The Drugs Act, 1940

(ACT NO. XXIII OF 1940)

An Act to regulate the import, export, manufacture, distribution and sale of drugs.♣

WHEREAS it is expedient to regulate the import into, export from, and the manufacture, distribution and sale in, Bangladesh of drugs;

[* * *]

It is hereby enacted as follows:-

CHAPTER I

INTRODUCTORY

Short title, extent and commencement

1. (1) This Act may be called the Drugs Act, 1940.

(2) It extends to the whole of Bangladesh.

[1][(3) It shall come into force at once; but Chapter III and IV shall take effect only from such date as the Government may, by notification in the official Gazette, appoint in this behalf.]

Application of other laws not barred

2. The provisions of this Act shall be in addition to, and not in derogation of, the Dangerous Drugs Act, 1930, and any other law for the time being in force.

Definitions

3. In this Act, unless there is anything repugnant in the subject or context,-

(a) “the Board” means the Drugs Technical Advisory Board constituted under section 5;

(b) “drug” includes┬¼-

(i) all medicines for internal or external use of human beings or animals, and all substances intended to be used for or in the treatment, mitigation

or prevention of diseases in human beings or animals, not being medicines and substances exclusively used or prepared for use in accordance with the ayurvedic, unani, homoeopathic or biochemic system of medicine,

(ii) diagnostic, abortive and contraceptive substances, surgical ligatures, sutures, bandages, absorbent cotton, bacteriophages, adhesive plasters, gelatine capsules and antiseptic solutions,

(iii) 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 vermins or insects which cause disease in human beings or animals,

(iv) any substance, mentioned as monograph in any of the editions of the British Pharmacopoeia or the British Pharmaceutical Codex or the United States Pharmacopoeia or the National Formulary of the United States or the International Pharmacopoeia, whether alone or in combination with any substance exclusively used in the unani, ayurvedic, homoeopathic or biochemic system of medicine and intended to be used for any of the purposes mentioned in sub clauses (i), (ii) and (iii), and

(v) any other substance which the Government may, by notification in the official Gazette, declare to be a “drug” for the purposes of this Act;

[2][(ba) “to export” means to take out of Bangladesh by sea, land or air;

(bb) “licensing authority” means such authority as may be prescribed;

(bc) “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, but does not include the compounding and dispensing or the packing of any drug in the ordinary course of retail business or on a prescription of a registered medical practitioner or dentist or of a veterinarian, and ÔÇÿto manufacture' shall be construed accordingly;]

(c) “to import”, with its grammatical variations and cognate expressions, means to bring into Bangladesh;

(d) “patent or proprietary medicine” means a drug which is a remedy or prescription prepared for internal or external use of human beings or animals, and which is not for the time being recognised by the Permanent Commission on Biological Standardisation of the World Health Organisation or in the latest edition of the British Pharmacopoeia or the British Pharmaceutical Codex or any other pharmacopoeia authorised in this behalf by the Government after consultation with the Board;

[3][(e) “prescribed” means prescribed by rules made under this Act.]

Presumption as to poisonous substances

4. Any substance specified as poisonous by rule made under Chapter III or Chapter IV shall be deemed to be a poisonous substance for the purposes of Chapter III or Chapter IV, as the case may be.

CHAPTER II

THE DRUGS TECHNICAL ADVISORY BOARD, THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE

The Drugs Technical Advisory Board

5. (1) The Government shall, as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Government on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act.

[4][(2) The Board shall consist of such members including a Chairman as the Government may, by notification in the official Gazette, appoint such members.]

(2A) [Omitted by section 3 and the Second Schedule of the Bangladesh Laws (Revision And Declaration) Act, 1973 (Act No. VIII of 1973).]

[5][(3) The member of the Board shall hold office for such term as the Government may fix.]

(4) The Board may, subject to the previous approval of the Government, make by laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.

(5) The Board may constitute sub committees and may appoint to such sub committees for such periods, not exceeding three years, as it may

decide, or temporarily for the consideration of particular matters, persons who are not members of the Board.

(6) The functions of the Board may be exercised notwithstanding any vacancy therein.

(7) The Government shall appoint a person to be Secretary of the Board and shall provide the Board with such clerical and other staff as the Government considers necessary.

The Central Drugs Laboratory

6. (1) The Government shall, as soon as may be, establish a Central Drugs Laboratory under the control of a Director to be appointed by the Government, to carry out the functions entrusted to it by this Act or any rules made under this Chapter:

Provided that, if the Government so prescribes, the functions of the Central Drugs Laboratory in respect of any drug or class of drugs shall be carried out at any prescribed Laboratory and the functions of the Director of the Central Drugs Laboratory in respect of such drug or class of drugs shall be exercised by the Director of that Laboratory.

(2) The Government may, after consultation with the Board, make rules prescribing-

(a) the functions of the Central Drugs Laboratory;

[6][* * *]

(d) the procedure for the submission to the said Laboratory under Chapter IV of samples of drugs for analysis or test, the forms of the Laboratory's reports thereon and the fees payable in respect of such reports;

(e) such other matters as may be necessary or expedient to enable the said Laboratory to carry out its functions;

(f) the matters necessary to be prescribed for the purposes of the proviso to sub section (1).

[Omitted.]

7. [The Drugs Consultative Committee.- Omitted by section 3 and the Second Schedule of the Bangladesh Laws (Revision And Declaration) Act,

1973 (Act No. VIII of 1973).]

CHAPTER III

IMPORT OF DRUGS

Standards of quality

8. (1) For the purposes of this Chapter the expression “standard quality” when applied to a drug means that the drug complies with the standard set out in the Schedule. (2) The Government, after consultation with the Board and after giving by notification in the official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend the Schedule for the purposes of this Chapter, and thereupon the Schedule shall be deemed to be amended accordingly.

Misbranded drugs

9. For the purposes of this Chapter a drug shall be deemed to be Misbranded-

(a) if it is an imitation of, or substitute for, or resembles in a manner likely to deceive, another drug, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(b) if it purports to be the product of a place or country of which it is not truly a product; or

(c) if it is imported under a name which belongs to another drug; or

(d) 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

(e) if it is not labelled in the prescribed manner; or

(f) 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; or

(g) if the label or container bears the 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.