English Version

National Drug Policy 2016

Index:

NATIONAL DRUG POLICY 2016

1. Proposal

1.1 The Government of Bangladesh is committed to provide effective health care service for the people of the country as per the constitution of the People's Republic of Bangladesh sections 15 (a), 15(d), and 18(1). Good quality drugs are pre-requisite along with the skilled physicians and standard medical devices and supplies for promoting improved health care service. Quality and safe veterinary drugs and vaccines are required to ensure safe food and keep live stocks healthy for protection of public health.

1.2 The pharmaceutical industry of Bangladesh is one of the first growing sectors. Once where almost 80% demand of drugs were imported, currently more than 97% of medicines are being produced in the country. Quality drugs locally produced are now being exported to 113 countries across the globe, including developed countries. Already, a number of drug manufacturing companies have been awarded with Good Manufacturing Practice (GMP) certificates by drug regulatory agencies of developed countries. Due to attaining required technology, Bangladesh pharmaceutical sector is capable of producing almost all conventional and high technology based dosage forms. The pharmaceutical sector is enriched with not only higher technological resources but also experienced and skilled pharmacists as well as other affiliated competent manpower. Since 2009, sufficient medicines of required quality are being supplied in line with expansion of health care center/facilities.

1.3 In the country raw material of medicine is being produced far less than in need. Moreover, scaling up of the production of essential drugs is required for effective treatment interventions. It is essential to comply strictly the recommended GMP by WHO, to prevent the sales of fake-adulterated, expired-unregistered-counterfeit-misbranded and smuggled drugs, to ensure rational use of drugs as per WHO recommendation, to establish community pharmacies progressively in the country and to set up hospital pharmacy in all tertiary level hospitals. Overall, in the context of the changing global economic it is necessary to prepare the pharmaceutical sector of the country in the light of intellectual property rights and trade law or TRIPS (Trade Related Aspects of Intellectual Property Rights) agreementof World Trade Organization (WTO) for public health protection and expansion of drug exports. From the inception of Present Government as per their election manifesto, initiate to formulate the

National health Policy, the National Population policy and the National Drug policy (NDP). The National Drug policy (NDP) 2016 has been formulated by keeping compliance with the National health policy 2011 and the National population policy 2012.

1.4 Newly independent Bangladesh had to import more than 80% of its demanded drugs. Among the domestically produced drugs many harmful and un necessary drugs were in the market. After the independence in 1973, Father of the Nation Bangabandhu Sheikh Mujibur Rahman formed a cell to import necessary medicines under the trading corporation of Bangladesh in order to prevent the loss of valuable foreign currency. Through this, the waste of huge foreign currency for importations of pharmaceuticals ended. Besides, Bangabandhu formed the 'Directorate of Drug Administration' in 1974 to increase production of quality medicines in the country and to help and control this industry. In order to safeguard the public health, he kept Bangladesh out of patent law as a poor country for production of foreign companies' patented drugs by local companies; As a result, domestic companies got huge incentives and due to the competitive market, life-saving medicines became available through reducing prices.. Thus both the people of the country and domestic pharmaceutical industries are benefitted.

1.5 The first National Drug Policy was formulated by the Government of Bangladesh in 1982 which was hailed and immensely praised by WHO and other international organizations. The first National Drug Policy led to ensure the drug safety, quality and control of drug prices. Reducing Import dependency country started to become more self-reliance in drugs, foreign dominance on the drug sector was lessened and local pharmaceutical industries began establishing large and modern technology based drug manufacturing facilities. Bangladesh pharmaceutical sector attained a glorious image in the international arena, transition of Bangladesh from a drug importing country to a drug exporting country.

1.6 The second National Drug Policy of 2005 consisted of a number of promising initiatives for the drug industry of the country; however those initiatives did not achieve the expected targets of the drug policy. It is therefore essential to formulate an updated third National Drug Policy by the government embracing the expectations that created in the field of possibilities in home and abroad for the pharmaceutical sector as well as protecting public interest. With this aim, the pharmaceutical sector of the country has to be more responsible and compliant with stringent adherence to the WHO recommended GMP guidelines in drug production and quality control.

1.7 Substantial progress has been made in the field of traditional medicine alongside that of allopathic drug sector. Now, the Ayurvedic, Unani, Herbal, Homeopathic and Biochemic drug industries that are local resource based according to their self-fundamental principles and in pursuance of GMP guidelines of WHO, successfully trying to produce drugs. The interest of a large segment of people towards traditional treatment system and effective incorporation of traditional methods of treatment into the national health care system, in light of WHO recommendations and alongside of modern treatment system the Ayurvedic, Unani, Herbal, Homeopathic and Biochemic drug industries need cooperation to make advancement. The National Health Policy 2011 has emphasized on alternative treatment system.

1.8 It is necessary to follow the GMP guidelines of WHO in the manufacture of veterinary drugs and vaccines to ensure livestock development, prevention and treatment of disease, ensure the control of safe food and maintain of nutrition.

2. Objectives of National Drug Policy

2.1 To ensure people can have easy access to safe, effective and good quality drugs at affordable prices.

2.2 To ensure rational and safe use of drugs and proper dispensing.

2.3 To achieve self-sufficiency in the manufacture of drugs and raw materials by providing services and facilities on a priority basis to all local drug manufacturing industries.

2.4 To expand the export of drugs that manufactured in the country.

2.5 To establish effective surveillance system of medicines.

3. Elements of National Drug Policy

3.1 The drug registration process has to be updated in accordance with the standards of the developed countries time to time, to ensure safe use, efficacy and usefulness.

3.2 The Directorate General of Drug Administration has to be strengthened through appropriate expansion of existing human resources and infrastructural facilities to serve as an effective National Regulatory Authority (NRA). The National Regulatory Authority has to be, at least, recognized by WHO and to be a member of PIC/S (The Pharmaceutical Inspection Convention /The Pharmaceutical Inspection Scheme).

3.3 The manufacture, sale and distribution of fake, adulterated, harmful, un-registered, counterfeit, misbranded and substandard drugs and medical devices must be forbade and exemplary punishment bestowed upon people responsible for such offences.

3.4 The selection, quantity fixation, procurement, storage and distribution system of drugs must be strengthened so that drugs are accessible to the public throughout the country. Appropriate preservation methods, such as temperature and humidity control, must be ensured at all drug wholesale shops or pharmacies or drug storage facilities and during drug transport and distribution in order to maintain quality, appropriate use and dispensing.

3.5 Develop and implement apposite guidelines to regulate all sorts of advertisements and promotion of drugs in public media and prevent unethical marketing and multi-level marketing of all recognized system of drugs to ensure safe, rational and effective use.

3.6 Ensure accessibility to drugs at affordable price and fix drug prices by transparent and rational methods. The government from time to time is to continue the process of drug pricing /re-pricing of enlisted drugs.

3.7 Encourage foreign research-based pharmaceutical industries to invest, produce and market drugs in the country with the objective of promoting transfer of technology and technical knowledge for innovative drugs or high-technology (e.g. biotechnology) based drugs. Motivate research-based drug manufacturers to invest, manufacture and sell drugs in Bangladesh with assurance of new technology and technical knowledge transfer.

3.8 Inspire drug manufacturers to carry out effective Research and Development (R&D) in their respective pharmaceutical industries. To reduce taxation on imported machineries for research laboratories and also provide encouragement for the universities, competent research agencies and drug manufacturers to engage in collaborative joint effort for applied research. Encourage collaboration among government, universities, research

institutes, professionals and drug manufacturers to adopt basic and applied research programs.

3.9 To ensure Pharmacovigilance and appropriate monitoring of Adverse Drug Reactions (ADR) through motivation for all concerned people to be accurately informed about adverse drug events.

3.10 To ensure employment of skilled staff and their regular training, so that Good Manufacturing Practices (GMP) are effectively followed and implemented in drug manufacturing companies of all recognized systems.

3.11 To take necessary steps and provide diverse incentives to expand export of drugs manufactured in the country.

3.12

a. To modernize the National Control Laboratory (NCL) as central drug testing laboratory to test and analysis of drugs and established its branches in different divisional level phase wise; to establish central autonomous national reference laboratory, to establish specialized modern laboratories for Unani, Ayurvedic, Herbal and Homeopathic-Biochemic system of drugs.

b. As a competent research organization involve Bangladesh Council of Scientific and Industrial Research (BCSIR) in test and analysis of modern and traditional medicine and with the activities of reference laboratory.

c. To recognize research organizations as third party quality evaluator, established at public, private and autonomous level for testing and analysis.

3.13 With a view of protecting public health, prepare separate essential drug lists for Allopathic, Unani, Ayurvedic, Herbal and Homeopathic system of medicines.

3.14 To prohibit sales and distribution of drugs without prescription from registered physician to ensure rational use of drugs.

3.15 Publish list of Over-the-Counter (OTC) drugs for general use aligning with the systems of developed countries.

3.16 Include scientific technology based quality control system in the manufacturing of Unani, Ayurvedic, Herbal and Homeopathic-Biochemic system of drugs for quality improvement.

3.17 Consider those substances as drugs that have medicinal value, manufactured as pharmaceutical dosage form and possess therapeutic indications and ensure appropriate regulation accordingly. The cosmetic products that lead to physiological changes in the body should bring under the regulatory control of Directorate General of Drug Administration.

3.18 Enlist medical devices and surgical equipment that come in contact with the human body under the regulatory control of Directorate General of Drug Administration.

3.19 To create Clinical trials and Bio-equivalence study facilities at public and private sectors with expert and trained personnel of relevant field.

3.20 Support the development of the pharmaceutical sector in Bangladesh in light of the WTO/TRIPS agreement.

3.21 Transform the 'Directorate General of Drug Administration' to 'Directorate General of Food and Drug Administration' for assurance of quality and safety of different types of food in addition to drugs and rearrange the jurisdiction and organizational structure to establish legal control over these products.

4. Areas of National Drug Policy

4.1 Implementation and Amendment of Current Law and Rules:

a. At present the existing different policies, laws and relevant rules become insufficient and inapt to control and monitoring of different system of medicines manufacturing, quality-

control, sale, distribution, storage, import and export. At the changed perspective, it is imperative to appositely amend these laws and rules in order to make them updated and effective.

b. An updated law will be formulated in Bangla version merging the 'Drug Act 1940' and the 'Drug (control) Ordinance 1982' in view of updating existing laws furthermore. Necessary rules will be made as soon as possible to execute the aforementioned laws.

c. Furthermore, for protection of public health by preventing spurious, adulterated and substandard food, required law for the Directorate General of Food and Drug administration will be formulated, considering the inadequacy of existing law.

d. The provisions of existing laws will be effectively implemented to ensure appropriate, effective and accountable drug management system in the country and to protect the consumer rights in this regard.

4.2 Availability to efficacious, safe and quality drugs:

a. The government will ensure availability of all kinds of drugs with essential drugs at all level considering the safety, usefulness and affordability as per the requirement of the people to ensure appropriate and effective health care system.

b. Accessibility to all drugs needed for prevention and eradication of Malaria, Kala-azar, Nipah virus, SARS, Tuberculosis, AIDS, and Dengue as well as other contagious diseases will be ensured.

c. Availability to different types of quality vaccines and related medicines for promotion of maternal and child health and disease prevention and availability to necessary quality vaccines and medicines for promotion of animal health and disease prevention will be ensured.

4.3 Rational and safe use of drugs:

a. Rational and safe use of drugs will be assured through pursuance of Standard Treatment Guidelines (STG).

b. To assure rational use of antibiotics all 100 or more than 100 bed hospitals at government and private level of the country must have their own 'Antibiotic user guidelines' which must be regularly updated and followed during delivery of health care services, later on subsequently 'Antibiotic user guidelines' will be formulated and implemented for all hospitals.

c. Bangladesh National Formulary- BDNF will be regularly updated and published in the website with the approval of Drug Regulatory Authority (DRA) to disseminate drug information and promote rational use of drugs. Similarly, as per approval of Drug Regulatory Authority, the 'Bangladesh National Ayurvedic Formulary', 'Bangladesh National Unani Formulary', 'Bangladesh National Herbal Formulary', and 'Bangladesh National Homeopathic Pharmacopoeia' will be regularly formulated, updated and published in the website.

d. Sale and dispensing of drugs will be conducted under direct supervision of professional pharmacists for providing counseling to patients on the appropriate use and storage of drugs. With this aim, Community Pharmacy will be accordingly established and developed.

e. Necessary steps will be taken to operate "Hospital Pharmacy" in all public and private hospitals phase wise under the direct supervision of graduate pharmacists. To ensure rational use of drugs each and every hospital will develop and update its own drug formulary and publish it in the website regularly.

f. Medicines will have to be manufactured and marketed mentioning generic or the name included in respective formulary perspicuously, alongside of trade name to make easy identification of all recognized system of drugs to all. The supply and use of drugs at all government levels will be encouraged by generic name.

g. Retail sales of drugs is prohibited without prescription by registered physicians/ veterinarians other than the OTC drugs.

h. To evaluate the rational use of drugs medical prescription and dispensing system of drugs will be monitored regularly in certain time interval.

i. Drugs and Therapeutic committee will be formed in all public and private hospitals to ensure rational use of drugs including antibiotics.

j. Essential Medicine List (EML) will be updated regularly based on Essential Medicine concept.

4.4 Drug registration:

a) Selection of drugs for registration:

1. All drugs that are produced in different dosage forms, imported, distributed or marketed or used have to be registered by licensing authority based on the recommendation of Drug Control Committee (DCC). Regular meetings of the DCC will convene to make faster availability of new life-saving drugs for the public.

2. The function of Drug Control Committee will be to give opinion/recommend for registration through evaluation of safety, efficacy and usefulness of all applied drugs and medical device for locally manufacture or for importation.With this objective the Drug Control Committee will be constituted with specialists and professionals.

b) Registration Criteria:

1. Registration will be given in accordance with established indication. No new indications for any drugs will be approved without the recommendation of Drug Control Committee.

2. Approval will not be given to manufacture drugs without appropriate infrastructure and quality assurance management. High-tech drugs or those that required different infrastructure and dedicated facilities for production will not be registered without required manufacturing infrastructure as per GMP guidelines of WHO. It is also mentionable that drugs already registered can be produced by competent pharmaceutical industries subject to re-evaluation.

3. Unless essential for treatment, the registration of combination allopathic drugs will be generally discouraged. The possibility of misuse of Combination Product will be given special consideration. In case of registration of allopathic drugs the reference of approval byUnited States Food and Drug Administration (US-FDA), the Medicines and Health Care Products Regulatory Agency (MHRA), or inclusion in British National Formulary (BNF) has to be pursued. If necessary, the registration of existing combination products will be re-evaluated.

4.Ayurvedic, Unani, Herbal, Homeopathic and Biochemic system of drugs will be registered on the basis of recommendation of Drug Control Committee (DCC). Only drugs included in Unani, Ayurvedic and Homeopathic Formulary/Pharmacopoeia will be considered for registration.

5.Only the 1x potency will be required for registration for mother tincture, crude trituration and 12 bio-chemic medicine, but no registration will be required for enhanced potencies of homeopathic and biochemic medicines.

6.As per Homoeopathic Pharmacopoeia it is usable by admixture/ converting with the addition of liquid form of medicine in solid vehicle, e.g., lactose/ globules etc. and solid form of medicine in liquid vehicle e.g., purified water/ alcohol etc. In case of potentized medicine through converting from liquid to solid form or solid to liquid form will not require to be registered.

c) Registration for import:

1. Foreign manufactured drugs registered in Bangladesh can be imported, subject to approval of licensing authority. Information of Bioequivalence Study and Clinical Trials have to be submitted for registration of imported products. For the registration of imported drugs, newly invented life-saving drugs will be given priority. The concerned drugs under same brand name have to be registered for marketing in at least one of the following developed countries: USA, UK, Germany, France, Switzerland, Japan and Australia, However, the imported drug must be collected from the original manufacturing site or from the manufacturing factories of any of the aforementioned countries.

2. Free Sale Certificate has to be submitted of at least any one of the following countries: European Union countries, USA, Switzerland, Canada, Australia, Japan, South Korea and Singapore along with the Source country for import registration and marketing of drugs used in treatment of live stocks &fish. It is noteworthy that such drugs must be registered for marketing under the same brand name in the listed country or countries.

3. With the objective of ascertaining the imported drugs and raw materials are being produced with GMP compliance accurately or not, submission of valid certificates, and if required, inspection of manufacturing premises by national drug regulatory authority will be arranged. In accordance with GMP guidelines and check list, the drug manufacturing sites of drug exporting countries will be subjected to validation and certification.

4. Herbal and Homepathic-Biochemic system of drugs has to be registered for import by Directorate General of Drug Administration (DGDA) based on the recommendation of Drug Control Committee. Import of Unani and Ayurvedic drugs will not be considered as these are derived from local medicinal plants, but the essential Unani and Ayurvedic medicines which are not produced locally may be considered for importation.

5. Certain specific drugs, even with the known possibility of their serious side-effects, in the absence of any other alternative drugs, can be approved for import in specific quantities only for regulated use.

4.5 Drugs and raw materials production:

a. The principle aim of the National Drug Policy is to ensure adequate production of good quality drugs. Therefore, the current Good Manufacturing Practices (cGMP) guidelines of WHO will be stringently followed.

b.As per the check list prepared by Directorate General of Drug Administration the drug manufacturing companies will conduct the internal audit at periodic intervals. Directorate General of Drug Administration will update the checklist on regular basis.

c. Drug companies will be classified based on their capabilities of drug manufacturing, taking into consideration the various aspects of drug production, such as: skilled manpower, establishments/premises, utility/services, installed machinery/equipment, therapeutic class of their finished drug products and dosage forms.

d. Exchanging views with internal resource division that is national board of revenue about remission of VAT or duty will be reduced logically for import of chemicals for production of raw materials and initiatives will be taken to provide incentives for motivation to produce raw materials. For this purpose institutions that are engaged in research for development of pharmaceutical raw materials will be encouraged and necessary incentives will be given. Finished drug products will not be allowed to manufacture under the license issued for raw material manufacture.

e. With a view of achieving self- sufficiency in drug sector, dependency on imported raw materials of all recognized system of medicine will be reduced. Initiatives will be taken to provide incentives in different stages to set up industries for drug raw material production, for contract based production, for

production under license agreement with foreign companies and for joint investment of domestic and foreign investors. In the same way the expansion of local drug packaging industry will be encouraged.

f. Raw materials used in drug manufactured in the country must meet with the specifications of quality as stated in the concerned Pharmacopoeia.

g. The allopathic drug manufacturer will be allowed to manufacture drugs in other allopathic drug manufacturing plant as per their choice under toll manufacturing agreements those have their own manufacturing plant in Bangladesh.

h. Foreign pharmaceutical industries not having drug manufacturing factories in Bangladesh, under contract manufacturing agreement/loan license can manufacture drugs of all recognized system of medicine for export only. By no means, the manufactured drugs will be marketed locally.

i. With a view to technology transfer or to ensure availability of newly developed drugs, foreign companies without manufacturing plant in the country will be granted approval to produce their research drug locally in partnership with any of their preferred local drug manufacturing company under the licensing agreement, provided the drug of same brand name is registered for marketing in, at least, any one of the following developed countries: USA, UK, Switzerland, Germany, France, Japan and Australia.

j. With the prior approval of Directorate General of Drug Administration, drugs that required high-technology test and analysis procedure, any pharmaceutical companies can have it tested and analyzed according to their choice of any public, private and autonomous organization recognized by Directorate General of Drug Administration which possess facilities for respective test and analysis under contract analysis agreement, this type of organization will be recognized. For this purpose, Directorate General of Drug Administration will prepare necessary guidelines.

k.Small quantities of raw materials used in manufacturing of drugs and reference standards could be imported by Drug manufacturing companies jointly having approval from Directorate General of Drug Administration (DGDA). In this respect, the GMP compliance has to be ensured by importers.

l. In any urgent necessity of the country or for public health protection, the government can direct any drug manufacturing company to produce any drugs and the companies will be obliged to do so.

m.Such foreign and multinational companies will be permitted to establish companies and manufacture drugs in Bangladesh on condition of having at least three of their original research drug products registered in at least two of the following countries: USA, UK, Switzerland, Germany, France, Japan and Australia.

n. Drugs that are not included in any of the previous three editions of British Pharmacopoeia (BP), United States Pharmacopoeia (USP), European Pharmacopoeia (EP), International Pharmacopoeia (IP), or British Pharmaceutical Codex (BPC) or not been included in the list of International Non-proprietary Names (INN) published by World Health Organization (WHO), will not be approved for manufacture.

o.In view of assurance of drug quality, the drug manufacturing companies will arrange regular training on cGMP for concerned human resources.

p. Inspectors of the Directorate General of Drug Administration will be trained up regularly on GMP guidelines and pertinent issues. Initiatives for training both at home and abroad will be undertaken and will arrange funding for the training courses.

4.6 National Regulatory Authority

a.It is essential to upgrade the Directorate General of Drug Administration (DGDA)as a more strengthen Drug regulatory agency. To accomplish all different activities as a drug regulatory authority, required number of professionally qualified and experienced human resources will be appointed. Regular training will be provided for the appointed personnel to enhance their skill and competency those involved in the area of drug registration, manufacturing, storage, distribution, sale, import, export and quality control. In case of veterinary medicines, training also will be provided by the veterinary specialist to enhance the skill of the personnel engaged in aforementioned areas.

b. An effective human resource development plan will be undertaken for the staff of Directorate General of Drug Administration and a career development plan must be put in effect along with promotion system based on skill, experience and performance of staff.

c. All necessary measures will be undertaken to fulfill prerequisites that will facilitate the Directorate General of Drug Administration (DGDA) to become WHO accredited and achieve PIC/S membership.

d. A legal cell with competent manpower will be established to execute the legal functions effectively of National Regulatory Authority. Judicial or executive magistrate in the Directorate General of Drug Administration will be appointed to expedite legal proceedings against the manufacture, distribution, storage and sale of fake, adulterated and substandard drugs.

e. The official website of National Regulatory Authority (NRA) will be regularly updated and the relevant information, procedures, and measures taken of Directorate General will be published. To accelerate the performance of Directorate General of Drug Administration, the activities will be conducted through on-line system respectively.

4.7 Prevention of production, sale & distribution of fake, adulterated, sub-standard drugs

a. The selling of fake, adulterated, expired, unregistered, counterfeit and misbranded drugs are punishable offences and due to hindrance to good governance in drug sector; consequently, drug manufacturers, importing organization, wholesale and retail sellers are all accountable. Any person or organization associated with the production, marketing, sale, distribution and storage of such drugs shall be subjected to stringent legal action and the respective license will be revoked by Directorate General of Drug Administration.

b. The existing laws will be amended for awarding exemplary punishment to unauthorized manufacturers and sellers, prescribing physicians and health care establishments of substandard, fake, adulterated and unregistered drugs (Allopathic, Ayurvedic, Unani, Herbal, Homeopathic and Biochemics) and medicines in the name of food supplements.

c. Storage, display of expired medicine in the pharmacy, selling drugs by changing or obscuring the expiry date on package or container will be considered as punishable offences.

d.The existing law will be amended to ensure appropriate compensation of the consumers harmed from the use of substandard, fake, adulterated, smuggled food or drugs.

4.8 Drug selection, quantity fixation. Drug procurement, storage and distribution processes

a. The government in times of national crisis or disaster with the opinion of Directorate General of Drug Administration (DGDA)will be enable to import unregistered drugs or receive as donations.

b. Drugs that are not registered can only be imported in specified quantity for personal use of patients or for research and clinical investigations in view of non-commercial purpose with prior approval of licensing authority.

c.A guideline on Good Distribution Practices (GDP) will be prepared by Directorate General of Drug Administration very soon. The transportation, distribution and storage of drugs will be ensured according to the guideline.

d.To ensure appropriate procurement, storage and sales/distribution of drugs all pharmacies, government and private drug storage facilities, and hospital-pharmacies will operate under the supervision of pharmacists registered by Bangladesh Pharmacy Council.

e.The pharmacies will be operated by the supervision of registered physicians of relevant systems or registered pharmacist to ensure the appropriate procurement, storage, sale and distribution of Ayurvedic, Unani, Herbal and Homeopathic-Biochemic system of drugs.

4.9 Control of drug advertising and promotion

a. 'Code of Pharmaceutical Marketing Practices' approved by Directorate General of Drug Administration (DGDA)will be followed in drug (Including OTC listed drugs) marketing to prevent circulation of false, unwanted, and misleading information. Drug manufacturing companies and drug marketing organizations will operate their marketing functions in accordance with the 'Code of Pharmaceutical Marketing Practices'. The aforementioned 'Code of Pharmaceutical Marketing Practices' will be regularly updated.

b. Drug advertisement of any type is prohibited without prior approval of licensing authority, and legal actions will be undertaken against unapproved advertising. With the same objective, any unethical marketing and multi-level marketing will be rigorously restrained.

c.With the prior approval of Drug Regulatory Authority, substantive, educational and public awareness typeof advertisement on oral rehydration salt, family planning drugs and devices, water purifying drugs, antiseptic drugs and vaccines used in expanded program on immunization will be permitted.

4.10 Transparent and rational pricing of drugs

a. The government will regularly update the guidelines for control of drug prices, taking public health interest into account.

b. At least once a year drug prices will be updated based on the government formulated guidelines .For public information, the retail prices of all drugs will be published in the official website of Directorate General of Drug Administration.

c. Prices of Ayurvedic, Unani, Herbal, Homeopathic and Biochemic system of drugs that are locally produced and imported will be fixed-up by the government.

d. Legal actions will be taken against person or establishments associated with selling of drugs above the fixed price.

4.11 New technology and technical knowledge transfer in Country

a. The role of research based domestic, foreign, public, private &autonomous organizations is important in technology transfer and in development of qualified professionals of international standards. With appropriate assurance of technology and technical knowledge transfer, research-oriented foreign companies will be encouraged to manufacture and market innovative and high-tech drugs such as-recombinant technology generated vaccines, Bio-similar, Hormones, Insulin, Anticancer drugs etc.

b. The country requires more of PIC/s, US_FDA, EMA, UK-MHRA, Australian-TGA certified drug manufacturing companies as pre-requisite to satisfy the conditions for entering in the international drug market. Henceforth; collaborative initiatives to jointly establish industry between research-based foreign drug manufacturing companies and drug companies of Bangladesh will be encouraged.

4.12 Joint collaborative research and development of drugs

a. Both local and multinational drug and raw material manufacturers will be encouraged to establish research and development facilities in the country. The initiative will be taken to reduce imposed duties on imported machineries for such research laboratories. Creating collaborative environment among universities, research institutes and drug manufacturers will be encouraged to conduct basic and applied research jointly on drugs.

b. Course of action to be undertaken to include: GMP, quality assurance, drug related law, National Drug Policy, concept of rational & safe use of drugs, essential drug concept and list and code of pharmaceutical marketing practices in all recognized pharmacy courses and in case of veterinary drugs above mentioned subjects will be included in veterinary pharmacology courses.

c. Drug manufacturing organizations will donate a certain proportion of their income under the monitoring of Ministry of Health &Family Welfare to the person, public, private and autonomous organization involved in research and development of drugs.

4.13 Effective Monitoring of Pharmacovigilance or Adverse Drug Reactions (ADR)

a. Pharmacovigilance programs will be strengthened at the national level for all drugs used in the country. The prevailing ADRM cell under Directorate General of Drug Administration will be strengthened further. Hospitals and clinics of the country, physicians, pharmacists and other health service providers, patients, drug manufacturers, drug marketing organizations and pharmacies will assist the ADRM cell by regularly providing relevant information, findings and reports.

b. 'Focal point' will be fixed up in all public and private hospitals having 100 or more than 100 bedded for monitoring the adverse drug reaction. A medical college will be declared as the 'National Centre' to strengthen the campaign. Subsequently, the program will be undertaken in all hospitals.

c. Phase wise 'Pharmacy and Therapeutics Committee' comprising physicians and pharmacists will be constituted in each of the specialized hospitals, medical colleges, and district level hospitals of the country.

d. Measures will be taken to conduct pharmacovigilance programs by Drug manufacturing and marketing organizations on their own

e. A National Drug Information Centre will be established under the disposal of DGDA.

4.14 Skilled human resources in drug manufacturing industries

a. The appointment of required number of graduate pharmacists and other skilled personnel as per GMP guidelines of World Health Organization will be ensured in allopathic drug manufacturing companies.

b. Required number of quality control and production officers will be appointed in Ayurvedic, Unani, Herbal, Homeopathic and Biochemic drug manufacturing companies having Bachelor of Ayurvedic (BAMS), Diploma in Ayurvedic (DAMS), Bachelor of Unani (BUMS), Diploma in Unani (DUMS), Bachelor of Homeopathic (BHMS), Diploma in Homeopathy (DHMS)degrees, bachelors' degree with honors in microbiology, pharmacy, botany, chemistry, biochemistry and applied chemistry.

4.15 Drug Export:

a. The export of manufactured drugs in the country will be encouraged and incentives will be provided to boost drug export.

b. Measures will be taken to eliminate all tariff and non-tariff barriers related to drug export.

c. In case of drug export, as per the demands of the importing countries, registration of desired drugs will be granted. However, registration will not be given to any drug which is deemed to be harmful to human or to any other animal or that are detrimental to the environment declared by World Health Organization and any other internationally recognized organization.

d. Foreign currency limit will be enhanced and sending of adequate drug samples for marketing &promotion of drugs in importing country will be permitted

e. In similar fashion, the permission for exporting of Ayurvedic, Unani, Herbal and Homeopathic drugs and the raw materials will be granted.

4.16 National Control Laboratory-NCL

a. National Control Laboratory-NCL will play the role of central laboratory for drug testing and analysis. Initiatives will be taken to achieve WHO accreditation for NCL enriched with modern facilities, apposite machineries and skilled human resources.

b. Branches of NCL will be established in all divisions of the country phase wise.

c.Centrally an autonomous Nationalreference laboratory will be established.

d.Specialized, modern laboratories for Unani, Ayurvedic, Herbal, Homeopathic and Biochemic system of drugs will be established.

e.Separate cell will set up in the drug testing laboratory for testing of Unani, Ayurvedic, Herbal, Homeopathic and Biochemic system of drugs.

f.National Control Laboratory will be given responsibility to prepare working standards importing reference standards in order to make reference standard/working standard easily available and cost-effective. These standards could be sold to drug manufacturers as per

requirement. In addition, the current practices of granting permission to drug manufacturers to import reference and working standards will be continued.

g. For test and analysis of modern and traditional system of medicines, ,capable public, private and autonomous research organizations will be recognized as reference laboratory of NCL.

h.BCSIR (Bangladesh Council of Scientific and Industrial Research), as capable research organization, will be endorsed for test and analysis of modern and traditional system of medicines and as a reference laboratory.

4.17 Formulationof separate Essential Drug Lists for Allopathic, Ayurvedic, Unani and Homeopathic system of drugs:

To effectively protect public health of the country, especially considering the emergency needs, affordability and accessibility of the majority of the people, separate "essential drug lists" have been published (appendix 1, 2, 3, 4) selecting a few number of drugs from drugs all system of treatment (Allopathic, Ayurvedic, Unani and Homeopathic) exists in the country. As per WHO recommendation and opinions of experts of respective system of drugs, the lists will be updated in every two years. In case of veterinary drugs, the list of essential veterinary drug will be prepared and published having opinion of the veterinary specialists and the list will be updated accordingly. The production and distribution of the essential drugs will be ensured as per the need.

To Adopting the fundamental principle of formulating the essential drug list nationally, a committee will be formed headed by the Secretary of Health and Family Welfare and members from Principals of Different Medical Colleges, Specialists in Different disciplines, Professors of Universities, representative from Concerned professional body, representative from Unani-Ayurvedic and Homeopathic Board, Director General of the Health Services, Director General of livestock and Director General of Drug Administration.

4.18 Over-the-counter (OTC) drugs

a. A number of drugs selected from locally registered Allopathic, Ayurvedic, and Unani system of drugs that can be used for general purposes and possess least side-effects, have been published(Appendix 5, 6, 7), as Over-the-Counter (OTC) drugs. These lists

will be up dated time to time by Directorate General of Drug Administration, based on the recommendation of WHO and relevant expert opinions. . In case of veterinary drugs, a list of Over the Counter (OTC) drugs will be prepared and published on the basis of the opinion of experts of veterinary specialists.

b. List of Homeopathic OTC drugs need not be published as because their uses are symptom-based and probable risk is associated in use without the prescription.

4.19 GMP guidelines and technology-based quality control system for quality improvement of Ayurvedic, Unani, Herbal, Homeopathic and Biochemic drugs

a. The GMP Guideline of WHO for Herbal Medicinal Products will be followed in the manufacture of Ayurvedic, Unani, Herbal, Homeopathic and Biochemic drugs. Considering the overall circumstances, an interim GMP guideline will be formulated for the next five years. In this respect, the Directorate General of Drug Administration will form a committee with relevant experts.

b. For Ayurvedic, Unani, Herbal, Homeopathic and Biochemic drugs, alongside to generic names, on the drug labels and cartons have to be mentioned clearly'Ayurvedic drugs', or 'Unani drugs', or 'Homeopathic-Biochemic drugs' or Herbal drugs.

c. No chemicals, other than active ingredient those stated in the Ayurvedic, Unani, formularies, can't be used as active ingredients in the manufacture of Ayurvedic, Unani, and Herbal drugs.

d. The test criteria and specifications for the raw materials, intermediate products and finished products for quality control of Ayurvedic, Unani, Homeopathic and Biochemic Herbal drugs will be formulated with the support of experts, in accordance with World Health Organization proposals, and following the procedures practiced in USA, UK, France, Germany, China and India.

e. As per the relevant standard criteria of World Health Organization and considering the technological competence and infrastructural facilities of the Ayurvedic, Unani, Herbal, Homeopathic and Biochemic drug manufacturers will be classified as per capability.

f. The Homeopathic drug industry of the country will be expanded by improving the quality of homeopathic drugs. Test criteria will be set by experts as per the homeopathic

Pharmacopoeia of USA and other developed countries and drug manufacturers will be directed to test drugs as per the test criteria.

g. In manufacturing of Ayurvedic, Unani, Herbal, Homeopathic drugs cannot use any unapproved chemicals (steroids, hormone, sexual stimulants or any other chemical substance). Moreover, the use of any color and flavoring agents, other than FDC color or certified food / color of pharmaceuticals grade is prohibited.

h. In case of manufacturing of homeopathic mother tincture and potentization of drugs only as per instructions of Homeopathy reference books the required quantity of ethyl alcohol(rectified spirit) stated therein will be allowed to prevent the abuse of alcohol Pack size more than 30ml Alcohol based Homeopathic potentized (potency/dilution) drugs, will not be approved

4.20 Products with medicinal substances and therapeutic value consider as drugs

a. Food or Nutritional or Herbal or Natural supplements manufactured as pharmaceutical dosage forms having substances of medicinal value and therapeutic indication will be under the regulation of Directorate General of Drug Administration.

b. The manufacture and import of the aforementioned Food or Nutritional or Herbal or Natural supplements will be in pursuance of the set directives of the Directorate General of Drug Administration. The manufacture of such products will be according to enforced GMP and quality control prerequisites of the National Regulatory Authority. The unapproved manufacture, import, distribution, storage and sales of such products are prohibited and will be tantamount to punishable offences.

4.21 Import of medical devices and surgical equipment

a. Medical devices and surgical equipment are installed/connected inside and outside the body for diagnosis, treatment or prevention of diseases, will be sustained under the regulation of Directorate General of Drug Administration.

b. GMP certificates issued by the regulatory authority of the manufacturing countries (under the circumstance where the concerned country does not have process to issue GMP

certificate in that case certificate/registration certificate from proper authority) must be submitted to import medical devices and surgical equipment.

c. 'Registration Guideline for Medical Devices, Bangladesh 2015'formulated by DGDA will be followed in case of registration of imported medical devices and surgical equipment.

4.22 Clinical trial and Bio-equivalence studies of drugs

Bioequivalence studies are being essential to be ensured about the quality and effectiveness of drugs, for this purpose an initiative will be taken to quickly establish a globally accredited Bioequivalence Study Centre and Clinical Trial Centre. In this respect, the public and private enterprises will be encouraged. For conducting the activities of Bioequivalence Study and Clinical Trial, the guideline formulated by the Directorate General of Drug Administration should be followed. The guidelines will be updated with time.

4.23 Assist the expansion of Pharmaceutical Industry of Bangladesh in the light of WTO/TRIPS agreement

a. The old drug patent law will be refurbished for public benefit. The pharmaceutical sector of the country will be prepared in the light of the World Trade Organization's Intellectual Property and Trade Laws or TRIPS Agreement.

b. Herbs and other plants used as medicine that are innate and grown within the geographical boundaries of the country, medicinal substances of them and their formula are part of our culture and heritage as well as legally our medicinal assets.For the protection of national assets and public health, initiative at government level will be taken to achieve intellectual property right.

4.24 Transformation to Directorate General of Food and Drug Administration and rearrangement of its Organizational Structure

a. For public health protection, with the necessary amendment of the existing law, 'Directorate General of Drug Administration' will be transformed to 'Directorate General of Food and Drug Administration', taking into consideration the importance for proper regulation of the manufacture, import, quality control, storage , sale , and distribution of different categories of medicine related processed food along with the medicines.

b. Medicine related processed food, food supplement, nutraceuticals, prebiotics, probiotics, medical devices and surgical equipment, vitamin premixes will be under the regulation of this proposed Directorate General.

c. Medicine related cosmetic products that claim to bring physiological changes in the body will be under the regulation of Directorate General of Drug Administration.

4.25 Ensuring of waste disposal by Drug manufacturer for prevention of environmental pollution

a. All recognized system of medicine manufacturing factories must have waste disposal management system for public health protection and prevention of environmental pollution.

b. Drug manufacturing companies that have factories at present in residential areas must relocate within the next five years to industrial or non-residential areas to reduce environmental pollution.

c. All drug manufacturing establishments must have Effluent Treatment Plants (ETP). The installation of incinerators for disposal of solid wastes will be encouraged; however, the approval of utilization of incinerators of other establishments for such disposal can be given.

4.26 Drugs used in treatment of livestock and fish

a. Appropriate quality control measures as per GMP guideline will be undertaken to manufacture drugs used for treatment of livestock.

b. Indications of use have to be specified on the label, literature, and packaging of drugs used in the treatment of livestock and fish and drugs that are used in livestock will be discouraged from being used in fish.

c. In addition to discouraging the use of Veterinary Medicinal Product (VMP) in fish, instruction will be given to the pharmaceutical companies to increase the production of Aquaculture Medicinal Product (AMP) for the treatment purpose.

4.27 Cancellation of drugs harmful for public health

a. Amendment of indications, dose, strength /potency, and dosage forms will be done evaluating the safety of drugs at periodic intervals for of all system of drugs in accordance with specific procedures.

b. All drugs declared harmful by international organizations such as: WHO, USFDA, UKMHRA, TGA, Australia, Health Canada, EMEA and similar international reputed drug regulatory authorities will be subjected to cancel the registration evaluating by Drug Control Committee (DCC).

c. Allopathic, Ayurvedic, Unani, Herbal, Homeopathic and Biochemic system of drugs that are harmful to public health will be cancelled the registration by re-evaluation of Drug Control Committee (DCC).

5Conclusion

National Drug Policy 2016 has been formulated upon review of National Drug Policy 2005. In this National Drug Policy, well-defined directives for drug safety, efficacy, rational use, effective drug control management, production, marketing, distribution, storage and import-export. This drug policy will facilitate further growth and expansion of the pharmaceutical sector, enhance capabilities of production of better quality drugs, and also augment the scopes and opportunities for drug export in many folds.