

# The Gazette of India



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PARLIAMENT SECRETARIAT

NOTIFICATION

New Delhi, the 8th June 1954

No. CS. 7(29)/54-L.—Under rule 49 of the Rules of Procedure and Conduct of Business in the Council of States, the Chairman has been pleased to order the publication in the *Gazette of India* of the following Bill together with the Statement of Objects and Reasons and the Financial Memorandum accompanying it, and the Bill, the Statement of Objects and Reasons and the Financial Memorandum are accordingly published for general information:—

(TO BE INTRODUCED IN THE COUNCIL OF STATES)

*Bill No. XIV of 1954*

*A Bill further to amend the Drugs Act, 1940.*

Be it enacted by Parliament in the Fifth Year of the Republic of India as follows:—

1. **Short title.**—This Act may be called the Drugs (Amendment) Act, 1954.

2. **Amendment of section 3, Act XXIII of 1940.**—In section 3 of the Drugs Act, 1940 (hereinafter in this Act referred to as the principal Act),—

(a) for clause (b), the following clause shall be substituted, namely:—

“(b) ‘drug’ includes—

(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 disease in human beings or animals other than medicines and substances exclusively used or prepared for use in accordance with the Ayurvedic or Unani systems of medicine; and

(ii) 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, as may be specified from time to time by the Central Government by notification in the Official Gazette;";

(b) after clause (b), the following clause shall be inserted, namely:—

"(bb) 'manufacture' in relation to any drug includes any process or part of a 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 or dispensing or the packing of any drug in the ordinary course of retail business; and 'to manufacture' shall be construed accordingly;";

(c) for clause (c), the following clause shall be substituted, namely:—

"(e) 'prescribed' means prescribed by rules made under this Act."

### 3. Amendment of section 5, Act XXIII of 1940.—In section 5 of the principal Act,—

(a) in sub-section (2),—

(i) after clause (i), the following clause shall be inserted, namely:—

"(ia) the Drugs Controller, India, *ex-officio*";

(ii) in clause (vii), for the words "the Indian Research Fund Association", the words "the Indian Council of Medical Research" shall be substituted;

(iii) for clause (ix), the following clause shall be substituted, namely:—

"(ix) three persons to be elected by the Pharmacy Council of India, two of whom shall be persons possessing qualifications for registration under the Pharmacy Act, 1948 (VIII of 1948) and one shall be a teacher in pharmacy or pharmaceutical chemistry or pharmacology or pharmacognosy in an Indian university or a college affiliated thereto which grants a degree or diploma in pharmacy;";

(iv) in clause (xi), the words "and one person to be elected by the branches in India of the British Medical Association" shall be omitted.

(b) in sub-section (3), the following proviso shall be added at the end, namely:—

"Provided that the persons nominated under clause (vi) of sub-section (2) shall hold office for so long as they hold the appointment of Government Analyst under this Act."

**4. Amendment of section 6, Act XXIII of 1940.**—In section 6 of the principal Act, in sub-section (2), clauses (b) and (c) shall be omitted.

**5. Amendment of section 10, Act XXIII of 1940.**—In section 10 of the principal Act, for clause (d), the following clause shall be substituted, namely:—

“(d) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of ingredients contained in it, in a manner readily intelligible to the members of the medical profession;”.

**6. Amendment of section 11, Act XXIII of 1940.**—In section 11 of the principal Act, for sub-section (2), the following sub-section shall be substituted, namely:—

“(2) Without prejudice to the provisions of sub-section (1), the Customs Collector or any officer of the Government authorised by the Central Government in this behalf, may detain any imported package which he suspects to contain any drug the import of which is prohibited under this Chapter and shall forthwith report such detention to the Drugs Controller, India and, if necessary, forward the package or sample of any suspected drug found therein to the Central Drugs Laboratory.”

**7. Amendment of section 12, Act XXIII of 1940.**—In section 12 of the principal Act,—

(a) in sub-section (1), the following proviso shall be added at the end, namely:—

“Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.”;

(b) in sub-section (2), in clause (d), for the words “to cure or mitigate”, the words “to prevent, cure or mitigate” shall be substituted.

**8. Amendment of section 16, Act XXIII of 1940.**—In section 16 of the principal Act, in sub-section (2), for the words “State Government”, the words “Central Government” shall be substituted.

**9. Amendment of section 18, Act XXIII of 1940.**—In section 18 of the principal Act,—

(a) in clause (a),—

(i) for sub-clause (iii), the following sub-clause shall be substituted, namely:—

“(iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on

the label or container thereof the true formula or list of ingredients contained in it in a manner readily intelligible to the members of the medical profession;";

(ii) in sub-clause (iv), for the words "to cure or mitigate", the words "to prevent, cure or mitigate" shall be substituted;

(b) in the second proviso, for the words "State Government", the words "Central Government" shall be substituted.

**10. Amendment of section 19, Act XXIII of 1940.**—In section 19 of the principal Act, in sub-section (2), after clause (a), the following clause shall be inserted, namely:—

"(aa) in the process of manufacture or preparation any one or more of the prescribed colours have been used, although such use may not be provided for in any of the pharmacopœias referred to in clause (d) of section 3; or"

**11. Substitution of new section for section 22 in Act XXIII of 1940.**—For section 22 of the principal Act, the following section shall be substituted, namely:—

"22. *Powers of Inspectors.*—(1) Subject to the provisions of section 23 and of any rules made by the Central Government in this behalf, an Inspector may, within the local limits of the area for which he is appointed,—

(a) inspect any premises wherein any drug is being manufactured and in the case of sera, vaccines and any other drug prescribed in this behalf, the plant and process of manufacture and the means employed for standardizing and testing the drug;

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

(c) enter and search at all reasonable times, with such assistants, if any, as he considers necessary, any place in which he has reason to believe that an offence under this Chapter has been or is being committed and order in writing the person in possession of any drug in respect of which the offence has been or is being committed, not to dispose of any stock of such drug for a specified period not exceeding twenty days, or, unless the alleged offence is such that the defect may be removed by the possessor of the drug, seize the stock of such drug;

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

(2) The provisions of the Code of Criminal Procedure, 1898 (Act V of 1898) shall, so far as may be, apply to any search or seizure under this Chapter as they apply to any search or seizure made under the authority of a warrant issued under section 98 of the said Code.

(3) If any person wilfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this Chapter, he shall be punishable with imprisonment which may extend to three years, or with fine, or with both."

**12. Amendment of section 27, Act XXIII of 1940.**—In section 27 of the principal Act, for the words "one year, or with fine which may extend to five hundred rupees", the words "three years, or with fine" shall be substituted.

**13. Amendment of section 28, Act XXIII of 1940.**—In section 28 of the principal Act, in sub-section (1), the words "whether as principal or agent" shall be omitted.

**14. Substitution of new section for section 30 in Act XXIII of 1940.**—For section 30 of the principal Act, the following section shall be substituted, namely:—

"30. *Penalty for subsequent offences.*—(1) Whoever, having been convicted of an offence under section 27 is again convicted of an offence under that section, shall be punishable with imprisonment which may extend to five years, or with fine, or with both.

(2) Whoever, having been convicted of an offence under section 28 or section 29 is again convicted of an offence under the same section shall be punishable with imprisonment which may extend to two years, or with fine, or with both."

**15. Amendment of section 33, Act XXIII of 1940.**—In section 33 of the principal Act,—

(a) for sub-section (1), the following sub-section shall be substituted, namely:—

"*Power of Central Government to make rules.*—(1) The Central Government may, after consultation with the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules."

(b) in sub-section (2), in clause (f), for the words "to cure or mitigate", the words "to prevent, cure or mitigate" shall be substituted.

16. Substitution of new Chapter for section 34 in Act XXIII of 1940.—For section 34 of the principal Act, the following Chapter shall be substituted, namely:—

# "CHAPTER V

## MISCELLANEOUS

34. *Offences by companies.*—(1) Where an offence under this Act has been committed by a company, every person who at the time the offence was 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 Act if he proves that the offence was 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 an offence under this Act 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 be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

*Explanation.*—For the purposes of this section—

(a) 'company' means a body corporate, and includes a firm or other association of individuals; and

(b) 'director' in relation to a firm means a partner in the firm.

35. *Publication of sentences passed under this Act.*—(1) If any person is convicted of an offence under this Act, it shall be lawful for the court before which the conviction takes place to cause the offender's name, place of residence, the offence of which he has been convicted and the penalty which has been inflicted upon him, to be published at the expense of such person in such newspapers or in such other manner as the court may direct.

(2) The expenses of such publication shall be deemed to form part of the costs relating to the conviction and shall be recoverable in the same manner as those costs are recoverable.

36. *Magistrate's power to impose enhanced penalties.*—Notwithstanding anything contained in section 32 of the Code of Criminal Procedure, 1898 (Act V of 1898) it shall be lawful for any presidency magistrate or any magistrate of the first class to pass any sentence authorised by this Act in excess of his powers under section 32 of the said Code.

37. *Protection of action taken in good faith.*—No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done under this Act."

17. Amendment of the Schedule, Act XXIII of 1940.—In the Schedule to the principal Act,—

(a) in the third column, in item 1 under the heading "Standard to be complied with", the words "or the formula disclosed to the Central Drugs Laboratory, as the case may be" shall be omitted;

(b) after item 3 the following item shall be inserted, namely:—

- "3A. Substances (other than food) intended to affect the structure or any part of the 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. Such standards as may be prescribed."

#### STATEMENT OF OBJECTS AND REASONS

The Drugs Act, 1940, which provides for the regulation of the import, manufacture, distribution and sale of drugs and prescribes the standards of quality of drugs, has been in force since April, 1947. In the light of the experience gained in the working of the Act during the last seven years, it is proposed to make certain amendments in the Act.

The term 'drug' as defined in the Act at present does not cover chemical contraceptives and insecticides. It is proposed to extend the scope of definition of the term so as to cover such of the contraceptives as well as insecticides as may be notified by the Central Government from time to time in the Official Gazette, so that their standards may be controlled where necessary. It has further been found necessary that with a view to maintaining uniformity throughout the States the power to make rules under Chapter IV with respect to the manufacture, sale and distribution of drugs, which is at present vested in the State Governments should be entrusted to the Central Government.

There have been complaints that the penalties provided in the Act for the contravention of the provisions thereof, are inadequate. The penalties provided in the Act are being enhanced so as to make them deterrent. Opportunity has also been taken to make certain other minor amendments.

AMRIT KAUR.

NEW DELHI;

The 10th May, 1954.

#### FINANCIAL MEMORANDUM

Section 5 of the Drugs Act, 1940 provides for the constitution of a board (called the Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administration of the Act. Clause (2) of section