. Tolnaftate
32. Clofazimine
33. Injection Methylprednisolone Acatate
34. Malphalan
35. 6-Mercaptopurine
36. Cytosine arabinoside
37. Bleomycin
38. Actinomycin-D
39. L-Asparaginase
40. Vinblastine
41. Methyl CCNU
42. Verapamil
43. Nifedipine
44. Disopyramide
45. Dipyridamole
46. Isosorbide dinitrate
47. procainamide
48. Oxprenolol
49. Trimethaphan
50. Saralasin
51. Prazosin
52. Sodium Nitroprusside Injection
53. Guanethidine tablets
54. Chlorpropamide
55. Clomiphene Citrate
56. ACTH Injection
57. Injection Vasopressin 20 unit
58. Oxymetholone

59. Desmopressin Nasal drop/injection
60. Codeine Phosphate tablets
61. Cholestyramine
62 Salazopyrine
63. Lactulose
64. Flufenazine injection
65. Naproxen
66. Injection Flupenthixol
67. Lithium Carbonate
68. Tab. Imipramine
69. D-Penicillamine tab./cap./inj
70. Sodium Aurothiomalate
71. Colchicine tabs
72. Sulphinpyrazone
73. Bocloten
74. Cinerazine
75. Niclosamide
76. Miconazole ointment/inj
77-100 to be determined by Expert Committee from time to time

ANNEXURE—III

GUIDELINES FOR EVALUATION OF MEDICINAL PRODUCTS

The Expert Committee constituted by Goverment Order No. S-DA/D-D-20/82/74 dated 27 April 1982 met at 10.00 a.m. on 28 April 1982 in the office of the Director, IPGMR, Dacca. under the Chairmanship of Professor Nurul Islam for evaluation of the pharmaceutical products available in the country and to draft a National Drug policy, keeping in view the health needs of the country.

Consistent with the declared guidelines of the Government to provide basic needs of life to the majority of the people through austerity, and to improve the economy of the country, prevent wastage of foreign exchange, the production and/or importation of unnecessary crugs or drngs of marginal value have to be stopped.

Almost any drug may produce unwanted or adverse reactions. The combination of two or more active ingredients not only makes the product costlier, it also increases the possibility of adverse reaction without increasing the efficacy over a single ingredient product. Hence, as general rule, combinations of similar or dis-similar drugs will be prohibited.

Combination drugs could be approved if the drug company can give definitive, approved scientific proof (i. e, WHO publications, British National Formulary, British Pharmacopoeia, European Pharmacopoeia, USP or other authoratitive guidelines like Goodman & Gilman's 'The pharmacological Basis of Therapeutics', 'Current Medical Diagnosis & Treatment', etc,) of the drugs' synergistic action and increased efficacy. They also have to prove conclusively that combining the elements creates no increase of toxicity or side effectsi, nor instability of the compound or shortening of the life of the product.

One of the greatest sources of drainage on the country's financial resources is the irresponsible prescribing and marketing and inappropriate self-use of vitamins. Another great wastage of meagre resources is cough mixtures, gripe water, alkali preparations, and digestive enzymes which are of little or no therapeutic value.

It is unanimously decided that the following criteria will serve as the guidelines in evaluating all the registered/licensed pharmaceutical products manufactured and/or imported in Bangladesh ;

i. The combination of an antibiotic with another antibiotic or antibiotics with corticosteroids or other active substances will be prohibited.

   Antibiotics harmful to children (e.g. Tetracycline) will not be allowed to be manufactured in liquid form.

ii. The combination of analgesics in any form is not allowed as there is no therapeutic advantage and it only increases toxicity, especially in the case of kidney damage. The cobination of analgesics with iron, vitamin or alcohol is also not allowed.

iii The use of codeine in any combination form is not allowed as it causes addiction.

iv. In general, no combination drugs will be used unless there in absolutley no alternative single drug available for treatment or if no alternative single drug is cost effective for the purpose.

Certain exceptions will be made in the cases of eye, skin, respiratory and haemorrhoidal preparations, co-trimoxazole, oral rehydration salts, antimalarial, iron-folic, etc, as well as certain vitamin preparations, allowing combinations of more than one active ingredients in a product.

v. Vitamins should be prepared as single ingredient products with the exception of B complex. Members of vitamin B complex with the exception of B12 may be combined into one product. B12 always has to be produced as a single injectable product. Other members of B complex may also be produced as a single ingredient product (e.g. B1 ; B2 ; B6 ; etc.). Vitamins will not be allowed to be combined with any other ingredient such as minerals, glycerophosphate, etc. It will be allowed to produce vitamins in tablets, capsules and injectable forms only.

No liquid forms will be permitted because of wastage of financial resources and the tremendous misuse involved. However, paediatric liquid multivitamin (with no B12,E,k and/or minerals) will be allowed to be manufactured in bottles of up to 15ml size with droppers. Paediatric liquid preparations of single ingredient vitamins will also be allowed to be manufactured in bottles of up to 15ml with droppers.

vi. No cough mixtures, throat lozanges, gripe water, alkalis, etc. will be allowed to be manufactured or imported as these are of little or no therapeutic value and amount to great wastage of our meagre resources.

vii. The sale of tonics, enzyme mixturas/preparations and so-called restorative products flourish on consumer ignorance. Most are habit forming and with the exception of pancreatin and lactase, these are of no therapeutic value. Henceforth local manufacture or importation of such products will be discontinued. However, pancreatin and lactase will be allowed to be manufactured and/or imported as single ingredient products.

viii. Some drugs are being manufacturd with only a slight difference in composition from another product but having similar action. This only confuses both patients and doctors. This will not be allowed.

ix. Products of doubtful, little or no therapeutic value and rather some times harmful, and subject to misuse will be banned.

x. All prescription chemicals and galenical preparations not included in the latest edition of British Pharmacopoeia or British Pharmaceutical Codex will be prohibited.

xi. Certain drugs in spite of known serious side-effects and possibility of misuse, having favourable risk-benefit ratio may be allowed to be produced in limited quantity for restricted use. These will be prescribed by specialists only.

xii. The same or close substitute of a drug which is being produced in the country will not be allowed to be inported as a measure of protection for the local industry. However, if local production is far short of needs, this condition may be relaxed in some cases.

xiii. A basic pharmaceutical raw material which is locally manufactured will be given protection by disallowing it or its substitute to be imported if suff cient quantity is available in the country.

xiv The role of Multinationals in providing medicinesfor this country is acknowledged with appreciation. In view of the calibre of machinery and technical know-how which lies in their hands for producing important and innovative drugs for the country, the task of producing antacids and vitamins will lie solely with the National Companies, leaving the Multinationals free to concentrate their efforts and resources on those items not so easily produced by smaller National Companies. Multinationals will, however, be allowed to produce injectable vitamins as single ingredient products.

xv. No foreign brands will be allowed to be manufactured under licence in any factory in Bangladesh if the same or similar products are available/manufactured in Bangladesh as this leads to unnecessary high prices and payment of royalties. In the light of this policy, all existing licensing agreements should be reviewed.

xvi. No Multinational Company without their own factory in Bangladesh will be allowed to market their products after manufacturing them in another factory in Bangladesh on toll basis.

:- After approval of these recommendations by Government, the licensing anthority for drugs (Director, Drug Administration) will have to issue necessary orders withdrawing/cancelling the licensing/registration of the products, with the provision of a maximum period of six (6) months grace for using up the present stock of corresponding raw materials. Henceforth no raw materials, should be allowed to be imported for the manufacture of these products. All future licensing/registration should be given after evaluation of the products on the basis of the above criteria.

N. B. In 1982 there were 4340 registered medicinal products, of which 2600 were locally manufactured and 1740 were foreign brands. The Expert Committee evaluated all these products on the bass of the above criteria and identified the brands which were to be banned and withdrawn from the market. On the basis of there recommenations, the Government cancelled the registration of 1666 medicinal produets under the Drugs (Control) Ordinance, 1982 (Ord. No. VIII of 1982) and its subsequent amendments. The banned products (listed in the said Ordinance) were gradually withdrawn from the market in phases, and the withdrawal was completed by June 1934. The Drugs (Control) Ordinance which was enacted on 12 June 1982, also incorporated the main elements of the new National Drug Policy of Bangladesh.

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