Act No. 29 of 2023

An Act to Regulate the Manufacture, Import, Export, Buying and Selling, Stocking, Storage, Display, Distribution and Quality Control of Drugs and Cosmetics Repealing the Drugs Act, 1940 And the Drugs (Control) Ordinance, 1982.

WHEREAS it is expedient to regulate the manufacture, import, export, sale, storage, display, distribution and quality of drugs and cosmetics and to prevent criminal activities in connection therewith: and

WHEREAS it is expedient and necessary to update Drugs Act, 1940 (Act No. XXIII of 1940) and Drugs (Control) Ordinance, 1982 (Ordinance No. VIII of 1982) and enact a new law:

Therefore, it is hereby enacted as follows:

CHAPTER 1
INTRODUCTORY

1. Short title and Commencement:
(1) This Act shall be called the Drugs and Cosmetics Act, 2023.
(2) It shall come into force at once.

2. Definitions: In this Act, unless there is anything repugnant in the subject or context:
(1) **"Directorate"** means the Directorate General of Drug Administration (DGDA) as referred to in section 4;
(2) **"standard quality"** means the standard quality as defined in section 36;
(3) **"appeal"** means the appeal referred to in sections 19, 27 and 64, as the case may be;
(4) "**manufacture"** in relation to any drug includes any process or part or stage of process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug with a view to its sale and distribution;
(5) **"Drug"** includes-
(a) Vaccines for internal or external use in humans or animals and all kinds of drugs, including biological drugs, and all kinds of substances useful for the treatment and medication, cure or prevention of human or animal diseases;
(b) Medical Devices;
(c) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human
beings or animals;
(d) any substance, mentioned as monograph in any of the editions of the British Pharmacopoeia, the United States Pharmacopoeia, the National Formulary of the United States, European Pharmacopoeia or in any International Pharmacopoeia;
(e) any substance of unani, ayurvedic, herbal, homoeopathic or biochemic system of drug or any substance used for preparing the same;

(f) dietary supplement, herbal supplement, nutritional supplement, medical nutrition or therapeutic nutrition or foodstuff or food supplement; And
(g) any other substance which the Government may, by notification in the official Gazette, declare to be a drug for the purposes of this Act;
Explanation. —As mentioned in this clause—
(a) "dietary supplement", "herbal supplement", "nutritional supplement". "Medical nutrition", "therapeutic nutrition", "food" or "supplementary food" means vitamins, minerals, Amino Acids Other than Tobacco Herbs and Botanical Extracts, Prebiotics, Probiotics, symbiotics, pharmabiotics or units of enzymes or preparations of combined substances, which are administered in the form of pharmaceutical dosages and which contribute to the prevention,cure, body composition or function of human or animal diseases; and
(b) "biological drugs" means any such drug, in which any such active ingredients exist that are manufactured or extracted from a biological living system and for which biological tests including physicochemical tests are required;
(6) **"Drug Courts"** means the Drug Courts referred to in section 62;
(7) **"Drugs Control Committee"** means the Drugs Control Committee constituted under section12;
(8) **"Cosmetics"** means rubbing, pouring, spraying, or cosmetics related to drug that claims to effect any biological change in the human body or human body thereby;
(9) **"Committee"** means any committee referred to in section 12, and shall include sub- committees;
(10) **"Company"** means any company formed and registered under the Companies Act, 1994 (Act No. 18 of 1994);
(11) **"Clinical trial"** means any new method in humans or animals clinical, pharmacological, pharmacodynamics, pharmacokinetics and bioavailability test or bioequivalence test of drug or researched new drug, through which the adverse reactions, safety, effectiveness and tolerance of the drugs are determined by the data obtained.
Explanation. —As mentioned in this clause—
(a) "bioavailability test" means the determination of the rate and quantity of a drug in the human or animal body which is present in the circulatory system;
(b) "bioequivalence test" means a standardized drug test under the same conditions and administration to determine the variation in the rate and amount of absorption of the active ingredient of a drug relative to the rate and amount of absorption of the active ingredient;
(12) **"Good Manufacturing Practice (GMP)"** means the pharmaceutical manufacturing and quality control practices set out in the World Health Organization guidelines;
(13) **"drug analyst"** means any drug analyst appointed under the provisions of section 51;
(14) **"Schedule"** means the Schedule to this Act;
(15) **"counterfeit drug"** or **"counterfeit cosmetics"** means any drug or cosmetics of the nature mentioned in sub-section (2) of section 38;
(16) **"registration"** means under section 22 or 32, as the case may be, of drugs or cosmetics registration;
(17) **"sub-standard"** means not of standard quality;
(18) **"prescribed"** means the prescribed by rules or with the written order notification ofDirectorate, as passed with prior approval of Government;

(19) **"new drug"** means-
(a) a drug or an active substance of a drug which is not registered by the Licensing Authority or not recommended by the Drugs Control Committee;
(b) different amounts or different dosage forms of a registered drug; or
(c) Composed or collective dosages of multiple drugs already registered separately as drugs:
(20) **"Laboratory"** means the National Drugs Control Laboratory referred to in section 10, and shall also include Drugs Laboratory;
(21) **"animal"** means other than human beings, all living thing, birds, bees, reptiles and other aquatic animals including fish and any other animals as time to time declared by the Government, by notification in the Official Gazette;
(22) **"Pharmacovigilance"** means the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine related problem;
(23) **"Pharmacist"** means pharmacist registered with the Register of Bangladesh Pharmacy Council as category "A" pharmacists;
(24) **"Criminal Procedure Code"** means the Code of Criminal Procedure, 1898 (Act No. V of 1898);
(25) **"rules"** means rules made under this Act;
(26) **"advertisement"** means any notice, leaflet, circular or document, displayed in any open place or inside or outside public transport or published or circulated in any newspaper, magazine, radio, television, online media or any other medium and any announcements, whether presented orally or by any other means of light or sound, and shall include any commercial circulars, inserts and levels;
(27) **"person"** means any individual, company, association, partnership. It shall also include statutory or other bodies or establishments or their representatives;
(28) **"Counterfeit Drugs"** or **"Counterfeit Cosmetics"** means the drugs or cosmetic mentioned in sub-section (2) of section 39;
(29) **"vaccine"** means any antigenic substance prepared from a disease-causing organism or alternative synthetic agent and which confers immunity against one or more diseases;
(30) **"Director-General"** means the Director-General of the Directorate General of Drug Administration;
(31) **"marketing authorization certificate"** means the marketing authorization certificate granted under sub-section (2) of section 22;
(32) **"Misbranded Drugs"** or **"Misbranded Cosmetics"** means any kind of drug or cosmetics mentioned in sub-section (3) of section 37;
(33) **"medical device"** means—
(a) any instrument, apparatus, implement, machine, appliance, implant, diagnostic reagent (in vitro, in vivo and in silico reagent), software or similar or related product, which, singly or in combination, relates to the treatment of human beings or animals under any of the following or Used for multiple purposes, namely: -

I. in the diagnosis, prevention, monitoring or treatment or alleviation of disease;
II. detection, monitoring, alleviation or compensation of injury
III. anatomy or physiological process, investigation, replacement, modification or in assistance;

IV. To preserve life or vitality:
V. As a birth control or pesticide device;
VI. to provide information through examination and analysis of samples collected from human or animal bodies, the desired function of which by pharmacological, immunological or metabolic action does not occur; And

(b) any device and diagnostic reagent declared by notification in the Official Gazette, by the Government, for carrying out the purposes of this Act;

(34) **"license"** means a license for drugs or cosmetics referred to in section 14 or 31, as the case may be;

(35) **"License Agreement"** means a license agreement executed between a manufacture of drugs within Bangladesh having a license issued by the licensing authority, and another local or foreign drugs manufacturing entity;

(36) **"Licensing Authority"** means the Director-General.

3. **Superiority of law**—Notwithstanding anything to the contrary contained in any other law for the time being in force, the provisions of this Act shall prevail.

CHAPTER II
DIRECTORATE, DIRECTOR GENERAL, NATIONAL DRUGS CONTROL LABORATORY , ETC

4. **Directorate General of Drug Administration**— To fulfill the objectives of this Act, the existing Directorate General of Drug Administration shall continue to exist as if it had been established under this Act.

5. **Office of the Directorate**— (1) The head office of the Directorate shall be located in Dhaka.

(2) Government, as the case may be, set up its connecting office at any Division, District, Upazila or at any other place of Bangladesh.

6. **Functions of the Directorate**—The functions of the Directorate shall be as follows, including:

(a) Licensing of establishments involved with manufacturing, sale, importing and exporting of drugs and cosmetics;

(b) registration of drugs and cosmetics and issuance of marketing authorization certificates;

(c) Market supervision and regulation of Drugs;

(d) Controlling cosmetic manufacture, distribution, quality, inspection, supervision and export;

(e) implementation of pharmacovigilance activities;

(f) inspection, supervision and control of establishments manufacturing and selling drugs and cosmetics;

(g) approval and monitoring of clinical trials;

(h) taking necessary measures including monitoring the activities of drug laboratories;

(j) activities related to release of lots of vaccines;

(j) taking measures relating to the determination and control of the quality of drugs;

(k) performing any other duties as time to time assigned by the Government; and

(l) any legal measures as may be necessary for the performance of the above-mentioned functions.

7**. Director General**— (1) There shall be a Director General at Directorate General of Drug Administration‟s office.
(2) The Director General shall be appointed by the Government and his terms and conditions of service will be determined by the Government.
(3) The Director General shall be the Chief Executive Officer of the Directorate.
(4) If the post of Director General becomes vacant, or if the Director General is unable to perform his duties due to absence, illness or any other reason, the Additional Director General of the Directorate or any other official as assigned by the Government shall act until the newly appointed Director General takes over the vacant post or until the Director General is again fit to perform his duties.

8. **Powers and functions of Director General**— (1) The Director General shall manage all the administrative and financial functions of the Directorate for the purposes of this Act and shall exercise the powers, and perform the functions assigned to him in accordance with this Act and the Rules.
(2) Without prejudice to the provisions of sub-section (1) the Director General may perform any duties as time to time assigned by the Government.

9. **Delegation of powers**—The Director General if necessary, by written order, may delegate any of his powers or duties to any of the employees subordinate to him.

10. **National Drugs Control Laboratory, Drugs Laboratory, etc.** —
(1) For the purpose of quality control of drugs, there shall be a laboratory in Dhaka under the Directorate, which shall be known as National Drug Control Laboratory (NDCL).
(2) The Laboratory as referred in sub-section (1), will carry out drugs related examination, analysis, evaluation, and all other tasks as time to time allocated by the government and the Directorate including and research works.
(3) Other than the laboratory referred to in sub-section (1), there will be Drug Testing Laboratories (DTL) in different parts of Bangladesh, as may be required.
(4) The functions of the laboratories mentioned in sub-sections (1) and (3) and ancillary matters including management, recruitment of employees etc shall be determined by the rules.

11. **Recruitment of Employees**— The Government, for the smooth operation of the Directorate, as per the organizational structure approved by the authority, the required number of employees may be appointed and their conditions of employment shall be determined by the rules as applicable.

12. **Constitution of Drugs and Cosmetics Control Committee and Subcommittee and determination of their Scope of Work, etc.** — (1) The Government may, for carrying out the purposes of this Act, by notification in the Official Gazette, constitute a committee called the Drugs Control Committee, including such number of other committees and sub-committees as may be necessary and determine their tenure, functions and other ancillary matters.
(2) The Government may, for the purpose of carrying out the purposes of this Act, by notification in the Official Gazette, constitute a committee called the Cosmetics Control Committee and such number of other committees and sub-committees as may be necessary and prescribe their tenure, functions and other ancillary matters.

13. **National Drug Advisory Council** — (1) The Government shall constitute a National Drug Advisory Council, consisting of a Chairman and such number of members as it may think fit from time to time.

(2) The National Drug Advisory Council shall advise the Government on the following matters, namely: - (a) implementation of the National Drug Policy formulated by the Government;
(b) Development of domestic pharmaceutical industry and production of drugs to meet the needs of the country Supply;
(c) to fulfill the purpose of clause (b) to publish a list declaring certain drugs from among allopathic, Ayurvedic, Unani, homeopathic and biochemical and herbal and veterinary drugs as „essential drugs" and to update the said list every two years;
(d) Import of drugs and raw materials;
(e) Coordinating the activities of different government agencies and ministries and individuals involved with production, import, distribution and sale drugs; and
(f) Any other matter as considered necessary and incidental in emergency situations.
(3) The Government shall, by notification in the Official Gazette, prescribe the constitution, tenure and functions of the National Drug Advisory Council.

CHAPTER III
LICENSING OF DRUGS, ETC.

14. **Obtaining license for manufacture, sale, stocking, distribution or display for the purpose of sale of drugs**— (1) No person or establishment shall manufacture, stock, distribute, sale or advertise for sale any drugs without obtaining a license from the Licensing Authority or in violation of the conditions imposed in the license:
Provided that nothing in this section shall, subject to the prescribed conditions, apply to the manufacture of a drugs in small quantities solely for the purposes of research, analysis or medical studies:
Provided further that, without the prior approval of the Licensing Authority, no new project or extension of an ongoing project of a manufacturing unit shall be accepted.
(2) No person or establishment shall use internet or web based platforms for selling, stocking, distributing or displaying for the purpose of sale of any drugs without having the license from the Licensing Authority or outside the conditions imposed in the license.
(3) Any person or establishment shall not dishonestly store drugs for the purpose of creating an artificial shortage of drugs in the market with an intention to make unfair profit.
(4) Eligibility to obtain license, application for license and license renewal, approval and rejection of application, license and license renewal fee and other related matters including license conditions shall be determined by the rules:
Provided that the Government, from time to time, by notification in the Official Gazette, licenses and license renewal fee and, as the case may be, late fee may be rescheduled.

15. **Expiration and renewal of license**-(1) The license shall be valid for 2 (two) years from the date of issue and shall be renewable.
(2) An application for license renewal shall be made to the Licensing Authority within no more than 90 (ninety) days before the expiry date of the license.

16. **Procedure to be followed by the Licensing Authority in granting and renewing licenses**— (1) The Licensing Authority shall, for the purpose of granting or renewing licences, inspect, as necessary, the premises of establishments for manufacturing and selling drugs and, in accordance with this Act and Rules, grant licenses only in favor of those premises which shall be deemed fit or, as the case may be, renew the licenses.

(2) The power to grant or refuse any applications for licenses or renewals of licences shall be vested upon the Licensing Authority.

17. **Good practices related to production and quality control, distribution, supply and storage of drugs**— (1) The establishments manufacturing or selling drugs in their production, quality control, distribution or supply and storage of drugs should follow the Good Practices (GxP) guidelines of the World Health Organization.

(2) The Government may formulate new guidelines related to drug manufacturing, quality control, distribution or supply and storage in light of the guidelines as time to time prepared by the World Health Organization and any other recognized international organizations. by followed guidelines can formulate.

18. **Cancellation of license, temporary suspension, etc.** (1) The Licensing Authority may cancel or, as the case may be, suspend the license of a drug for any of the following reasons. If the licensee—

(a) violates or contravenes this Act or the rules or any condition of the license;

(b) fails to manufacture the drug following Good Manufacturing Practices (GMP);

(c) provides any false information or withhold any material information in obtaining the license;

(d) uses the license for any purpose other than establishing or operating a factory or establishment for the purpose of manufacturing and processing drugs;

(e) alters the physical infrastructure of the premises of the concerned establishment without obtaining the prior approval of the Licensing Authority in a manner which adversely affects or is likely to affect the quality of the product; or

(f) does not comply with any prescribed conditions.

(2) Before canceling or suspending any license under sub-section (1), the licensing authority shall issue a show-cause, if any, notice to the concerned licensee specifying the reasons and time limit.

(3) After receiving the written reply to the notice given under sub-section (2), if the said reply is not satisfactory, the Licensing Authority may, after recording the reasons, cancel the license or temporarily suspend the license for such period as it thinks fit and immediately stop the production of the drug by the concerned establishment.

(4) If the written reply referred to in sub-section (2) is satisfactory, the Licensing Authority shall discharge the licensee from the charges brought against him.

19. **Reconsideration or appeal against the order of temporary suspension of license and stoppage of production**— (1) If the license is temporarily suspended by the licensing authority under section 18 and the production of drug of the concerned establishment is stopped, the licensee, within 30 (thirty) working days, can apply for reconsideration of the decision before the Licensing Authority or can file an appeal before the government.

(2) In the revision or disposal of the appeal referred to in sub-section (1) the concerned authority shall give its decision after giving an opportunity of hearing to the licensee.

(3) The decision rendered by the Licensing Authority or, as the case may be, the Government on disposal of the revision or appeal shall be final.

20. **Production of Drugs under License Agreement, etc**.— (1) The Licensing Authority may, subject to the conditions necessary for the protection of public interest, grant permission to manufacture drugs within Bangladesh to any foreign establishment under a license agreement executed with any pharmaceutical manufacturing establishment of Bangladesh:

Provided, however, that before granting such permission, the Licensing Authority shall be satisfied that any drug researched by the said drug manufacturing company is registered under the same trade name in any country as mentioned in sub-section (3) of section 41.

(2) A drug manufacturing company in Bangladesh may be granted permission to manufacture drugs under a written agreement with a drug manufacturing company of the same type.

(3) A foreign company that does not have a pharmaceutical manufacturing plant in Bangladesh can manufacture all recognized drugs under contract manufacturing or loan license only for the purpose of export:

Provided that the drugs manufactured is in no way can be marketed locally.

(4) The Licensing Authority, in granting approval under this section, can impose such conditions as it thinks fit if it feels it is necessary for protecting public health.

(5) The Licensing Authority may, notwithstanding anything contained in this section, withdraw the approval granted to a foreign drugs manufacturer in respect of the manufacture of any drug if it is considered necessary to avoid any adverse effect on public health.

Explanations-

(a) **"Loan License"** means a license issued by the Licensing Authority in favor of any person or establishment which does not have its own facilities or facilities for the manufacture of drugs, but is owned by another licensee for the manufacture of drugs.

(b) **"Contract manufacturing"** production contracts executed between foreign companies who do not have pharmaceutical factories in Bangladesh and pharmaceutical manufacturing companies of Bangladesh who have such units and establishments in Bangladesh for manufacturing approved drugs only for export purpose.

21. **Amendment of license agreement executed with foreign entity**— (1) If any license agreement entered into by a foreign entity with a Bangladeshi entity for the manufacture of drugs within Bangladesh contains any provisions contrary to national interest, the licensing authority may direct the said entity to amend the relevant provisions of the agreement.

(2) If the entity concerned fails to comply with the directions given under sub-section (1), the Licensing Authority can cancel the license granted for the manufacture of drug in favor of the said establishment.

CHAPTER IV
DRUG REGISTRATION, MARKETING AUTHORIZATION CERTIFICATE, ETC

22. **Drug registration and marketing authorization certificate, etc.** — (1) No person or establishment shall manufacture, import, export, sale, distribute, store or exhibit any drug without obtaining registration from the Licensing Authority.

(2) Notwithstanding anything contained in sub-section (1), the Marketing Authorization Certificate shall be obtained from Licensing Authority before the distribution, marketing and sale of any registered drugs.

(3) The Licensing Authority shall not register any drug without the recommendation of the Drugs Control Committee.

(4) Notwithstanding anything contained in sub-section (3), in case of sudden calamities, epidemics, public health and national emergencies, without the prior recommendation of the Drugs Control Committee, the registration certificate of a drug shall be granted, subject to the prescribed conditions:

Provided that, after such registration, within a maximum of 90 (ninety) days, the same shall be submitted for recommendation to the Drugs Control Committee.

(5) Eligibility to obtain registration, application for registration and renewal of registration, application granted conditions of disallowance and registration and other related matters shall be determined by the rules.

(6) Notwithstanding anything contained in sub-section (5), the licensing authority, in registration of any drug, may, where appropriate, impose such conditions as it deems fit in the public interest. (7) Anyone applying for the registration of a drug and marketing authorization certificate shall submit necessary supporting documents to establish in the satisfaction of licensing authority that they meet required quality standard, safety and efficiency.

(8) No person or establishment shall sell or distribute any drugs unless the brand or generic name of the said drug is approved by the licensing authority.

(9) If a brand name of drug is marketed by more than one company, the ownership of such brand name shall be vested in the company which obtained the registration first.

(10) The licensing authority may seek submission of the information related to the clinical trial or bioequivalence study for registration of a certain drugs.

(11) The Licensing Authority may require any manufacturing establishments to put special identification marks for certain drugs, during the packaging, in order to prevent duplication or counterfeiting.

(12) For the purpose of registration of homoeopathic and biochemical drugs, if the Government, by notification in the Gazette, specifies the pharmacopoeia of any specific country, in which particular standards have been adopted for the methods of preparation and use of homoeopathic and biochemical drugs, the licensing authority shall follow such standards.

(13) For the purpose of registration of Unani, Ayurvedic and Herbal drugs, the Licensing Authority shall follow such standards as may be prescribed by the Government.

23. **Registration and Duration of Marketing Authorization Certificate** - (1) Registration of drugs shall remain valid and effective for 5 (five) years.

(2) Registration shall be renewable and an application for renewal of registration shall be made within not later than 90 (ninety) days before the expiry, in accordance with the provisions of this Act.

(3) The power is vested with Licensing authority to grant or reject application for renewal of registration.

(4) Marketing Authorization Certificate shall remain in force and effect for the entire validity period of the registration of a drug.

24. **Registration and registration renewal fees, etc.** (1) The fee for registration and renewal of registration of drugs and, as the case may be, late fee, shall be prescribed by rules:

Provided that the Government may, from time to time, by notification in the Official Gazette, re-fix the said fees.

(2) The Licensing Authority shall not register or, as the case may be, renew the registration of any drugs unless the prescribed fee is paid in accordance with sub-section (1).

25. **Cancellation or suspension of registration**— (1) The Licensing Authority may, upon the recommendation of the Drugs Control Committee, cancel the registration of any drug.

(2) Notwithstanding anything contained in sub-section (1), if the Licensing Authority is satisfied that any drug is substandard, fake, adulterated, misbranded or the facilities required for its

manufacture are not up to standard, the registration of the drug concerned shall be cancelled, suspended or stopped production and suspend marketing.

(3) The Licensing Authority shall, before canceling or suspending the registration of any drug under sub-section (2), give show-cause notice to the relevant person or establishment with proper reasons and time limit for reply.

(4) After receiving the reply to the notice given under sub-section (3), if the said reply is not satisfactory, the Licensing Authority may, after recording the reasons, cancel the registration of the concerned drug or suspend the registration of the concerned drug for such period as the Authority deems fit.

(5) If the reply mentioned in sub-section (3) is satisfactory, the Licensing Authority shall exonerate the person or establishment from the charges brought against, and other consequential orders shall be withdrawn.

26. **Withdrawal from the market, destruction, stoppage of sale or suspension of marketing, etc**.— (1) In case of cancellation or temporary suspension of the registration of substandard drug or drugs, the licensing authority may issue necessary orders for the withdrawal of such drugs from the market.

(2) If the use of a registered drug causes any harmful reaction in human or animal body or if any human or animal dies as part of the reaction, the Licensing Authority may, forthwith, order the suspension of the sale and marketing of the drug concerned until further orders.

(3) After issuing the order under sub-section (2) subject to the confirmation of the harmful reaction through the test and analysis report of the concerned laboratory or any other means or method, if the licensing authority issues an order to withdraw the drug from the market and destroy it, the concerned authority shall destroy the same and inform the licensing authority accordingly.

27. **Revision or appeal against order of suspension of registration, and suspension of manufacturing and marketing of drugs** — (1) If the registration of any drug under section 25 is temporarily suspended by the Licensing Authority and the production and marketing of the said drug is suspended, the person or establishment concerned shall within 30 (thirty) working days apply to the Licensing Authority for reconsideration of the said order or may file an appeal to the Government.

(2) In case of the revision or disposal of the appeal referred to in sub-section (1), the concerned authority shall give its decision in the matter after giving an opportunity of hearing to the parties concerned.

(3) The decision given by licensing authority or, as the case may be, the Government during the disposal of the revision or appeal, shall be considered as final.

28. **The functions of Drugs Control Committee in drugs registration, and cancellation or suspension of drugs registration**— (1) The duties and functions of the Drugs Control Committee for carrying out the purposes of this Chapter shall be as follows, namely—

(a) recommending the registration of new drugs, to assess the safety, effectiveness and utility of the drug concerned; and

(b) making recommendations for cancellation or suspension of registration of drugs, evaluation of registered or registrable drugs and evaluation of drugs that may be manufactured or imported, for the purpose of ascertaining the safety, effectiveness and usefulness of drugs.

(2) After the evaluation under sub-section (1), if it appears to the Drugs Control Committee that

the drug concerned is safe, useful or effective for use, it shall make a recommendation to the Licensing Authority for the registration of the drug concerned, and if it is found not to be safe, useful or effective, recommend to the Licensing Authority for cancellation or temporary suspension of the registration of the said drug.

29. **Publication of list of registered drugs** — The Directorate shall, on its website, publish the list of registered drugs with prescribed information and, from time to time, update the said list.

30. **Fixation of Price of drugs and raw materials** — (1) The Government may, by notification in the Official Gazette, fix the maximum retail price of drugs listed and imported under sub-section (2).

(2) The Government may, for the purpose of sub-section (1), fix the maximum retail price of any drug, and prepare a list thereof and publish it by notification in the Government Gazette.

(3) the Government may, by notification in the Gazette, set the maximum selling price of any local raw materials.

(4) No person or establishment can supply and sale drugs or raw materials at a price higher than the price fixed under this section.

CHAPTER V
COSMETICS, ETC.

31. **License for Cosmetics**— (1) No person or establishment shall produce, distribute, import or export cosmetics without obtaining a license from the licensing authority or outside the conditions imposed in the license.

(2) Details eligibility criteria for obtaining license, application for license and renewal, rules relating to granting of application or disallowance, license and license renewal fees and other matters relating thereto, including license conditions shall be determined by rules:

Provided that, pending the making of rules, the Directorate may, with the prior approval of the Government, by issuing orders make necessary provisions in the said matter:

Provided further that the Government may, from time to time, by notification in the Official Gazette, revise the license renewal fee and, as the case may be, the late fee.

32. **Registration of Cosmetics** - (1) No person or establishment shall manufacture, distribute, import or export any type of cosmetics without obtaining registration from the licensing authority.

(2) Eligibility for obtaining registration, applications for registration and renewal of registration, approval and rejection grounds of applications, registration and registration renewal fees and other matters relating thereto, including conditions of registration, to be prescribed by rules.

Provided that, pending the making of rules, the Directorate may, with the prior approval of the Government, by issuing orders, make necessary provisions in the said matter:

Provided further that the Government may, from time to time, by notification in the Official Gazette, regulate the registration and registration renewal fees and, as the case may be, late fees.

33. **Special provisions regarding manufacture, distribution, import and export, etc. of existing cosmetics** -(1) The existing factories or business establishments concerned with the manufacture, distribution, import and export of cosmetics shall make an application to the licensing authority for license and registration, as the case may be, within 6 (six) months from the issuance of rules or, as the case may be, orders under this Act.

(2) On receipt of an application under sub-section (1), the Licensing Authority shall, subject to

the provisions of section 31 or 32, as the case may be, take measures to dispose of the application concerned.

34. **Application of section 48** — To fulfill the purpose of this chapter the provisions relating to the powers of the inspector as provided in the ninth chapter, so far as applicable, shall be applicable for the execution and implementation of provisions of sections 31, 32 and 33.

35. **Standardization, regulation, application, etc. of Cosmetics**— (1) The Government, in carrying out the purposes of this Act, will prescribe and regulate the standards of cosmetics, laboratories, analysts and their reports, advertising and identification of misbranding, counterfeit, adulterated and spurious and other incidental matters thereto under the rules, as to be legislated.

Provided, however, that in determining the quality of cosmetics the standard as currently exist in Bangladesh, and set by international organizations and countries including EU, USFDA and ASEAN can be followed as standard.

(2) No one except the doctors registered under Bangladesh Medical and Dental Council (BMDC) or under the direct supervision of such a doctor can inject or otherwise insert Filler, Botox, Glutathione or similar cosmetics into a human body.

(3) The Government may, by rules, make necessary provisions regarding the application and use of cosmetics by beauty parlors to prevent misuse and abuse of cosmetics in beauty parlors.

CHAPTER VI
STANDARD QUALITY OF DRUGS AND MISBRANDED, FAKE AND ADULTERATED DRUGS OR COSMETICS, ETC

36. **Standards of quality of drugs** - (1) No person or establishment shall manufacture, sale, store, distribute, display or import for the purpose of sale any substandard drug, which is not of standard quality.

(2) No person, in selling a substandard quality of drugs, shall, as the proprietor or representative, give any assurance to the purchaser that the consumption or use of the said drug will not result in any harm and thereby it will not contravene any provision of this Act.

(3) For the purposes of this section, standards of quality mean—

(a) in respect to any drugs including Unani, Ayurvedic, Homoeopathic and biochemical or herbal drug, the standard as prescribed by the Government; and

(b) In case of other drugs, the standards would be standards set out in the latest 5 (five) editions of the Official Compendia or, in absence of specific monographs for any drug in the Official Compendia, the general guidelines set out in the Official Compendia or the specifications laid down by the Inventor.

Explanation: In this clause "Official Compendia" means the British Pharmacopoeia, United States Pharmacopoeia, United States National Formulary, European Pharmacopoeia or recognized International Pharmacopoeia.

37. **Misbranded drugs or misbranded cosmetics** — (1) No person or establishment shall manufacture, sell, store, distribute or exhibit for sale any misbranded drugs or misbranded cosmetics.

(2) The Licensing Authority shall preserve the brand names of drugs and cosmetics, and hence shall not approve any misbranded drug or misbranded cosmetics.

(3) For the purposes of this section, any drugs or cosmetics shall be deemed to be misbranded,

if-
(a) if it is so coloured, coated, powdered or polished that damage is concealed, or if it is made to appear of better or greater therapeutic value than it really is; or
(b) it is not labeled in the prescribed manner;
(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular; and
(d) its brand name is similar to or sounds similar to or appears similar to any existing brand name, by which the user of the said drug or cosmetics is likely to be deceived.

38. **Counterfeited drugs or cosmetics**— (1) No person or establishment shall manufacture counterfeit drugs or cosmetics or knowingly sell, stock, distribute or exhibit for sale any counterfeit drugs or cosmetics.
(2) For the purposes of this section, the following drugs or cosmetics shall be deemed to be counterfeit or falsified or spurious, if:
(a) with the intention of counterfeiting, using of bottles, strips, foil, label, monogram, logo, etc of a well-known brand or commonly used drugs or cosmetics, and imitating it in such a way that outwardly the said drug or cosmetic appears to be the original drug or cosmetic;
(b) it is a substitute for or similar to any other drug or cosmetic, by which the public is likely to be deceived;
(c) if it purports to be the product of a place or country of which it is not truly a product;
(d) if it is imported under a name which belongs to another drug; or
(e) if the label or container bears die name of an individual or company purporting to be the manufacturer or producer of the drug, which individual or company is fictitious or does not exist.

39. **Adulterated drugs and cosmetics** — (1) No person or establishment shall produce adulterated drugs or cosmetics, or display the same for the purpose of sale, stock, or distribution.
(2) For the purposes of this section, any drug or cosmetics shall be deemed to be adulterated, which is used or sold or knowing that it may be sold or used, willfully or dishonestly, for the purpose of obtaining unjust profit, or any substance, material or substance which is hazardous or otherwise any substance, material or ingredient so mixed or removed in such a way as to reduce the effectiveness or alter the effectiveness of the said drug or cosmetic or otherwise cause harm to body or endanger life.

40. **Prohibition on sale of certain drugs** —No person or establishment shall sell or, where applicable, store or display for sale the following drugs, namely:
(a) Government drugs;
(b) expired drugs and drugs banned by the Government;
(c) Drugs such as physician samples; or
(d) Antibiotics or any other drug except over the counter drug without a prescription from a registered physician.

CHAPTER VII
PROHIBITION ON IMPORT AND EXPORT OF DRUGS

41. **Prohibitions on importation of certain drugs** — (1) No person or establishment shall import any drugs without having license from authority or acting in breach of the conditions as

laid down in the license granted.
(2) No registered drug shall be imported without the prior approval of the Licensing Authority.
(3) The Licensing Authority shall not grant registration or license for the purpose of importation of any drug for human or animal use unless the drug has been registered under the same brand name in those countries, a list of which (countries) may be published by the Government from time to time.
(4) Nothing in this section shall, subject to the conditions prescribed, apply to the import of drugs in small quantities for examination, analysis, research or personal use, and to the import of drugs to meet national emergencies.
(5) The Directorate, for registration of an importable drugs, may, if necessary, visit the manufacturing units/premises or establishments for verification as to compliance with Good Manufacturing Practice (GMP).
(6) All expenses related to the inspection referred to in sub-section (5) shall be incurred by the manufacturer in the rate as time to time fixed by the Government vide rules or order, as applicable.

42. **Prohibition on procurement and importation of raw materials, and packaging materials for drugs, etc**— (1) Raw materials for the manufacture of drugs or packaging materials for drugs, shall not be procured locally or imported without the prior approval of the Licensing Authority.
(2) Without the prior approval of the Licensing Authority, no semi-finished drugs or any other substance or ingredients necessary for the manufacture of drugs shall be imported.
(3) The Directorate, for registration of raw materials for manufacturing of drugs and packaging materials, if necessary, may visit the manufacturing unit/premises of the manufacturing establishment with a view to assess whether the applicant follows Good Manufacturing Practice (GMP).
(4) All expenses related to the inspection referred to in sub-section (5) shall be incurred by the manufacturer in the rate as time to time fixed by the Government vide rules or order, as applicable.

43. **Prohibition on export of drugs without license** — (1) No drug can be exported without obtaining a license from the Licensing Authority.
(2) The licensing authority may, for the purpose of export, register any kind of drug.
(3) Notwithstanding anything to the contrary contained in this section, subject to the permission of the Licensing Authority, the provisions of sub-sections (1) and (2) shall not apply to the export or shipment out of the country of any drug in small quantities for research, analysis or personal use.

CHAPTER VIII
SUPERVISION OF QUALIFIED PERSONS INCLUDING PHARMACISTS IN THE MANUFACTURING PROCESS OF DRUGS

44. **Presence and supervision of qualified person in manufacturing process of drugs, etc.** — (1) No person shall manufacture allopathic drugs without the direct supervision of 02 (two) institutionally qualified persons mentioned in clauses (a) and (b), namely:
(a) a pharmacist; and

(b) A person holding Bachelor‟s or Master‟s degree with honors in Chemistry, Biochemistry, Applied Chemistry, Microbiology, Pharmacology, Pharmacy, Drug, Genetic Engineering or Chemical Engineering from any University or Institute recognized by the Government.

(2) No person shall prepare Unani, Ayurvedic, Homeopathic and Biochemical and Herbal drugs without the direct supervision of 02 (two) institutionally qualified persons referred to in clauses (a) and (b), namely:-

(a) A graduate degree holder in a related subject from any university or institute recognized by the government or a diploma holder with at least 01 (one) year of practical experience in pharmaceutical industry and quality control work in the related subject; and

(b) A person holding Bachelor‟s or Master‟s degree with honors in Pharmacy, Chemistry, Botany, Biochemistry, Applied Chemistry or Microbiology from any University or Institute recognized by the Government.

45. **Supervision of qualified person in sale of drugs, etc.** — (1) No person shall sell allopathic drugs as a retail dealer without the personal supervision of a pharmacist, diploma pharmacist or pharmacy technician.

(2) No person shall sell unani, ayurvedic or herbal drugs as a retailer without the supervision of a registered unani physician, ayurvedic physician pharmacist, diploma pharmacist or pharmacy technician.

(3) No person shall sell drugs of homeopathic and biochemical methods without the personal supervision of a registered homoeopathic physician.

(4) Notwithstanding anything contained in sub-sections (1), (2) and (3), the supervision of a pharmacist, diploma pharmacist, pharmacy technician, registered unani physician, ayurvedic physician or homeopathic physician shall not be required for the wholesale of drugs.

Explanation —**mentioned in this clause**:

(a) "Diploma Pharmacist" means a „B‟ category Diploma Pharmacist who is registered with the Register of Bangladesh Pharmacy Council; and

(b) "Pharmacy Technician" means a „C‟ category Pharmacy Technician who is registered with the Register of Bangladesh Pharmacy Council.

46. **Information about qualified persons** — The person or establishment engaged in drug manufacturing and selling shall provide updated information of qualified persons including pharmacists, diploma pharmacists and pharmacy technicians, as the case may be, engaged in such drug manufacturing and selling establishments, to the licensing authority.

CHAPTER IX
APPOINTMENT OF INSPECTORS, THEIR POWERS, ETC.

47. **Inspectors** —(1) The Government may, by notification in the official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for the purposes Act:

Provided that no person who has any financial interest in the manufacture, import or sale of drugs and cosmetics shall be appointed to be an Inspector under this subsection.

(2) Every Inspector shall be deemed to be a public servant within the meaning of the Pakistan Penal Code, and shall be officially subordinate to such authority as the Provincial Government may specify in this behalf.

48. **Powers of Inspector** -(1) For the purposes of section 47, an inspector may, within the local

limits for which he is appointed, and in any other area with the permission of the licensing authority—

(a) may inspect and verify the place of manufacture, manufacturing plant and production capacity, manufacturing process, equipment used for standardization and testing and analysis and related records and registers of any drugs and cosmetics;

(b) may inspect the imported raw materials and packaging materials for the manufacture of drugs and cosmetics and the archives and related records of the imported drugs and cosmetics;

(c) may inspect any place of sale of drugs and cosmetics or place of storage, display or distribution for the purpose of sale and storage arrangements and related records and registers;

(d) take samples of any drug which is being manufactured, or being sold or is stocked or exhibited for sale or is being distributed;

(e) if it appears that any offense under this Act or Rules has been committed, is being committed or is likely to be committed in any building or place or in any conveyance by land, water or air, himself or, if necessary, such assistance to the proper authorities or law enforcement agencies as he thinks necessary, shall, by receiving such assistance, enter and search the relevant buildings, places or vehicles at reasonable times and may seize or detain the relevant drugs, cosmetics and other related goods;

(f) call any person from the neighborhood to be present as witness in course of search, seizure or in connection with, any other matter where the presence of witnesses is necessary;

(g) require any person to appear before him at any reasonable time at any proper place to give statement, assistance or information relating to, or in connection with the investigation of an offence under this Act or rules made thereunder:

Provided that the exemptions mentioned in sections 132 and 133 of the Code of Civil Procedure, 1908 (Act No. V of 1908) shall apply to summons for appearance under this clause;

(h) lock and seal any factory, laboratory, shop, building, storehouse or godown or a part thereof where any drug is, or is being manufactured, stored, sold or exhibited for sale without the necessary license under this Act, or where he has reason to believe that an offence under this Act has been committed or may continue to be committed;

(i) forbid for a reasonable period not exceeding three months any person in charge of any premises from removing or disposing of any drug, article or other thing likely to be used in evidence ol the commission of an offence under this Act or any rules made thereunder; and

(j) exercise such other, powers as may be necessary for carrying out the purposes of this Act or any rules made thereunder.

(2) No person or establishment shall obstruct the inspector in the exercise of his powers under sub-section (1).

(3) The provisions of the Code of Criminal Procedure, 1H98 (Act V of 1898), in so far as they are not inconsistent with the provisions of this Act, shall apply to searches and seizures made under this Chapter.

49. **Persons bound to disclose place where drugs and cosmetics are manufactured, kept, stored, sold or distributed, etc.** — Every person for the time being in charge of any premises whereon any drug or cosmetic is being manufactured or is kept for sale or distribution shall, on being required by an Inspector so to do, be legally bound to disclose to the Inspector the place where the drug is being manufactured or is kept, as the case may be.

50. **Procedure to be followed by Inspector** — (1) Where the Inspector seizes any drug,

cosmetic or any other article under this chapter, he shall tender a receipt in the prescribed form to the person from whom he takes it.

(2) Where an Inspector takes a sample of a drug for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of (lie portions so sealed and marked:

Provided that, if the person giving the sample is absent or absconding at the time of collection of the sample or refuses to sign the sample and the form while present, the Inspector shall confirm and seal the matter himself in the presence of two witnesses:

Provided further that if any establishment is closed or sealed at the time of collection of samples, the inspector may open and collect samples in the manner described in this sub-section after taking the assistance of the said establishment, the officer-in-charge of the concerned nearest police station or the concerned Directorate or authority;

Provided further that the inspector may, if necessary, take a small portion of the sample described for the purpose of preliminary examination and examine and analyze it by an approved scientific method before taking the complete sample described in this subsection.

(3) If a sample of any drug or cosmetics is collected from a manufacturing establishment or depot, it shall be necessary to divide the collected sample into three parts only and required to be provided to the person or establishment mentioned in clauses (a), (b) and (d) of sub-section (5).

(4) Where an inspector fails to collect samples of drugs or cosmetics in sufficient quantity and it is absolutely necessary to collect samples of the drugs or cosmetics concerned, subject to the permission of the Director-General, without the division mentioned in sub-sections (2) to (3), that collect as many samples as possible and mark and, if necessary, seal them.

(5) The inspector shall, subject to sub-section (2), collect and divide samples of drugs or cosmetics and supply the parts thereof to the following persons or establishments for the purposes or reasons specified below, namely—

(a) First Part: for the purpose of preservation by the person providing the specimen;

(b) Second Part: examination and analysis by Drug Analyst or, as the case may be, Analyst Purpose;

(c) Third part: for the purpose of dispatching it to the manufacturer, importer, marketer or warrantor, if any;

(d) Fourth Part: for the purpose of presentation in the trial court.

Explanation: For the purposes of this section, „other materials‟ include registers, receipts, invoices and bills of lading, including equipment used in production, which may be considered as evidence of the commission of offence.

CHAPTER X
DRUG ANALYST, ETC.

51. **Drug analyst—** The Government may, by notification in the Official Gazette, appoint such number of prescribed qualified persons as Drug Analysts as may be required, at the place or jurisdiction specified in the notification for the examination and analysis of any class of drugs.

52. **Drug analyst's report—** (1) If the drug sample is sent to the drug analyst in accordance with clause (b) of sub-section (5) of section 50 for testing and analysis, he shall send three copies of the report prepared in the prescribed form to the concerned inspector before signing.
(2) On receipt of the report referred to in sub-section (1), the inspector shall keep one copy of the report for use in any case relating to the sample and send the remaining copies to the person providing the sample and to the manufacturer, importer, marketer or warrantor, if any.
(3) If any person applies to the trial court with evidence against the report of the drug analyst, the court may, if necessary, send the sample preserved under sub-section (2) to the inspector for re-examination and analysis and the drug analyst shall re-examine and analyze the said sample at the National Drugs Control Laboratory present before the court in the form of a report.
(4) The report received under sub-section (3) shall be considered as final evidence before the court.
(5) The cost of examination and analysis by the National Drugs Control Laboratory under sub-section (3) shall, as directed by the court, be paid by the accused person.
(6) No person or establishment shall use the report received under sub-section (1) as advertisement.

53. **Right to obtain report of drug test and analysis.—** If a person applies to the Licensing Authority or through an inspector, on payment of the prescribed fee, for the test and analysis of any drug purchased or imported, exportable or manufactured by him, he will be entitled to receive test and analysis report duly signed by the Drug Analyst.

CHAPTER XI
CRIME, PUNISHMENT, INVESTIGATION AND PROSECUTION

54. **Penalty for violation of the provisions of this Act-** If any person commits any of the acts as mentioned in column (3) in accordance with the clause mentioned in column (2) of the Schedule, the said act shall be deemed to be an offense under this Act and for the said offense he shall be liable to punishment as mentioned in column (4), or shall be punished with both penalties.

55. **Confiscation-** If any person is convicted by a court of competent jurisdiction for violation of any provision of this Act or Rules, the relevant drugs or cosmetics in respect of which this Act or Rules have been contravened including the factories, warehouses, machinery, equipment or the said drugs or cosmetics or the said drugs or items related to ingredients and materials for the manufacture of cosmetics may be confiscated by the court.

56. **Penalty for re-offense-** If a person convicted of an offense mentioned in this Act commits the same offense again, he shall be punished with double of the maximum penalty as provided in this Act for the relevant offence.

57. **Commission of offense by company-** (1) If any offense under this Act is committed by a company, it would be deemed that the said offense is directly connected with its owner, director, executive officer, manager, secretary, partner or any other officer or employee of the said company, unless he can prove that the said crime was committed without his knowledge and that he has tried his best to prevent it.

(2) Where any offense under this Act is committed by any company, if it is proved that the said offense was committed with the connivance of any owner, director, manager, secretary, partner or any other officer or employee of the company, or due to their negligence, in such case the said owner, director, manager, secretary, partner or related officer or employee shall be deemed liable and accordingly he shall be punished under relevant provision.

58**. Investigation and Investigating Officer-** (1) Without prejudice to the provisions of section 61, an officer empowered by the Director General or an Inspector deputed to the local jurisdiction may, within the prescribed manner and time limit, investigate any complaint mentioned in column (3) of the Schedule as an Investigating Officer.

(2) In conducting the investigation of any complaint under this Act, the Investigating Officer may exercise the same powers as the Officer-in-Charge of the Police Station in accordance with the provisions of the Code of Criminal Procedure.

(3) During the investigation under sub-section (1), the investigating officer may, if necessary, seek the assistance of any other agency or authority including the law enforcement agency and if such assistance is sought, the law enforcement agency or authority shall be bound to render the assistance required.

59. **Cognizance and Bailability of offences-** Notwithstanding anything contained in the Code of Criminal Procedure, mentioned in column (1) of the Schedule—

(a) Serial Nos. 2, 3, 6, 7, 8, 10, 12, 14, 16, 18, 19, 20, 22, 23, 24, 25, 26, 27, 28, 29, and 30 against provisions referred in Column (2) offenses mentioned in column (3) are non-cognizable and bailable.

(b) Serial Nos. 1, 4, 5, 9, 11, 13, 15, 17 and 21, against provisions referred in Column (2) offenses mentioned in column (3) are cognizable and nonbailable.

60. **Criminal prosecution-** Notwithstanding anything contained in the Code of Criminal Procedure, no court as referred to in sub-section (2) of section 61 shall take any matter for trial for any offense punishable under this Act except on the written report of the Director General or any officer authorized by him for the purpose.

61. **Investigation, trial, etc. of offences- (**1) The Code of Criminal Procedure shall apply to the investigation, trial and arrest or detention of the accused person and other related matters of the offense committed under this Act.

(2) Notwithstanding anything to the contrary contained in the Code of Criminal Procedure, in column (1) of the Schedule as mentioned.

(a) Serial Nos. 1, 4, 5, 9, 11, 13, 15, 17 and 21 against provisions referred in Column (2) offenses mentioned in column (3) shall be tried by the Drugs Court; And

(b) Serial Nos. 2, 3, 6, 7, 8, 10, 12, 14, 16, 18, 19, 20, 22, 23, 24, 25, 26, 27, 28, 29 and 30, against provisions referred in Column (2) offenses mentioned in column (3) shall be tried by the Chief Judicial Magistrate or Special Magistrate or, as the case may be, by the Chief Metropolitan Magistrate or Special Metropolitan Magistrate.

62. **Drug Courts-** (1) In order to carry out the purpose of this Act, there shall be one Court called Drug Court at every district for the trial of the offenses mentioned in clause (a) of sub-section (2) of section 61.

(2) Notwithstanding anything contained in sub-section (1), the Government may, if necessary, can set up more than one Drug Court in a district and determine local jurisdiction therewith.

(3) A Drug Court shall consist of one Judge, and the Government in consultation with the Supreme Court, shall appoint the Judges of the said Court from the District and Session Judges.

(4) Notwithstanding anything contained in sub-section (3), the Government may, if necessary, appoint any District and Sessions Judge as a Drug Court Judge in addition to his regular office.

Explanation- In this section "District and Sessions Judge" shall include "Additional District and Sessions Judges".

63. **Application of Mobile Courts Act, 2009-** Notwithstanding anything contained in any other law for the time being in force, in respect of an offense committed under this Act, the Mobile Court may impose punishment subject to addition of the offences within the Schedule to the Mobile Courts Act, 2009 (Act No. 59 of 2009).

64. **Appeal-** (1) A person aggrieved by an order, judgment or sentence passed by a Drugs Court or a Chief Judicial Magistrate or a Special Magistrate or, as the case may be, a Chief Metropolitan Magistrate or a Special Metropolitan Magistrate, can appeal to the court prescribed in the Code of Criminal Procedure, within 30 (thirty) days of order, judgment or sentence passed.

(2) Section 13 of the Mobile Court Act, 2009 shall be followed in case of appeal against the penalty imposed by the Mobile Court.

CHAPTER XII
CLINICAL TRIALS OF DRUGS, PHARMACOVIGILANCE, LOT RELEASE OF VACCINES, ETC.

65. **Pre-clinical trials, clinical trials, field trials, performance trials, bio-compatibility and bio-equivalence studies of drugs, vaccines and medical devices-** (1) Pre-clinical trials, clinical trials, field trials of drugs, vaccines and medical devices, performance trials and biocompatibility or bioequivalence studies can be carried out with contract research organization provided prior approval of the licensing authority is obtained.

(2) Notwithstanding anything contained in sub-section (1), the contract research organization shall not, without obtaining protocol approval from the Licensing Authority, carry out any pre-clinical, clinical, field trial or performance trial and bio compatibility study or bio equivalence study on any type of medical product including drugs, vaccines and medical devices used in treatment for human or animal.

(3) If any activity is conducted by the contract research organization without the approval of the Licensing Authority mentioned in sub-sections (1) and (2), the Licensing Authority may stop the

said activity and impose the prescribed administrative fine.

(4) In carrying out the activities mentioned in sub-section (1), the Good Clinical Practice (GCP) guidelines approved by the government or the guidelines published by the World Health Organization or recognized international standards organizations shall be followed.

(5) The Licensing Authority may, from time to time, inspect the pre-clinical, clinical, field trial or performance trial and the biocompatibility study or bioequivalence study mentioned in sub-section (2).

(6) The contract research organization to ensure the safety and rights protection of the participants in the clinical trial, subject to the approval of the licensing authority, should form Institutional Ethics Committee (IEC), Institutional Review Board (IRB) or Animal Ethics Committee (AEC).

(7) Licensing authorities may stop the activity temporarily or permanently if there is any risk to the participants during the clinical trial.

(8) Prior approval of the Directorate shall be obtained for the importation of investigational medical products and for sending any samples collected from trial participants to abroad for testing and analysis.

(9) The Directorate may accept clinical trial information or approved data received from foreign drug regulatory authorities.

(10) The Directorate may, subject to the approval of the Government, approve fast track clinical trials in case of new drugs for emergency health care or epidemic diseases. Explanation— "Contract Research Organization" means any establishment or body which, under a contract entered into with any person or body, and as per its requirements carry out pre-clinical trials, clinical trials, field trials or performance trials and bio-compatibility or bio-equivalence studies.

66. **Pharmacovigilance-** (1) The stakeholders including drug manufacturers, importers and marketers, hospitals, clinics, establishments related to public health programs and other related organizations are required to conduct pharmacovigilance activities and send related reports and data to the licensing authorities so that the side effects or adverse reactions of drugs in humans or animals can be monitored.

(2) The instructions published by the National Pharmacovigilance Guideline or Good Vigilance Practice or World Health Organization or the recognized international standard organization should be followed in conducting the activities mentioned in sub-section (1).

(3) The licensing authority shall, from time to time, monitor and inspect the pharmacovigilance activities referred to in sub-section (1).

(4) If the pharmacovigilance program is not conducted effectively, the licensing authority may temporarily suspend or cancel the license of the concerned establishment to manufacture or import drug or the registration of any drug.

67. **Release of lot of vaccines-** (1) The lot release certificates shall be obtained from the

licensing authority for all human vaccines either manufactured locally or imported:
Provided that, for the vaccines pre-qualified by the World Health Organization and supplied through any organization of the United Nations shall be released on the basis of the lot release certificate of the country of manufacturing.
(2) In view of the urgency of public health or the importance, scarcity of time and urgency of use in the event of a disaster or emergency, any specific vaccine may be marketed or supplied without lot release, subject to the prior approval of the Licensing Authority;
Provided that the Lot Release Certificate is obtained from the Licensing Authority later.
(3) In case of import of small quantity of vaccine for research or personal use, No Objection Certificate shall be accepted from Licensing Authority instead of Lot Release Certificate.

68. **Formulation of policies or guidelines, etc. -** The Government may, in order to carry out the objectives of this Act, by issuing administrative orders or notifications, formulate necessary policies or guidelines and determine the scope of the same including formation of cells or committees.

CHAPTER XIII
GENERAL AND MISCELLANEOUS

69. Administrative measures to be adopted by the Directorate- (1) Notwithstanding anything to the contrary contained in this Act, the Director General or any officer duly authorized under this Act shall, for offences committed under this Act, against column (1) serial Nos. 6, 7, 8, 12, 14, 16, 18, 19, 20, 23, 26, 28, and 29 where any offense mentioned in column (2) has been committed, if it thinks fit, can only take administrative measures by imposition of fines and suspending licenses on a temporary or permanent basis.
(2) In relation to the imposition of fines in administrative proceedings under sub-section (1) of the offence, no additional fine shall be imposed over the maximum amount as allowed under this Act.
(3) In respect of any fine imposed in administrative proceedings under sub-sections (1) and (2), imprisonment cannot be imposed in default.
(4) The penalty imposed under this section shall voluntarily be paid within five (5) days.
(5) If the fine imposed in accordance with the provisions of sub-section (4) is not voluntarily paid by the convict, the imposing authority may recover the amount of the fine by crook and sale of property in accordance with the procedure prescribed in clause (a) of sub-section (1) of section 386 of the Code of Criminal Procedure, and in such case 25 percent of the fine can be recovered as additional expenses.

70. **Prohibitions on sale of drugs on streets-** No person shall sell, distribute or offer to distribute any drug of pharmaceutical specialty of allopathic, unani, ayurvedic, homeopathic and biochemical, herbal on any public walkways, highways, footpath, park or in any public transport or in any vehicle.

71. **Regulation of advertising and claims relating to drugs and cosmetics-** (1) No person shall, without the prior approval of the Licensing Authority, publish or promote any such advertisement or participate in the publication or promotion of any advertisement, which contains any claim relating to the use of drug or to health or treatment.
(2) A manufacturer, importer, marketer or seller of cosmetics shall not prepare, publish or circulate any advertisement which contains false or untrue claims regarding the use or results of use of the cosmetics.

72. **Prescription of unregistered drugs prohibited-** (1) No physician shall prescribe in his prescription to a patient the use of any drug which is not registered under this Act.
(2) For registered drugs which are imported after taking prior approval of the licensing authority, the doctor may give advice in his prescription.

73. **Following the decision of the listed authorities of the World Health Organization-** The Directorate in taking any decision, may follow the decisions of the authorities as listed by the World Health Organization.

74. **Implementation of Narcotics Control Act, 2018-** The Narcotics Control Act, 2018 (Act No. 63 of 2018) shall be applicable in case of import, export, production, storage and sale of any drug or raw materials.

75. **Acts done in good faith-** No civil or criminal suit or any other legal proceeding shall be instituted against the Directorate or any employee of the Directorate if any person is aggrieved or is likely to be aggrieved as a result of any act done in good faith under this Act or the rules.

76. **Power to make rules-** For the purposes of this Act, the Government may, by notification in the Official Gazette, make rules.

77. **Government's ability to resolve complications-** If there is any difficulty in implementing the powers and responsibilities of the Directorate due to ambiguity in the provisions of this Act, the Government may clarify or explain the said provisions by gazette notification and provide guidance on the duties of the Directorate.

78. **Cooperation and support of law enforcement agencies and other agencies-** In order to fulfil the purpose of this Act, if necessary, the Directorate may send letter seeking the cooperation and assistance of any related organization or authority including the law enforcement agencies, the relevant forces, organizations. In such case, the relevant authorities shall provide the necessary cooperation and assistance to the Directorate.

79. **Notification to superior officer of seizure and storage of seized or seized drugs and other articles-** If any drug, cosmetics or other related articles under this Act are seized or seized, in the prescribed manner, the list of such seized or seized goods shall be submitted by the officer immediately to his superior officer and send a copy of the report to the Director General and store the seized or impounded goods in the designated place.

80. **Obtaining expert opinion-** (1) For the purposes of this Act, if it appears to the Directorate that there is a need to obtain a legal opinion or technical analysis or opinion on any matter, the

Directorate may obtain an opinion on the said matter from one or more persons who are experts or have special knowledge or experience in the matter concerned or may invite them to attend meetings.

(2) The person providing the opinion referred to in sub-section (1) shall be paid appropriate remuneration or honorarium at the prescribed rate, or in accordance with the rules and regulations of Government financial affairs.

CHAPTER XIV
ABOLITION AND CUSTODY ETC.

81. **Revocation and Custody-** (1) As soon as this Act comes into force, the Drugs Act, 1940 (Act XXIII of 1940) and the Drugs (Control) Ordinance, 1982 (Ordinance No. VIII of 1982), hereinafter referred to as the said Act or Ordinance, shall be hereby repealed.

(2) Notwithstanding the repeal under sub-section (1)—

(a) Under the said Act or Ordinance, as the case may be, made, issued or issued rules, notices, orders, instructions, forms, circulars, approvals, etc., subject to being consistent with this Act, under similar provisions of this Act, as the case may be, made, shall be deemed to have been issued or given and shall remain in force until repealed, amended or re-enacted under this Act.

(b) If any action or proceeding under the said Act or Ordinance is pending immediately before the promulgation of this Act, the said action or proceeding shall be disposed of in accordance with the provisions of the said Act or Ordinance as if this Act had not been promulgated.

(3) Notwithstanding the repeal of the Act and Ordinance under sub-section (1)—

(a) any license, registration or marketing authorization certificate granted or issued by the Licensing Authority or any act done, any measure taken or any proceeding initiated shall be deemed to have been granted, issued, accepted or initiated under this Act;

(b) pending applications for licenses or registrations shall be disposed of in accordance with the rules or regulations which were disposed of before the enactment of this Act;

(c) any cancelled or suspended license or registration or any measures taken or proceedings instituted for the same shall be deemed to have been cancelled, suspended, taken or instituted under this Act;

(d) if any suit or proceeding filed is pending or pending, it shall be disposed of or pending as if the said Act or Ordinance had not been repealed;

(e) the Drugs Court deferred under the said Ordinance shall be deemed to have been constituted as a Drugs Court subject to the provisions of this Act and pending cases in the said Court shall be disposed of as if they were triable by the Drug Courts

constituted under this Act;

(f) any agreement or memorandum of understanding, legal document or instrument executed shall remain in force as if it had been executed under this Act;

(g) the seized or seized drug in the condition in which it is stored shall be stored as if it had been stored under this Act.

(4) The officers and employees appointed under the said Act shall be employed on the same terms and conditions under which they were employed, until modified or amended under this Act.

(5) All types of loans, liabilities, projects and legal obligations of the Government or the Directorate under the said Act or Ordinance shall be considered as loans, liabilities, projects and legal obligations of the Government or the Directorate under the same conditions as per the provisions of this Act.

82. **Publication of authentic English text-** (1) After the commencement of this Act the Government may, by notification in the Official Gazette, publish an authentic English text of this Act.

(2) In case of conflict between the Bengali and English texts of this Act, the Bengali text shall prevail.

SCHEDULE

[see section 2(14)]

Serial no.	Section	Type of offense	Penalties for commission of offences
(1)	(2)	(3)	(4)
1.	14 (1)	Manufacturing drugs without a license or without following the conditions imposed by the license.	shall be punishable with rigorous imprisonment for a term which may extend to 10 (ten) years, or with fine which may extend to 10 (ten) lac taka, or with both.
2.	14 (1)	Whoever sells, stocks, distributes, or displays for selling drugs withouthaving a license orwithout following the conditions imposed by thelicense.	shall be punishable with rigorous imprisonment for a term which may extend to 5 (five) years, or with fine which may extend to 5 (five) lac taka, or with both.
3.	14 (2)	Whoever sells, stocks, distributes, or displays for selling drugs through internet or web-based process without having a license or without following the conditions imposed by the license.	shall be punishable with rigorous imprisonment for a term which may extend to 5 (five) years, or with fine which may extend to 5 (five) lac taka, or with both.
4.	14 (2)	When drugs are stockpiled for higher profit by creating artificial shortage of drugs for nefarious purposes.	shall be punishable with imprisonment for life or rigorous imprisonment for a term which may extend to 14 (fourteen) years, or with fine which may extend to 10 (ten) lac taka, or with both.
5.	22 (1)	Manufacturing, importing, exporting, selling, distributing, storing or displaying drugs without registration.	shall be punishable with rigorous imprisonment for a term which may extend to 10 (ten) years, or with fine which may extend to 10 (ten) lac taka, or with both.
6.	30 (4)	If any drug or raw material for making drug	shall be punishable with imprisonment for a term which may extend to 2 (two) years, or with fine

		is sold at a price higherthan the maximum retail price/indicative price.	which may extend to 2 (two) lac taka, or withboth.
7.	31 (1)	Whoever manufactures, distributes, imports or exports cosmetics withouthaving a license or without following the conditions imposed by the license.	shall be punishable with imprisonment for a term which may extend to 1 (one) year or with fine which may extend to 1 (one) lac taka, or withboth.
8.	32 (1)	Manufacturing, distributing, importing, orexporting, cosmetics without having registration.	shall be punishable with imprisonment for a term which may extend to 1 (one) year or with fine which may extend to 1 (one) lac taka, or withboth.
9.	35 (2)	When cosmetics such as filler, botox, glutathione or similar cosmetics are applied to the human body by injection or by other method without the supervision of a registered physician or registered physician by Bangladesh Medical and Dental Council (BMDC).	shall be punishable with imprisonment for a term which may extend to 6 (six) months or with fine which may extend to 3 (three) lac taka, or with both.
10.	35 (3)	If any cosmetics are applied and used in violation of the rules by the beauty parlor.	shall be punishable with imprisonment for a term which may extend to 3 (three) months or with finewhich may extend to 1 (one) lac taka, or with both.
11.	36 (1)	Whoever manufactures, sells, stocks, distributes, imports or displays for selling sub-standard drugs.	shall be punishable with rigorous imprisonment for a term which may extend to 7 (seven) years, or with fine which may extend to 10 (ten) lac taka, or with both.
12.	36 (2)	If the owner or the agent/representative of the company knowingly gives a false assurance to the purchasers regarding the quality of substandard/ adulterated drug that the consumption or use of the said drug	shall be punishable with imprisonment for a term which may extend to 1 (one) year or with fine which may extend to 5 (five) lac taka, or withboth.

		will not cause any harmand will not violate any provision of this Act.	
13.	37 (1)	Whoever manufactures, sells, stocks, distributes, or displays for selling misbranded drugs.	shall be punishable with rigorous imprisonment for a term which may extend to 10 (ten) years, or with fine which may extend to 10 (ten) lac taka, or with both.
14.	37 (1)	Whoever manufactures, sells, stocks, distributes, or displays for selling misbranded cosmetics.	shall be punishable with rigorous imprisonment for a term which may extend to 1 (one) year, or with fine which may extend to 1 (one) lac taka, or with both.
15.	38 (1)	Whoever manufactures, or knowingly sells, stocks, distributes, or displays for selling counterfeit drugs.	shall be punishable with imprisonment for life or rigorous imprisonment for a term which may extend to 14 (fourteen) years, or with fine which may extend to 10 (ten) lac taka, or with both.
16.	38 (1)	Whoever manufactures, or knowingly sells, stocks, distributes, or displays for selling counterfeit cosmetics.	shall be punishable with rigorous imprisonment for a term which may extend to 5 (five) years, or with fine which may extend to 5 (five) lac taka, or with both.
17.	39 (1)	Whoever makes adulterated drug or manufactures, sells, stocks, distributes, or displays for selling adulterated drug.	shall be punishable with imprisonment for life or rigorous imprisonment for a term which may extend to 14 (fourteen) years, or with fine which may extend to 10 (ten) lac taka, or with both.
18.	39 (1)	Whoever makes adulterated cosmetics or manufactures, sells, stocks, distributes, or displays for selling adulterated cosmetics.	shall be punishable with rigorous imprisonment for a term which may extend to 5 (five) years, or with fine which may extend to 5 (five) lac taka, or with both.
19.	40 (a)	Whoever sells, or stocksand/or displays Government drugs for selling.	shall be punishable with rigorous imprisonmentfor a term which may extend to 10 (ten) years, or with fine which may extend to 10 (ten) lac taka, orwith both.
20.	40 (b)	Whoever sells, stocks, distributes, or displays for selling expired drugs or drugs banned by theGovernment.	shall be punishable with imprisonment for a term which may extend to 1 (one) year or with fine which may extend to 50 (fifty) thousand taka, or with both.
21.	40 (c)	Whoever sells,	shall be punishable with fine which may extend to 10 (ten) thousand taka.

		stocks/displays physician's sample for selling.	
22.	40 (d)	Whoever sells antibiotics or any other drug without a prescription from a registered doctor except Over-the-Counter drug.	shall be punishable with fine which may extend to20 (twenty) thousand taka.
23.	41 (1)	Whoever imports drugs without a license or in violation of the conditions imposed in the license.	shall be punishable with rigorous imprisonment for a term which may extend to 10 (ten) years, or with fine which may extend to 10 (ten) lac taka, or with both.
24.	41 (2)	Whoever imports any registered drugs without prior approval of the Licensing Authority.	shall be punishable with fine which may extend to10 (ten) lac taka.
25.	42 (1)	Whoever procures raw materials for the manufacture of registered drugs or the packaging material for drugs locally without prior approval of the Licensing Authority.	shall be punishable with fine which may extend to20 (twenty) thousand taka
26.	42 (1)	Whoever imports raw material for the manufacture of registered drugs or packaging material for drugs without prior approval of the Licensing Authority.	shall be punishable with fine which may extend to10 (ten) lac taka.
27.	42 (2)	Whoever imports semi- finished drugs or any other substance or ingredients necessary for the manufacture of drugs without prior approval of the Licensing Authority.	shall be punishable with fine which may extend to10 (ten) lac taka.
28.	43 (1)	Whoever exports drugs without having a license.	shall be punishable with imprisonment for a term which may extend to 3 (three) years, or with fine which may extend to 1 (one) lac taka, or with both.
29.	48 (2)	Whoever obstructs the inspector in the exercise	shall be punishable with fine which may extend to 3 (three) lac taka.

		of his statutory power oferred by or under this Act.	
30.	52 (6)	Whoever publishes the reports or part of the report prepared by the National Drugs Control Laboratory or by any drug analyst for the purpose of advertisement.	shall be punishable with fine which may extend to2 (two) lac taka.
31.	70	Whoever sells, distributes or offer to distribute any drug of pharmaceutical specialty of allopathic, unani, ayurvedic, homeopathic and biochemical, herbal on any public walkways, highways, footpath, park or in any public transport or in any vehicle.	shall be punishable with imprisonment for a term which may extend to 2 (two) years, or with fine which may extend to 50 (fifty) thousand taka, or with both.
32.	71 (1)	Whoever, without the prior approval of the Licensing Authority, publishes or promotes any such advertisement or participate in the publication or promotion of any advertisement, which contains any claim relating to the use of drug or to health or treatment.	shall be punishable with imprisonment for a term which may extend to 3 (three) years, or with fine which may extend to 5 (five) lac taka, or withboth.
33.	71 (2)	Any Manufacturer, importer, marketer or seller of cosmeticspreparing, publishing or promoting any suchadvertisement forcosmetics, which containsfalse or misleading claimsregarding the use or results of use of the cosmetics concerned.	shall be punishable with fine which may extend to3 (three) lac taka.

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