

National Drug Policy May 5, 2005

MINISTRY OF HEALTH AND FAMILY WELFARE

Public Health Section-1.

NOTIFICATION

Dated, the 18 April, 2005

No. Public Health-1/Drug-22/2004/154-Ministry of Health and Family Welfare has promulgated the following “National Drug Policy 2005” which is duly approved by the Cabinet.

Preamble

In order to remedy the tile deplorable situation that existed in the drug and health sector of the country at the time of Independence and thereafter and to ensure adequate supply and availability of good quality essential drugs at affordable prices, a radical and far-reaching National Drug Policy (NDP) was formulated in 1982. Following the guidelines of this NDP a Drug (Control) Ordinance was also promulgated in the same year by the then Marshal Law Government. These two national documents, which were highly applauded all over the world, produced tremendous positive effects on rapid development of the local Pharmaceutical industries and gradual improvement and gains in the drug sector of the country which are evident from the following facts:

- * local production of both allopathic, traditional and complimentary alternative drugs increased substantially.
 - * availability of essential drugs also increased remarkably with the increase in the volume of local production of all types of recognized drugs, the monetary value of which grew from Taka 1,730 million in 1981 to about Taka 41,000 million in 2002.
 - * Local companies increased their share of production from 30% in 1970 to more than 80% in 2002.
 - * drug prices stabilized, increasing (practically a drop in price in real terms) by only 20% compared to an increase of 179% in the consumer price index. This made drugs more affordable to consumers.
 - * quality of products improved and the proportion of substandard drugs fell from 36% in 1970 to only about 2% in 2002.
- 21
- * volume of import of drugs and medicine in the country reduced drastically.

- * commendable progress in the research, education and manufacturing of Unani, Ayurvedi and Homeopathic-Biochemic systems of medicine.
- * less dependency on imports and prioritization of useful drugs saved the country approximately US\$ 600 million every year.
- * a drug-importing country, Bangladesh turned into a drug-exporting country.

Pursuance of the NDP objectives to procure raw materials of acceptable quality at the most competitive prices led to a sharp decrease in the prices of raw materials and, in turn, to a fall in Maximum Retail Prices (MRP) of finished drugs.

Drug manufacturers' total profits have also gone up, because of the increased volume of production, while the unit profit has gone down, to the benefit of the consumers. The NDP and the Ordinance effectively brought to an end to transfer pricing and over-invoicing for imports of capital machinery, raw materials and packaging materials which were common practices before 1982.

While these spectacular achievements of the Drug Policy and Drug (Control) Ordinance of 1982 were well appreciated, these documents of national pride were not reviewed or updated regularly to keep pace with time and the remarkable developments that were taking place in the medicine world.

Since the introduction of the Drug Policy, in the last two decades, there have been spectacular changes in the socio economic sectors nationally and internationally. Besides, the world has witnessed remarkable achievements in the areas of pharmaceutical industry, medical science and also in the usage of medicine. Under the umbrella of WTO the global free trade policies are in the offing. To keep pace with the changed circumstances, it has become imperative to modernise and expand our pharmaceutical sector aiming beyond national horizon to the international export markets and also to attract the foreign investment in this sector. The aforesaid perspectives have made it inevitable to update and modernize the present national drug policy.

Although the successive Governments strongly felt that an updated Drug policy should be formulated and the Drug (control) Ordinance of 1982 should be amended to keep pace with time in order to regulate the drug sector of the country, no effective steps were taken before the present Government came to power in 2001

Immediately after formation of the Government in October 2001, the Ministry of Health & Family Welfare realized the pressing need for reviewing the Drug Policy of the country and

22

updating the Drug (Control) Ordinance of 1982. The process got momentum when the Honorable Prime Minister reiterated the Government's determination to review and update the Policy and the Ordinance in various meetings with the experts and the professional related to pharmaceutical industries in different times. The Minister of Health and Family Welfare was given the responsibility to take immediate necessary

measures to review and update the Drug Policy and to amend the Drug (Control) Ordinance of 1982 accordingly.

The Ministry then constituted a National Drug Policy Review Committee with members from all relevant sectors. After a thorough discussion over a period of about two years the National Drug Policy Review Committee decided that an updated policy should be formulated including all the relevant and useful elements of the 1982 Policy and incorporating necessary changes, updated information and new elements in the new Policy and the Drug (Control) Ordinance be amended accordingly in order to properly deal with the changes and developments that have taken place in the drug sector over this long period of time. The National Drug Policy 2005, which has been formulated now to meet the requirements of the current needs of the country, is thus an updated version of the National Drug Policy of 1982. The present Policy has been formulated.

- i) to make it more applicable, effective and adaptive to the remarkable technological advancements that have been made in the medicine world
- ii) to guide the Drug Sector of the country to perform better in the competitive world market
- iii) to make the country a producer and exporter of good quality drugs in the world.

Objectives and Elements of the Policy

While the above-mentioned achievements are impressive by themselves, there are certain areas in the drug sector of the country, which need immediate attention. Although many pharmaceutical manufacturers of the country have commendable records of adherence to the current Good Manufacturing Practices (cGMP), there are still ample scopes and needs for further improvement in many of them. Concerted efforts of all the manufacturers to adopt cGMP will ensure availability of adequate quantities of safe, efficacious and useful drugs in the country at affordable prices. The present Drug Policy is thus formulated in order to achieve the following objectives:

- a) to ensure that the common people have easy access to useful, effective, safe and good quality essential and other drugs at affordable prices.
- b) to strengthen the Directorate of Drug Administration by raising its status to that of a Directorate General of Drug Administration with corresponding increase in its manpower and infra-structure facilities to make it more effective as a Drug Regulatory Authority (DRA).
- c) to update, from time to time, the criteria of registration for import of all systems of medicines in line with the quality guidelines followed in developed countries to ensure safety, efficacy and usefulness of such medicines.
- d) to provide, on a priority basis, required services and facilities to local drug manufacturing industries of all the recognized systems of drugs so that self-sufficiency is attained in the manufacture of both drugs and pharmaceutical raw materials.

- e) to exercise government control over advertisement so that common people are not hood-winked by commercial advertisement on drugs and health matters.
- f) to encourage all local and foreign companies to manufacture good quality essential drugs in adequate quantities in the country.
- g) to ban the manufacture, sale and distribution of counterfeit, adulterated and sub-standard drugs and to award exemplary punishment to persons guilty of such actions.
- h) to strengthen the system of procurement, storage and distribution of drugs and medicines so that these are accessible to people in all areas of the country,
- i) to allow manufacturers to manufacture, distribute and sell drugs by their Generic or Formulary names and Trade or Brand names (except in Homeopathic medicines) as appropriate for best identity of the product.
- j) to continue the current system of controlling prices of the commonly used essential drugs as listed and updated from time to time by the Government.
- k) to encourage foreign manufacturers to invest, manufacture and sell drugs in Bangladesh with corresponding assurance of transfer of new technology and technical knowledge in the country.
- l) to ensure that no discrimination is made between the local and multinational companies, which have manufacturing plants in Bangladesh while applying the principles of this policy.
- m) to encourage both local and multinational manufacturers to establish full—fledged Research & Development (R & D) facilities in the country.
- n) to encourage investors to set up facilities for manufacturing pharmaceutical raw materials in the country.
- o) to encourage collaboration between universities, research institutes and manufacturers for undertaking basic and applied research in medicine, pharmacy, biotechnology, genetic engineering and biomedical sciences.
- p) to ensure rational use of drugs (RUD) by proper counseling and motivation of both the prescriber and the end-users.
- q) to ensure proper monitoring of Adverse Drug Reactions (ADR) in the country by motivating the physician and the patients to report cases of adverse reactions of drugs.
- r) to put emphasis on training of the people working in the Directorate of Drug Administration and in the Quality Control and Production departments of the manufacturing units.

24

Policy Areas

1. Laws and regulations

Relevant Laws and Regulations commensurate with the prevailing circumstances usually control and regulate production, distribution, sale and use of drugs in a country and ensure that they are of good quality, efficacious and safe. Currently the Drugs Act, 1940 of (XXIII of 1940) and the Drugs (Control) Ordinance 1982 (Ordinance No. VIII of 1982) regulate the process of registration, manufacture, distribution, sale, import and export of drugs in Bangladesh. These drug regulatory legal instruments of the country are now quite old. They should be updated through necessary amendments to keep pace with newer developments in the drug sector. Similarly the Rules made under the above Act and Ordinance should also be updated and integrated into one set of Rules.

If the functioning of these laws regulations and their compatibility with other laws, either under the responsibility of the Ministry of Health & Family Welfare or other Ministries and Departments, affect implementation all the different aspects of the NOR. they should be amended accordingly.

2. Drug Regulatory Authority (DRA)

A strong administrative set-up is essential for effective management of the various aspects of the drug sector of a country. The Directorate of Drug Administration of Bangladesh has a very limited number of qualified technical personnel and totally insufficient infra-structure facilities to effectively perform the various functions of the regulatory authority.

Strengthening of the Drug Regulatory Authority (DRA):

The following measures should be taken for the strengthening of the DRA:

- I. The status of the Directorate of Drug Administration (DDA) should be raised to that of the Directorate General of Drug Administration (DGDA) with corresponding increase in its manpower and infra-structure facilities.
- II. The organogram of the DGDA should accommodate all lawful systems of drugs and regulate them under unified control.
- III. The regulatory responsibilities should be delegated to different Directors under DGDA to expedite and facilitate the functional processes.
- 25
- IV. The decision-making processes should be guided by the objective, non-discriminatory and transparent guidelines and procedures.
- V. The staff of the DGDA should be adequately trained, have clearly defined functions and powers, and be entrusted with responsibility in relation to all aspects of registration, manufacture, storage, distribution, sale, import, export and quality of drugs in order to ensure compliance with the laws, rules and regulations.

3. Drug Registration

All drugs and medicine and other medicinal substances in finished dosage forms, which are manufactured, imported, distributed, marketed or consumed in the country must be registered with the Drug Regulatory Authority (DRA) of the country in the specific dosage form and strength as recommended by the Drug Control Committee (DCC).

However, the Licensing Authority may allow manufacture of any drug in any dosage form and strength for export purpose only as per the requirements of the importing country.

a) Selection of Drugs for registration

- i) Selection of a drug either for manufacture or import is one of the important functions of the National Regulatory Authority (NRA). For this purpose the current system of having a drug registration advisory committee, i.e., the Drug Control Committee (DCC), which comprises of experts and professionals from all lawful systems, should continue.
- ii) Quality, safety, efficacy and usefulness should always be the predetermining criteria for approval for sale of a pharmaceutical product.
- iii) The Directorate of Drug Administration, in consultation with the experts committee formed by the government, will prepare a list of non-prescription (OTC) drugs that will be updated from time to time.

b) Registration Criteria

- i) As a general principle, registration for manufacture, import and sale of combination drugs other than those of Unani, Ayurvedic & other Herbal preparations, vitamins and nutritional preparations should not be allowed in the country.

However, combinations like vitamins, nutritional preparations and other drugs which are therapeutically useful and are registered in the developed countries could be considered for registration.

In case of the Homeopathic system also, registration for manufacture, import and sale of combination medicines shall be allowed according to the principles of Homeopathy.

26

- ii) In case of imported allopathic drugs, the manufacturing site will be inspected for GMP validation by the inspectors of the drug regulatory authority of Bangladesh. The inspections will be scheduled by the DRA and the concerned manufacturers will bear the cost of any such inspection. However, the inspections will not be a bar to the consideration of a new drug application manufactured in a developed country included in the list of the Licensing Authority.
- iii) Bioavailability and bioequivalence data will be considered as important criteria for the registration of any imported medicine.
- iv) Any Unani, Ayurvedic or other Herbal drugs included in the official formulary of other countries, if considered essential and useful by the National Unani, Ayurvedic & Herbal Formulary Committee, may be granted registration for manufacture and sale in the country. National Unani, Ayurvedic & other Herbal Formulary Committee will be constituted by the government with the experts on Unani, Ayurvedic and Herbal drugs.

- v) Foreign and multinational company's will be allowed to invest and manufacture drugs in Bangladesh as long as they have at least three of their original research product drugs registered in at least two of the following countries: USA, UK, Switzerland, Germany, France, Japan and Australia.
- v) Manufacture of drugs that are not included in the last five editions of the British Pharmacopoeia (BP) or United States Pharmacopoeia (USP) or International Pharmacopoeia (IP) or the British Pharmaceutical Codex (B PC); or in the WHO lists of the International Non—proprietary Names (INN), will be prohibited.
- vi) In order to encourage transfer of technology and availability of the newly developed drugs, foreign companies, with or without having manufacturing

28

- plants in Bangladesh will be allowed to manufacture drugs in the country under licensing agreements with any partners of their choice if the drug in the same brand name is registered and marketed in at least two of the following developed countries: USA. UK, Switzerland. Germany, France. Japan and Australia.
- vii) Only for marketing outside Bangladesh, foreign companies without having manufacturing units in Bangladesh will be allowed to manufacture drugs in the country under toll/licensing agreement with any partner of their choice.
- viii) The task of producing Unani, Ayurvedic and other Herbal drugs will lie solely with national manufacturers with a view to attaining self-sufficiency in respect of local resource based drugs.
- ix) Both local and foreign companies having manufacturing plants in Bangladesh will be allowed to manufacture drugs under toll/contract manufacturing arrangements at any other manufacturing plants of their choice.
- x) For the purpose of export only, any drug may be allowed to be produced in the country in accordance with the specific requirements of the importing country.

5. Drug Procurement

- ii) Drugs and pharmaceuticals may be procured by government by local purchase or import, and by receiving as donation or gift. Under registered drugs and pharmaceuticals should be avoided in case of import, donation and gift received by the Government in emergency situation. However, in emergency situation these types of drugs and pharmaceuticals can be received with the prior approval of DGDA.
- iii) Drugs for personal use of individual patients or to meet any national emergency situation or for the purpose of research and clinical trials or for any other specific use, which are not registered, may be imported with

prior approval of the Licensing Authority (Drugs) for specific quantity and for non commercial purpose.

iii) All procurements by the public sector should normally be made directly from the manufacturers through open tenders in generic names.

*iv) To reduce dependence on imported drugs, the local pharmaceutical manufacturers will be offered necessary cooperation to produce quality medicines in adequate quantities. The drugs registered for import in Bangladesh may be imported subject to prior approval of the Drug Regulatory Authority. The recently innovated life-saving drugs will be preferred while considering registration of drugs for import. The application for registration of a drug for import will be taken into consideration

29

only if the drug is registered under the same brand name in at least one of the following developed countries

:USA, UK, Switzerland, German, France, Japan and Australia.

*v) To reduce the cost of procurement of drugs produced locally, the production of active pharmaceutical ingredients will be encouraged through offering various facilities including setting up of a dedicated industrial park.

*vi) To encourage transfer of technology the foreign investors will be encouraged to produce locally the active pharmaceutical ingredients of their innovative life saving drugs.

6. Drug Distribution, Sale and Storage

Prompt and safe distribution and ethical sale of drugs from public/private storage Facilities to the end should be ensured so that the quality of the products is maintained throughout the whole process and good quality essential drugs are always as available to those who need them.

i) Only the drugs, which are registered in Bangladesh should be allowed to be distributed and sold in the country.

ii) No person without having professional qualification or holding valid profession licence should be allowed to stock, distribute or sell drugs and medicines.

iii) No drugs or medicines, other than non-prescription (OTC) drugs, should be sold or dispensed without prescriptions.

iv) Maintenance of quality and safety of drugs in retail outlets and in storage should be ensured by currying out regular checks by Inspectors of drugs on the quality of stored drugs at all levels.

7. Drug Pricing

i) Rational pricing of drugs should be ensured to make essential drugs available to the end-users at affordable prices.

- ii) The current system of controlling prices of commonly used essential drugs should be continued and the existing list of the price-controlled drugs should be updated in the light of current pattern of changes of drugs used in the primary healthcare.
- iii) existing system of linking prices of the aforesaid locally produced drugs with costs of raw and packing materials and that of imported finished drugs with landed cost should be revised for rational fixing of Maximum Retail Prices (MRP) of drugs.

30

8. Quality Assurance of Drugs and Pharmaceuticals

One of the most important objectives of the NDP is to make good quality drugs available at affordable prices. In order to achieve this objective, quality building in a drug at the manufacturing stage by in-process quality control and quality keeping in the drug in transit and storage should be ensured by testing it at different stages before it reaches the end-users.

* As amended by the Ministry of Health & Family Welfare on 19th May 2005 (Bangladesh Gazette notification dated, 23 June 2005)

- I. Each pharmaceutical company should have a quality control and quality assurance system, which would monitor the entire process from the acquisition of raw material to its conversion into a finished product.
- II. Each manufacturer should have a dedicated team of professionals or adequate product and process design and statistical control of the process through in-process and end-product testing.
- III. There should be documented Standard Operating Procedure (SOP) based on WHO recommended cGMP guidelines for manufacture of each product as well as for each manufacturing unit process.
- IV. All the unit process should be periodically validated to ensure correct end-results. The validation results should be properly documented.
- V. Qualified professionals related to pharmaceutical sciences should be employed in all the relevant departments, related to quality control and quality assurance, of a manufacturing plant following the guidelines of WHO in order to ensure production of good quality drugs.
- VI. Quality of marketed drugs should be ensured by frequent post-market surveillance by the Drug Inspectors and testing random samples of the marketed drugs in the Quality Control laboratories.
- VII. In addition to the QC laboratories of the companies there should be one Central Drug Testing/Quality Control Laboratory and a number of Regional Drug Testing/Quality Control Laboratories under the Directorate of Drug Administration with separate units for Unani, Ayurvedic, herbal and homeopathic-biochemic drugs, manned by technical experts of the respective disciplines.

9. Manpower of the Manufacturing Units

- i) All manufacturing units should be staffed with adequate number of Professionals related to Pharmaceutical sciences in accordance with WHO guidelines in order to produce good quality, safe and effective drugs and pharmaceuticals.

However, the unani, ayurvedic, herbal and homeopathic-biochemic drug manufacturing units should be staffed with adequate number of Qualified persons of the respective disciplines and, where necessary, pharmacists, chemists/biochemists, and botanists.

31

- ii) Persons with relevant qualifications should be employed in the various departments of the manufacturing units following the guidelines of WHO and strictly following the relevant laws of the country.
- iii) Adequate number of other supporting trained and skilled technical personnel should be employed for smooth functioning of the manufacturing plant.

10. Drug Information and Monitoring

- i) The Directorate of Drug Administration should have a well-equipped Drug monitoring and information Unit.
- ii) Data on production, import, export, procurement storage, distribution and sale should be compiled, monitored and evaluated to ensure availability of drugs at all levels of the country's health care facilities both in public and private sectors.
- iii) Safety, efficacy and quality of all registered drugs should be monitored regularly and information on any substandard, spurious and counterfeit drugs should be made freely available to all concerns by wide publicity in both print and electronic media.
- iv) Rational use of drugs (RUD) should be ensured by conducting surveys on the systems of prescribing, dispensing and patient compliance.
- v) Monitoring and reporting of adverse reactions of drugs (ADR) should be seriously done to ensure safe and rational use of drugs in the country.
- vi) Objective and educational advertisements of Non-prescription (OTC) drugs based on scientifically established evidence and in good taste may be allowed with prior approval of the Drug Regulatory Authority, (current lists of OTC drugs of allopathic, ayurvedic and unani systems are appended to this Policy).

11. Essential Drugs

- iv) There shall be an Essential Drug List for Bangladesh. The Directorate of Drug Administration, in consultation with the experts committee formed by the government, shall update from time to time and maintain the list of essential drugs in line with the current list of Essential Drugs of the World Health Organization.

12. It will come into force immediately

By order of the President

Fazlul Karim

Assistant Secretary.