The Drugs (Control) Ordinance, 1982

(Ordinance NO. VIII OF 1982)

[12th June, 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,-

(a) a foreign manufacturer may be allowed to manufacturer any drug under licensing agreement with any manufacturer in Bangladesh if the drug is its

agreement etc.

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-

(i) Master's degree or Bachelor degree with Honours (4 years curricula) in Chemistry, Biochemistry, Applied Chemistry, Microbiology, Pharmacology or Genetic Engineering; or

(ii) Bachelor degree in Pharmacy, Medicine or Chemical Engineering;

(b) any Unani, Ayurvedic or Homeopathic or Biochemic system of medicine or other herbal drug except under the personal supervision of two whole time employees of the relevant manufacturing plant or unit, out of whom one shall be a person having degree or diploma in the field of respective system of medicine from any university or institution recognised by the Government with at least one year's practical experience in the manufacture and quality control of drugs of the relevant system and another shall be a person having Bachelor degree in Pharmacy or Bachelor degree with Honours (4 years curricula) in Chemistry, Botany, Applied Chemistry, Biochemistry, with specialisation in Phytochemistry or Pharmacognosy, from any university recognised by the Government with at least one year's practical experience in the manufacture and quality control of drugs of the relevant system.]

(2) No person, being a retailer, shall sell any drug without the personal supervision of a pharmacist registered in any Register of the Pharmacy Council of Bangladesh:

Provided that this provision shall not apply to the retail sale of any drug under the ayurvedic, unani, or homeopathic or biochemic [16][system of medicine or herbal drugs].

Control of advertisement and claims in respect of drugs

14. No person shall publish or take any part in the publication of any advertisement which relates to the use of any drug or contains any claim in respect of therapics or treatment without the prior approval of the licensing authority.

Explanation.- “Advertisement” includes any notice, circular or other document displayed on or in any public place or public transport or published in any newspaper or periodical and any announcement made orally or by any means of producing or transmitting light or sound and any trade circular, insert and level.

Prescription of

unregistered medicine prohibited

[17][14A. (1) No Physician shall prescribe for any patient any medicine which is not registered under this Ordinance.

(2) Nothing in this section shall apply to the prescription of any drug which is-

(a) manufactured in a foreign country after testing its efficacy and usefulness;

(b) imported with the permission of the licensing authority for the purpose of examination, test or analysis or for personal use.]

Good practices in the manufacture and quality control of drugs

15. (1) Every manufacturer of drugs shall follow the good practices in the manufacture and quality contol of drugs recommended by the World Health Organisation.

(2) If any manufacturer does not follow such good practices his manufactured licence may be cancelled or suspended.

Penalty for manufacture, etc., of certain drugs

16. Whoever manufactures, imports, distributes [18][, stocks, exhibits or sells]-

(a) any medicine which is not registered under this Ordinance, or

(b) any medicine in contravention of the provisions of section 8, or

(c) any drug which is adulterated [19][, misbranded, spurious or imitated],

shall be punishable with rigorous imprisonment for a term which may extend to ten years, or with fine which may extend to two lakh Taka, or with both, and any implements used in the manufacture or sale of such medicine or drug may, by order of the Drug Court, be forfeited to the Government.

Penalty for manufacture, [20][stock or sale] of sub-standard drugs

17. Whoever manufactures [21][, stocks or sells] any sub-standard drug shall be punishable with rigorous imprisonment for a term which may extend to five years, or with fine which may extend to one lakh Taka, or with both.

Penalty for unauthorised import of drugs

18. Whoever imports any drug or pharmaceutical raw material without the prior approval of the licensing authority shall be punishable with rigorous imprisonment for a term which may extend to three years, or with fine which may extend to fifty thousand Taka, or with both and such drug or raw material may, by order of the Drug Court, be forfeited to the Government.

Penalty for sale of medicine or import or sale of pharmaceutical raw material at a higher price

19. Whoever sells any medicine or imports or sells any pharmaceutical raw material at a price higher than the maximum price fixed by the Government under section 11 shall be punishable with rigorous imprisonment for a term which may extend to two years, or with fine which may extend to ten thousand Taka, or with both.

Penalty for theft, etc., of Government drugs

20. Whoever commits theft in respect of any drug in any Government store, hospital, clinic or health centre or sells any such drug or keeps in his possession any such drug for sale shall be punishable with rigorous imprisonment for a term which may extend to ten years, or with fine which may extend to two lakh Taka or with both.

Penalty for illegal advertisement and claims

[22][21. Whoever contravenes the provision of section 14 shall be punishable with rigorous imprisonment for a term which may extend to three years, or with fine which may extend to two lakh Taka, or with both.]

Offences by companies

[23][21A. (1) Where an offence under this Ordinance has been committed by a company, every person who at the time the offence has been committed, was in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Ordinance if he proves

that the offence has been committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where any offence under this Ordinance has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to, any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also to be deemed to be proceeded against and punished accordingly.

Explanation.- For the purposes of this section,-

(a) “company” means any body corporate and includes a firm or other association of individual, and

(b) “director”, in relation to a firm, means partner in the firm.]

Cognizance of offences

22. Notwithstanding anything contained in the Code of Criminal Procedure, 1898 (V of 1898),-

(a) an offence punishable under this Ordinance shall be non-cognizable;

(b) no Court other than a Drug Court shall try an offence punishable under this Ordinance;

(c) no Drug Court shall take cognizance of an offence punishable under this Ordinance except on a report in writing made by the licensing authority or an officer authorised by him in this behalf.

Drug Courts

23. (1) The Government may, by notification in the official Gazette establish as many Drug Courts as it considers necessary and where it establishes more than one Drug Court, shall specify in the notification the territorial limits within which each one of them shall exercise jurisdiction under this Ordinance.

(2) A Drug Court shall consist of a person who is or has been a Sessions Judge and he shall be appointed by the Government.

(3) A Drug Court shall sit at such place as the Government may direct.

(4) A Drug Court may pass any sentence authorised by this Ordinance and shall have all the powers conferred by the Code of Criminal Procedure, 1898 (V of 1898), on a Court of Session exercising original jurisdiction.

(5) A Drug Court shall not, merely by reason of a change in its composition, be bound to recall and rehear any witness who has given evidence, and may act on the evidence already recorded by or produced before it.

(6) A Drug Court shall, in all matters with respect to which no procedure has been prescribed by this Ordinance, follow the procedure prescribed by the Code of Criminal Procedure, 1898 (V of 1898), for the trial of summons cases by Magistrates.

(7) A Drug Court may, on application in this behalf being made by the prosecution, try an offence under this Ordinance summarily in accordance with the provisions contained in sections 262 to 265 of the Code of Criminal Procedure, 1898 (V of 1898).

(8) An appeal from the judgment of a Drug Court shall lie to the High Court Division.

National Drug Advisory Council

24. (1) The Government shall constitute a National Drug Advisory Council consisting of a Chairman and such other members as it may appoint from time to time.

(2) The Council shall advise the Government on-

(a) measures to be adopted for the implementation of the national drug policy that may be adopted by the Government from time to time;

(b) measures for the promotion of local pharmaceutical industries and production and supply of essential drugs for meeting the needs of the country;

(c) matters relating to the import of drugs and pharmaceutical raw materials;

(d) measures for the co-ordination of the activities of the various Ministries, agencies and persons dealing with manufacture, import, distribution and

sale of drugs.

Power to make rules

25. The Government may, by notification in the official Gazette, make rules for carrying out the purposes of this Ordinance.

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[1] The commas and the words ", stocked, exhibited or sold" were substituted for the words "or sold" by section 2 of the Drugs (Control) (Amendment) Ordinance, 1984 (Ordinance No. XLIII of 1984)

[2] Sub-section (1A) was inserted by section 2 of the Drugs (Control) (Amendment) Act, 2006 (Act No. IV of 2006)

[3] Section 6A was inserted by section 3 of the Drugs (Control) (Amendment) Ordinance, 1984 (Ordinance No. XLIII of 1984)

[4] The commas and the words ", stocked, exhibited or sold" were substituted for the words "or sold" by section 4 of the Drugs (Control) (Amendment) Ordinance, 1984 (Ordinance No. XLIII of 1984)

[5] The words "twelve months" were substituted for the words "six months" by section 2 of the Drugs (Control) (Amendment) Ordinance, 1982 (Ordinance No. XXVIII of 1982)

[6] The commas and the words ", stock, exhibition and sale" were substituted for the words "and sale" by section 4 of the Drugs (Control) (Amendment) Ordinance, 1984 (Ordinance No. XLIII of 1984)

[7] The words "eighteen months" were substituted for the words "nine months" by section 2 of the Drugs (Control) (Amendment) Ordinance, 1982 (Ordinance No. XXVIII of 1982)

[8] The commas and the words ", stock, exhibition or sale" were substituted for the words "or sale" by section 4 of the Drugs (Control) (Amendment) Ordinance, 1984 (Ordinance No. XLIII of 1984)

[9] The semi-colon (;) was substituted for the full-stop (.) and clause (d) was added thereafter by section 2 of the Drugs (Control) (Amendment) Ordinance, 1982 (Ordinance No. XXVIII of 1982)

[10] The commas and the words ", stock, exhibition and sale" were substituted for the words "and sale" by section 4 of the Drugs (Control) (Amendment) Ordinance, 1984 (Ordinance No. XLIII of 1984)

[11] The comma and the words ", semi-finished bulk drug" were inserted by section 3 of the Drugs (Control) (Amendment) Act, 2006 (Act No. IV of 2006)

[12] The colon (:) was substituted for the full-stop (.) and thereafter the proviso was added by section 3 of the Drugs (Control) (Amendment) Act, 2006 (Act No. IV of 2006)

[13] Section 10 was substituted by section 4 of the Drugs (Control) (Amendment) Act, 2006 (Act No. IV of 2006)

[14] The word, comma and the abbreviation "Pharmacists, etc." were substituted for the word "pharmacists" by section 5 of the Drugs (Control) (Amendment) Act, 2006 (Act No. IV of 2006)

[15] Sub-section (1) was substituted by section 5 of the Drugs (Control) (Amendment) Act, 2006 (Act No. IV of 2006)

[16] The words "system of medicine or herbal drugs" were substituted for the words "system of medicine" by section 5 of the Drugs (Control) (Amendment) Act, 2006 (Act No. IV of 2006)

[17] Section 14A was inserted by section 5 of the Drugs (Control) (Amendment) Ordinance, 1984 (Ordinance No. XLIII of 1984)

[18] The commas and the words ", stocks, exhibits or sells" were substituted for the words "or sells" by section 6 of the Drugs (Control) (Amendment) Ordinance, 1984 (Ordinance No. XLIII of 1984)

[19] The commas and words ", misbranded, spurious or imitated" were substituted for the words "or spurious" by section 6 of the Drugs (Control) (Amendment) Ordinance, 1984 (Ordinance No. XLIII of 1984)

[20] The comma and the words ", stock or sale" were substituted for the words "or sale" by section 7 of the Drugs (Control) (Amendment) Ordinance, 1984 (Ordinance No. XLIII of 1984)

[21] The comma and the words ", stocks or sells" were substituted for the words "or sell" by section 7 of the Drugs (Control) (Amendment) Ordinance, 1984 (Ordinance No. XLIII of 1984)

[22] Section 21 was substituted by section 2 of the Drugs (Control) (Amendment) Act, 1997 (Act No. XVIII of 1997)

[23] Section 21A was inserted by section 8 of the Drugs (Control) (Amendment) Ordinance, 1984 (Ordinance No. XLIII of 1984)