The Drugs (Control) Ordinance, 1982

(Ordinance NO. VIII OF 1982)

An Ordinance to control manufacture, import, distribution and sale of drugs.

WHEREAS it is expedient to control manufacture, import, distribution and sale of drugs;

NOW, THEREFORE, in pursuance of the Proclamation of the 24th March, 1982, and in exercise of all powers enabling him in that behalf, the Chief Martial Law Administrator is pleased to make and promulgate the following Ordinance:-

Short title

1. This Ordinance may be called the Drugs (Control) Ordinance, 1982.

Application of other Laws, etc.

2. The provisions of this Ordinance shall be in addition to, and not in derrogation of, the Drugs Act, 1940 (XXIII of 1940), and any other law for the time being in force and shall have effect notwithstanding anything to the contrary contained in that Act or in any such law or in any contract, agreement or document.

Definitions

3. (1) In this Ordinance, unless there is anything repugnant in the subject or context,-

(a) “Act” means the Drugs Act, 1940 (XXIII of 1940);

(b) “Committee” means the Drugs Control Committee constituted under this Ordinance;

(c) “Council” means the National Drugs Advisory Council constituted under this Ordinance;

(d) “Drug” shall have the same meaning as in the Act and shall also include any substance exclusively used or prepared for use in accordance with the ayurvedic, unani and homeopathic or biochemic system of medicine;

(e) “Schedule” means Schedule to this Ordinance.

(2) Words and expressions used but not defined in this Ordinance shall have the same meaning as in the Act.

Drug Control Committee

4. (1) The Government shall constitute a Drug Control Committee consisting of a Chairman and such other members as it may appoint from time to time.

(2) The Committee shall perform such functions as are specified in this Ordinance.

Registration of Medicines

5. (1) No medicine of any kind shall be manufactured for sale or be imported, distributed [1][, stocked, exhibited or sold] unless it is registered with the licensing authority.

[2][(1A) For the purpose of registration of Homeopathic and Biochemic medicines the licensing authority shall follow the quality standards set out in the Homeopathic and Biochemic pharmacopoeias accepted in such country as the Government may by notification in the official Gazette, specified.]

(2) The licensing authority shall not register a medicine unless such registration is recommended by the Committee.

(3) A registration shall be granted on such conditions as may be specified by the licensing authority.

(4) A registration shall, unless cancelled earlier, be valid for a period of five years.

Cancellation or suspension of registration

6. (1) The licensing authority may cancel the registration of any medicine if such cancellation is recommended by the Committee.

(2) The Committee shall evaluate every medicine registered before the commencement of this Ordinance and every medicine that may be manufactured or imported after such commencement in order to determine its safety, efficacy and usefulness.

(3) If on such evaluation the Committee finds that any such medicine is not safe, efficacious or useful, it may recommend to the licensing authority cancellation of registration of the medicine.

(4) The licensing authority may, if it is satisfied that a medicine is sub-standard, suspend the registration of such medicine till he is satisfied that the medicine has attained its standard.

Appeal

[3][6A. (1) Whoever is aggrieved by an order or decision of the licensing authority under sections 5 and 6 may, within one month from the date of making of the order or decision, prefer an appeal to the Appellate Authority appointed under sub-section (2).

(2) The Government shall, for the purpose of this section, appoint an Appellate Authority consisting of a Chairman and such number of other members as it may think fit.

(3) The Appellate Authority shall give its decision on an appeal after giving the parties concerned an opportunity of being heard.

(4) The decision of the Appellate Authority shall be final and shall be binding upon the parties and shall not be called in question before any Court or authority.]

Fees for registration

7. No registration of a medicine shall be granted unless a fee to be determined by the Government is paid at the time of application for registration.

Prohibition of Manufacture, etc., of certain medicines

8. (1) On the commencement of this Ordinance, the registration or licence in respect of all medicines mentioned in the Schedules shall stand cancelled, and no such medicine shall, subject to the provisions of sub-section (2), be manufactured, imported, distributed [4][, stocked, exhibited or sold] after such commencement.

(2) Notwithstanding anything contained in sub-section (1),-

(a) the medicines specified in Schedule I shall be destroyed within three months from the date of commencement of this Ordinance;

(b) the medicines specified in Schedule II may be manufactured or sold for a period of [5][twelve months] from the date of commencement of this Ordinance and thereafter their manufacture [6][, stock, exhibition and sale] shall be permitted only if they are registered after change in their formulation in accordance with the direction of the licensing authority;

(c) the medicines specified in Schedule III may be manufactured, imported, distributed and sold for a period of [7][eighteen months] after the commencement of this Ordinance, and thereafter there shall not be any manufacture, import, distribution [8][, stock, exhibition or sale] of such medicines [9][;

(d) the medicines specified in Schedule IV may be manufactured, distributed and sold for a period of eighteen months after the commencement of this Ordinance, and thereafter their manufacture, distribution [10][, stock, exhibition and sale] shall be permitted only if they are registered again with the licensing authority:

Provided that no fresh import of raw materials for the manufacture of the medicines specified in Schedule III and Schedule IV shall be permitted.]

Restriction on import of certain pharmaceutical raw material

9. (1) No pharmaceutical raw material necessary for the manufacture of any medicine specified in any of the Schedules shall be imported.

(2) No drug [11][, semi-finished bulk drug] or pharmaceutical raw material shall be imported except with the prior approval of the licensing authority.

(3) The licensing authority may award an approval under sub-section (2) on such conditions as it deems fit to specify [12][:

Provided that in case of awarding approval to import any finished medicine, such medicine shall be registered for sale under the same brand name in any of the countries specified under sub-section (1A) of section 5.]

Manufacture of drugs under licensing

[13][10. Subject to the approval of the licensing authority,-

agreement etc.

(a) a foreign manufacturer may be allowed to manufacturer any drug under licensing agreement with any manufacturer in Bangladesh if the drug is its research product and is registered under the same brand name in any of the countries specified under sub-section (1A) of section 5;

(b) a manufacturer in Bangladesh may be allowed to manufacture any drug under any written contract with any pharmaceutical manufacturing plant in Bangladesh.]

Fixation of price of drugs

11. (1) The Government may, by notification in the official Gazette, fix the maximum price at which any medicine may be sold.

(2) The Government may by notification in the official Gazette, fix the maximum price at which any pharmaceutical raw material may be imported or sold.

Review of certain licensing agreement with foreign concerns

12. (1) The Government may, review any licensing agreement between a Bangladeshi concern and a foreign concern for manufacture of any drug in Bangladesh in order to find out if it contains any provision against the national interest.

(2) If on such review the Government finds that any such provision of any such agreement is against the national interest, it may direct the concerns to modify such provision.

(3) If any such concern fails to comply with the direction given under sub-section (2) the manufacturing licence of such concern may be cancelled by the Government.

Employment of [14][Pharmacists, etc.]

13. [15][(1) No person shall manufacture-

(a) any allopathic drug except under the personal supervision of two personnel, out of whom one shall be a pharmacist registered in Register “A” of the Pharmacy Council of Bangladesh and another shall be a person having the following academic qualification from any university recognised by the Government-