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GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH

MINISTRY OF LAW AND LAND REFORMS

(Law and Parliamentary Affairs Division)

NOTIFICATION Dacca, the 12th

June, 1982

No. 354-Pub. — The following Ordinance made by the Chief Martial Law Administrator of the People's Republic of Bangladesh, on the 11th June, 1982, is hereby published for general information: —

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: —

1. **Short title.**— This Ordinance may be called the Drugs (Control) Ordinance, 1982.

2. Application of other Laws, etc.—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.

3. **Definitions.**— (1) In this Ordinance, unless there is anything repugnant in this 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;

(c) "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.

4. **Drug Control Committee.** —(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.

5. **Registration of Medicines.**—(1) No medicine of any kind shall be manufactured for sale or be imported, distributed or sold unless it is registered with the licencing authority.

(2) The licencing 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 licencing authority.

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

6. **Cancellation or suspension of registration**. —(1) The licencing authority may cancel the registration of any medicine if the Committee recommends such cancellation.

(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 sale, efficacious or useful it may recommend to the licencing authority cancellation of registration of the medicine.

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

7. **Fees for registration.**—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.

8. **Prohibition of Manufacture, etc, of certain medicines.—(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 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 six months from the date of commencement of this Ordinance and thereafter their manufacture and sale shall be permitted only if they are registered alter change in their formulation in accordance with the direction of the licencing authority;

(c) the medicines specified in Schedule III may be manufactured, imported, distributed and sold for a period of nine months after the commencement of this Ordinance, and thereafter there shall not be any manufacture, import, distribution or sale of such medicines.

9. **Restriction on import of certain pharmaceutical raw material.**—(1) No pharmaceutical raw material necessary for the manufacture of any medicine specified in any of the Schedules shall be imported.

(2) No drug or pharmaceutical raw material shall be imported except with the prior approval of the licencing authority.

(3) The licencing authority may award an approval under sub-section (2) on such conditions as it deems fit to specify.

10. **Restriction on manufacture** of certain drugs **under** licence.—No drug shall, alter six months from the date of commencement of this Ordinance, be manufactured in Bangladesh under licence granted by a foreign company having no manufacturing plant in Bangladesh if, such drug or its substitute is produced in Bangladesh.

11. **Fixation of price of drugs.**—(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.

12. **Review of certain licencing agreement with foreign concerns**.—(1) The Government may review any licencing 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 (he national interest, it may direct the concerns to modify such provision.

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

13. **Employment of pharmacists**. —(i) No person shall manufacture any drug except under the personal supervision of a pharmacist registered in Register 'A' of the Pharmacy Council of Bangladesh:

Provided that this provision shall not apply to the manufacture of any drug under the ayurvedic, unani, or homeopathic or biochemic system of medicine.

(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 system of medicine.

14. **Control of advertisement and claims in respect of drugs**.—No person shall publish or take any part in die publication of any advertisement which relates to the use of any drug or contains any claim in respect of therapies or treatment without the prior approval of the licencing 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.

15. **Good practices in the manufacturer and quality control of drugs**.—(1) Every manufacturer of drugs shall follow the good practices in the manufacture and quality control 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.

16. **Penalty for manufacture, etc., of certain drugs**.—Whoever manufactures, imports, distributes 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 or spurious.

shall be punishable with rigorous imprisonment for a term which may extend to ten years, or with fine which may extend to two lac 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.

17. Penalty for manufacture or sale of sub-standard drugs.—-Whoever manufactures or sells any sub-standard drug shall be punishable with rigorous imprisonment for a term which may extend to live years, or with fine which may extend to one lac taka, or with both.

18. **Penalty for un-authorised import of drugs.**—Whoever imports any drug or pharmaceutical raw material without the prior approval of the licencing 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 be order of the Drug Court, be forfeited to the Government.

19. **Penalty for sale of medicine or import or sale of pharmaceutical raw material at** a **higher price.**—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 any extend to ten thousand taka, or with both.

20. **Penalty for theft, etc., of Government drugs.**—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 lac taka or with both.

21. **Penalty for illegal advertisement and claims.**—Whoever contravenes the provision of section 14 shall be punishable with fine which may extend to twenty-five thousand taka.

22. **Cognizance of offences.**—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 oilier 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 licencing authority or ;in officer authorised by him in this behalf.

23. **Drug Courts.**— (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 ill is behalf being made by the prosecution.try an offence under this Ordinance summarily in accordance win the provisions contained in sections 262 to 265 ol the Code of Criminal Procedure, 1898 (V of 1898).

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

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

(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.

25. **Power to make rules**. — The Government may, be notification in the *official Gazelle,* make rules for carrying out the purposes of this Ordinance.