

# THE DRUGS AND COSMETICS (AMENDMENT) ACT, 1982

No. 68 of 1982

[13th November, 1982.]

An Act further to amend the Drugs and Cosmetics Act, 1940.

BE it enacted by Parliament in the Thirty-third Year of the Republic of India as follows:—

1. (1) This Act may be called the Drugs and Cosmetics (Amendment) Act, 1982.

Short title and commencement.

(2) It shall come into force on such date<sup>1</sup> as the Central Government may, by notification in the Official Gazette, appoint.

23 of 1940.

2. In the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the principal Act),—

Substitution of certain expressions by new expressions.

(a) for the words and brackets "Ayurvedic (including Siddha) or Unani", wherever they occur, the words "Ayurvedic, Siddha or Unani" shall be substituted;

(b) for the words and brackets "Ayurvedic (including Siddha) and Unani", wherever they occur, the words "Ayurvedic, Siddha and Unani" shall be substituted.

3. In section 3 of the principal Act,—

Amendment of Section 3.

(a) in clause (a),—

(i) for the words "disease in human beings, mentioned in, and processed and manufactured" the words "disease or disorder in human beings or animals, and manufactured" shall be substituted;

(ii) for the words and brackets "Ayurvedic (including Siddha) and Unani (Tibb) systems of medicine", the words "Ayurvedic, Siddha and Unani Tibb systems of medicine" shall be substituted;

<sup>1</sup>1-2-1983; vide notification No. G.S.R. 39(E), dated 25-1-1983, Gazette of India, Extraordinary, 1983, Pt. II, Sec. 3(i).

(b) in clause (aa), in sub-clause (i), for the words "Ayurvedic and Unani Drugs Technical Advisory Board", the words "Ayurvedic, Siddha and Unani Drugs Technical Advisory Board" shall be substituted;

(c) in clause (aaa), the words " , but does not include soap" shall be omitted;

(d) in clause (b),—

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

"(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;"

(2) after sub-clause (ii), the following sub-clauses shall be inserted, namely:—

"(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;"

(e) in clause (f), for the words "sale and distribution", the words "sale or distribution" shall be substituted;

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

(h) "patent or proprietary medicine" means,—

(i) in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (a);

(ii) in relation to any other systems of medicine, a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other

Pharmacopoeia authorised in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board constituted under section 5;

4. For the heading under Chapter III, the following heading shall be substituted, namely:—

Substitution of new heading for heading under Chapter III.

“IMPORT OF DRUGS AND COSMETICS”.

5. For section 9 of the principal Act, the following section shall be substituted, namely:—

Substitution of new section for section 9.

“9. For the purposes of this Chapter, a drug shall be deemed to be misbranded—

Misbranded drugs

(a) 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

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

(c) 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.”.

6. For sections 9A and 9B of the principal Act, the following sections shall be substituted, namely:—

Substitution of new sections 9A, 9B, 9C and 9D for sections 9A and 9B.

“9A. For the purposes of this Chapter, a drug shall be deemed to be adulterated,—

Adulterated drugs.

(a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

Spurious  
drugs.

9B. For the purposes of this Chapter, a drug shall be deemed to be spurious—

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

(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive 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

(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by another drug or substance; or

(e) if it purports to be the product of a manufacturer of whom it is not truly a product.

Misbran-  
ded  
cosmetics.

9C. For the purposes of this Chapter, a cosmetic shall be deemed to be misbranded—

(a) if it contains a colour which is not prescribed; or

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

(c) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

Spurious  
cosmetics.

9D. For the purposes of this Chapter, a cosmetic shall be deemed to be spurious,—

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

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

(c) if the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist; or

(d) if it purports to be the product of a manufacturer of whom it is not truly a product.”

7. In section 10 of the principal Act,—

(a) in clause (b), for the words “or misbranded cosmetic”, the words “or misbranded or spurious cosmetic” shall be substituted;

(b) in clause (bb), for the word “adulterated”, the words “adulterated or spurious” shall be substituted;

(c) in clause (d), for the words “the true formula or list of ingredients contained in it, in a manner readily intelligible to the members of the medical profession”, the words “the true formula or list of active ingredients contained in it together with the quantities thereof” shall be substituted;

(d) the *Explanation* shall be omitted.

8. After section 10 of the principal Act, the following section shall be inserted, namely:—

“10A. Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do then, that Government may, by notification in the Official Gazette, prohibit the import of such drug or cosmetic.”

9. In section 12 of the principal Act,—

(a) in sub-section (1), for the words “after consultation with the Board”, the words “after consultation with or on the recommendation of the Board” shall be substituted;

(b) in sub-section (2),—

(i) in clause (a), for the words “and prescribe the form and conditions of such licences, the authority empowered to issue the same, and the fees payable therefor”, the words “and prescribe the form and conditions of such licences, the authority empowered to issue the same, the fees payable therefor and provide for the cancellation, or suspension of such licence in any case where any provision of this Chapter or the rules made thereunder is contravened or any of the conditions subject to which the licence is issued is not complied with” shall be substituted;

(ii) in clause (cc), for the word, figure and letter “section 9B”, the word, figure and letter “section 9A” shall be substituted;

Amendment of section 10.

Insertion of new section 10A.

Power of Central Government to prohibit import of drugs and cosmetics in public interest.

Amendment of section 12.

(iii) in clause (k), after the words "of imported drugs or cosmetics", the words "including the use of packing material which comes into direct contact with the drugs" shall be inserted.

Substitution of new section for section 13.

10. For section 13 of the principal Act, the following section shall be substituted, namely:—

Offences.

"13. (1) Whoever himself or by any other person on his behalf imports,—

(a) any drug deemed to be adulterated under section 9A or deemed to be a spurious drug under section 9B or any spurious cosmetic referred to in section 9D or any cosmetic of the nature referred to in clause (ee) of section 10 shall be punishable with imprisonment for a term which may extend to three years and a fine which may extend to five thousand rupees;

(b) any drug or cosmetic other than a drug or cosmetic referred to in clause (a), the import of which is prohibited under section 10, or any rule made under this Chapter, shall be punishable with imprisonment for a term which may extend to six months, or with fine which may extend to five hundred rupees, or with both;

(c) any drug or cosmetic in contravention of the provisions of any notification issued under section 10A, shall be punishable with imprisonment for a term which may extend to three years, or with fine which may extend to five thousand rupees, or with both.

(2) Whoever having been convicted of an offence—

(a) under clause (a) or clause (c) of sub-section (1), is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten thousand rupees, or with both;

(b) under clause (b) of sub-section (1), is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to one thousand rupees, or with both.

(3) The punishment provided by this section shall be in addition to any penalty to which the offender may be liable under the provisions of section 11."

Amendment of section 15.

11. In section 15 of the principal Act, for the words "of a Presidency Magistrate or of a Magistrate of the first class", the words "of a Metropolitan Magistrate or of a Judicial Magistrate of the first class" shall be substituted.

12. In the heading under Chapter IV, for the word "DRUGS", the words "DRUGS AND COSMETICS" shall be substituted.

Amendment of heading under Chapter IV

13. For sections 17, 17A and 17B of the principal Act, the following sections shall be substituted, namely:—

Substitution of new sections in sections 17, 17A and 17B.

17. For the purposes of this Chapter, a drug shall be deemed to be misbranded,—

Misbranded drugs.

(a) 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

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

(c) 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.

17A. For the purposes of this Chapter, a drug shall be deemed to be adulterated,—

Adulterated drugs.

(a) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

17B. For the purposes of this Chapter, a drug shall be deemed to be spurious,—

Spurious drugs.

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

(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive 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

(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by another drug or substance; or

(e) if it purports to be the product of a manufacturer of whom it is not truly a product.

Misbranded cosmetics.

17C. For the purposes of this Chapter, a cosmetic shall be deemed to be misbranded,—

(a) if it contains a colour which is not prescribed; or

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

(c) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

Spurious cosmetics.

17D. For the purposes of this Chapter, a cosmetic shall be deemed to be spurious,—

(a) if it is manufactured under a name which belongs to another cosmetic; or

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

(c) if the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist; or

(d) if it purports to be the product of a manufacturer of whom it is not truly a product.”

Amendment of section 18.

14. In section 18 of the principal Act,—

(a) in clause (a),—

(i) in the opening portion, for the words “manufacture for sale, or sell, or stock or exhibit for sale,” the words “manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale,” shall be substituted;

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

“(i) any drug which is not of a standard quality, or is misbranded, adulterated or spurious;



(ii) any cosmetic which is not of a standard quality or is misbranded or spurious;";

(iii) in sub-clause (iii), for the words "the true formula or list of ingredients contained in it in a manner readily intelligible to the members of the medical profession", the words "the true formula or list of active ingredients contained in it together with the quantities thereof" shall be substituted;

(b) in clause (b), for the words "sell, or stock or exhibit for sale," the words "sell, or stock or exhibit or offer for sale," shall be substituted;

(c) in clause (c),—

(i) for the words "manufacture for sale, or sell, or stock or exhibit for sale," the words "manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale," shall be substituted;

(ii) in the second proviso, for the words "manufacture for sale, sale", the words "manufacture for sale or for distribution, sale, stocking or exhibiting or offering for sale" shall be substituted;

(iii) the *Explanation* shall be omitted.

15. After section 18A of the principal Act, the following section shall be inserted, namely:—

Insertion  
of new  
section  
18B.

"18B. Every person holding a licence under clause (c) of section 18 shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act."

Mainten-  
ance of  
records  
and  
furnish-  
ing of  
informa-  
tion.

16. In section 19 of the principal Act, in sub-section (2), in the opening portion, for the word "adulterated", the words "adulterated or spurious" shall be substituted.

Amend-  
ment of  
section 19.

17. In section 20 of the principal Act, after sub-section (3), the following sub-section shall be inserted, namely:—

"(4) No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be a Government Analyst under sub-section (1) or sub-section (2) of this section."

Amend-  
ment of  
section  
20.

18. In section 21 of the principal Act, in sub-section (4), after the words "such authority", the words "having the prescribed qualifications," shall be inserted.

Amend-  
ment of  
section  
21.

Amend-  
ment of  
section 22.

19. In section 22 of the principal Act,—

(1) in sub-section (1),—

(a) for clauses (a), (b) and (c), the following clauses shall be substituted, namely:—

“(a) inspect,—

(i) any premises wherein any drug or cosmetic is being manufactured and the means employed for standardising and testing the drug or cosmetic;

(ii) any premises wherein any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed;

(b) take samples of any drug or cosmetic,—

(i) which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed;

(ii) from any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee;

(c) at all reasonable times, with such assistance, if any, as he considers necessary,—

(i) search any person, who, he has reason to believe, has secreted about his person, any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed; or

(ii) enter and search any place in which he has reason to believe that an offence under this Chapter has been, or is being, committed; or

(iii) stop and search any vehicle, vessel or other conveyance which, he has reason to believe, is being used for carrying any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed,

and order in writing the person in possession of the drug or cosmetic in respect of which the offence has been, or is being, committed, not to dispose of any stock of such drug or cosmetic 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 or cosmetic, seize the stock of such drug or cosmetic and any substance or article by means of which the offence has been, or is being, committed or which may be employed for the commission of such offence;”;

(b) in clause (cc), for the words, brackets and letter “in any place mentioned in clause (c)”, the words, brackets and letter “with any person, or in any place, vehicle, vessel or other conveyance referred to in clause (c)” shall be substituted;

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

“(cca) require any person to produce any record, register, or other document relating to the manufacture for sale or for distribution, stocking, exhibition for sale, offer for sale or distribution of any drug or cosmetic in respect of which he has reason to believe that an offence under this Chapter has been, or is being, committed;”;

(2) in sub-section (2),—

5 of 1898.  
2 of 1974.

(a) for the words and figures “the Code of Criminal Procedure, 1898”, the words and figures “the Code of Criminal Procedure, 1973” shall be substituted;

(b) for the word and figures “section 98”, the word and figures “section 94” shall be substituted;

(3) after sub-section (2), the following sub-section shall be inserted, namely:—

“(2A) Every record, register or other document seized under clause (cc) or produced under clause (cca) shall be returned to the person, from whom they were seized or who produce the same, within a period of twenty days of the date of such seizure or production, as the case may be, after copies thereof or extracts therefrom certified by that person, in such manner as may be prescribed, have been taken.”;

(4) in sub-section (3), after the words “under this Chapter,”, the words, brackets, letters and figure “or refuses to produce any record, register or other document when so required under clause (cca) of sub-section (1),” shall be inserted.

20. In section 23 of the principal Act, in clause (b) of sub-section (5) and in sub-section (6), for the words “a Magistrate”, the words “a Judicial Magistrate” shall be substituted.

Amendment of section 23.

21. After section 26 of the principal Act, the following section shall be inserted, namely:—

Insertion of new section 26A.

“26A. Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, prohibit the manufacture, sale or distribution of such drug or cosmetic.”.

Power of Central Government to prohibit manufacture, etc., of drug and cosmetic in public interest.

Substitution of new sections for sections 27 and 27A.

22. For sections 27 and 27A of the principal Act, the following sections shall be substituted, namely:—

Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter.

“27. Whoever, himself or by any other person on his behalf, manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes,—

(a) any drug deemed to be adulterated under section 17A or spurious under section 17B or which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt within the meaning of section 320 of the Indian Penal Code, solely on account of such drug being adulterated or spurious or not of standard quality, as the case may be, shall be punishable with imprisonment for a term which shall not be less than five years but which may extend to a term of life and with fine which shall not be less than ten thousand rupees;

45 of 1860.

(b) any drug—

(i) deemed to be adulterated under section 17A, but not being a drug referred to in clause (a), or

(ii) without a valid licence as required under clause (c) of section 18,

shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and with fine which shall not be less than five thousand rupees:

Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than one year and of fine of less than five thousand rupees;

(c) any drug deemed to be spurious under section 17B, but not being a drug referred to in clause (a) shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and with fine which shall not be less than five thousand rupees:

Provided that the Court may, for any adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less than three years but not less than one year;

(d) any drug, other than a drug referred to in clause (a) or clause (b) or clause (c), in contravention of any other provision of this Chapter or any rule made thereunder, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and with fine:

Provided that the Court may for any adequate and special reasons to be recorded in the judgment impose a sentence of imprisonment for a term of less than one year.

27A. Whoever himself or by any other person on his behalf manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale—

(i) any cosmetic deemed to be spurious under section 17C shall be punishable with imprisonment for a term which may extend to three years and with fine;

(ii) any cosmetic other than a cosmetic referred to in clause (i) above in contravention of any provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to one thousand rupees or with both.”.

Penalty for manufacture, sale, etc., of cosmetics in contravention of this Chapter.

23. In section 28 of the principal Act,—

(a) after the word, figures and letter “section 18A”, the words and figures “or section 24” shall be inserted;

(b) for the words “five hundred rupees”, the words “one thousand rupees” shall be substituted.

Amendment of section 28.

24. After section 28 of the principal Act, the following sections shall be inserted, namely:—

Insertion of new sections 28A and 28B.

“28A. Whoever without reasonable cause or excuse, contravenes the provisions of section 18B shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to one thousand rupees or with both.

Penalty for not keeping documents, etc., and for non-disclosure of information.

28B. Whoever himself or by any other person on his behalf manufactures or sells or distributes any drug or cosmetic in contravention of the provisions of any notification issued under section 26A, shall be punishable with imprisonment for a term which may extend to three years and shall also be liable to fine which may extend to five thousand rupees.”.

Penalty for manufacture, etc., of drugs or cosmetics in contravention of section 26A.

25. In section 30 of the principal Act,—

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

“(1) Whoever having been convicted of an offence,—

(a) under clause (b) of section 27 is again convicted of an offence under that clause, shall be punishable with

Amendment of section 30.

imprisonment for a term which shall not be less than two years but which may extend to six years and with fine which shall not be less than ten thousand rupees:

Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than two years and of fine of less than ten thousand rupees;

(b) under clause (c) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than six years but which may extend to ten years and with fine which shall not be less than ten thousand rupees;

(c) under clause (d) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to four years or with fine which shall not be less than five thousand rupees, or with both;";

(b) in sub-section (1A), for the words "one thousand rupees", the words "two thousand rupees" shall be substituted.

Amend-  
ment of  
section  
31.

26. In section 31 of the principal Act,—

(1) in sub-section (1),—

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

"(i) manufacture of any drug deemed to be misbranded under section 17, adulterated under section 17A or spurious under section 17B; or";

(b) in clause (ii), for the words "manufacture for sale, or sale, or stocking or exhibiting for sale," the words "manufacture for sale, or for distribution, sale, or stocking or exhibiting or offering for sale," shall be substituted;

(2) in sub-section (2), for the words "misbranded or adulterated drug, or misbranded cosmetic," the words "misbranded, adulterated or spurious drug or misbranded or spurious cosmetic," shall be substituted.

Amend-  
ment of  
section  
32.

27. In section 32 of the principal Act, in sub-section (2), for the words "a Presidency Magistrate or of a Magistrate of the first class", the words "a Metropolitan Magistrate or of a Judicial Magistrate of the first class" shall be substituted.

Amend-  
ment of  
section  
32A.

28. In section 32A of the principal Act, for the words, brackets and figures "in sub-section (1) of section 351 of the Code of Criminal Procedure, 1898", the words, brackets and figures "in sub-sections (1), (2) and (3) of section 319 of the Code of Criminal Procedure, 1973" shall be substituted.

## 29. In section 33 of the principal Act,—

Amend-  
ment of  
section  
33.

(a) in sub-section (1), for the words “after consultation with the Board”, the words “after consultation with, or on the recommendation of, the Board” shall be substituted;

(b) in sub-section (2),—

(1) in clause (dd), for the word, figures and letter “section 17B”, the word, figures and letter “section 17A” shall be substituted;

(2) in clause (e),—

(i) for the words “for the manufacture for sale”, the words “for the manufacture for sale or for distribution” shall be substituted;

(ii) after the words “authority empowered to issue the same”, the words “, the qualifications of such authority” shall be inserted;

(iii) the words “and provide for the cancellation or suspension of such licences in any case where any provision of this Chapter or the rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with” shall be inserted at the end;

(3) after clause (e), the following clauses shall be inserted, namely:—

“(ee) prescribe the records, registers or other documents to be kept and maintained under section 18B;

(eea) prescribe the fees for the inspection (for the purposes of grant or renewal of licences) of premises, wherein any drug or cosmetic is being or is proposed to be manufactured;

(eeb) prescribe the manner in which copies are to be certified under sub-section (2A) of section 22;”;

(4) in clause (i), after the words “other containers of drugs or cosmetics”, the words “including the use of packing material which comes into direct contact with the drugs” shall be inserted;

(5) in clause (n), after the words “of Inspectors”, the words “and the qualifications of the authority to which such Inspectors shall be subordinate” shall be inserted.

## 30. In section 33C of the principal Act,—

(a) in sub-section (1), for the words “Ayurvedic and Unani Drugs Technical Advisory Board”, the words “Ayurvedic, Siddha and Unani Drugs Technical Advisory Board” shall be substituted;

Amend-  
ment of  
section  
33C.

(b) in sub-section (2),—

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

“(iii) the principal officer dealing with Indian systems of medicine in the Ministry of Health, *ex-officio*;”;

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

“(viii) four persons to be nominated by the Central Government, two from amongst the members of the Ayurvedic Pharmacopoeia Committee, one from amongst the members of the Unani Pharmacopoeia Committee and one from amongst the members of the Siddha Pharmacopoeia Committee;”;

(iii) for clauses (xi) and (xii), the following clauses shall be substituted, namely:—

“(xi) one teacher in Gunapadam to be nominated by the Central Government;

(xii) three persons, one each to represent the Ayurvedic, Siddha and Unani drug industry, to be nominated by the Central Government;

(xiii) three persons, one each from among the practitioners of Ayurvedic, Siddha and Unani Tibb systems of medicine to be nominated by the Central Government.”.

Substitution of new sections for sections 33D and 33E.

31. For sections 33D and 33E of the principal Act, the following sections shall be substituted, namely:—

The Ayurvedic, Siddha and Unani Drugs Consultative Committee.

“33D. (1) The Central Government may constitute an Advisory Committee to be called the Ayurvedic, Siddha and Unani Drugs Consultative Committee to advise the Central Government, the State Governments and the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board on any matter for the purpose of securing uniformity throughout India in the administration of this Act in so far as it relates to Ayurvedic, Siddha or Unani drugs.

(2) The Ayurvedic, Siddha and Unani Drugs Consultative Committee shall consist of two persons to be nominated by the Central Government as representatives of that Government and not more than one representative of each State to be nominated by the State Government concerned.

(3) The Ayurvedic, Siddha and Unani Drugs Consultative Committee shall meet when required to do so by the Central Government and shall regulate its own procedure.

Misbranded drugs.

33E. For the purposes of this Chapter, an Ayurvedic, Siddha or Unani drug shall be deemed to be misbranded—

(a) 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

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

(c) 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.

33EE. For the purposes of this Chapter, an Ayurvedic, Siddha or Unani drug shall be deemed to be adulterated,—

Adulterated  
drugs.

(a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

*Explanation.*—For the purpose of clause (a), a drug shall not be deemed to consist, in whole or in part, of any decomposed substance only by reason of the fact that such decomposed substance is the result of any natural decomposition of the drug:

Provided that such decomposition is not due to any negligence on the part of the manufacturer of the drug or the dealer thereof and that it does not render the drug injurious to health.

33EEA. For the purposes of this Chapter, an Ayurvedic, Siddha or Unani drug shall be deemed to be spurious—

Spurious  
drugs.

(a) if it is sold, or offered or exhibited for sale, under a name which belongs to another drug; or

(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive, 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

(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by any other drug or substance; or

(e) if it purports to be the product of a manufacturer of whom it is not truly a product.

Regulation of manufacture for sale of Ayurvedic, Siddha and Unani drugs.

Prohibition of manufacture and sale of certain Ayurvedic, Siddha and Unani drugs.

33EEB. No person shall manufacture for sale or for distribution any Ayurvedic, Siddha or Unani drug except in accordance with such standards, if any, as may be prescribed in relation to that drug.

33EEC. From such date as the State Government may, by notification in the Official Gazette, specify in this behalf, no person, either by himself or by any other person on his behalf, shall—

(a) manufacture for sale or for distribution—

(i) any misbranded, adulterated or spurious Ayurvedic, Siddha or Unani drug;

(ii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true list of all the ingredients contained in it; and

(iii) any Ayurvedic, Siddha or Unani drug in contravention of any of the provisions of this Chapter or any rule made thereunder;

(b) sell, stock or exhibit or offer for sale or distribute any Ayurvedic, Siddha or Unani drug which has been manufactured in contravention of any of the provisions of this Act, or any rule made thereunder;

(c) manufacture for sale or for distribution, any Ayurvedic, Siddha or Unani drug, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter by the prescribed authority:

Provided that nothing in this section shall apply to *Vaidyas* and *Hakims* who manufacture Ayurvedic, Siddha or Unani drug for the use of their own patients:

Provided further that nothing in this section shall apply to the manufacture, subject to the prescribed conditions, of small quantities of any Ayurvedic, Siddha or Unani drug for the purpose of examination, test or analysis.

Power of Central Government to prohibit manufacture, etc., of Ayurvedic, Siddha or Unani drugs in public interest.

33EED. Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied on the basis of any evidence or other material available before it that the use of any Ayurvedic, Siddha or Unani drug is likely to involve any risk to human beings or animals or that any such drug does not have the therapeutic value claimed or purported to be claimed for it and that in the public interest it is necessary or expedient so to do then, that Government may, by notification in the Official Gazette, prohibit the manufacture, sale or distribution of such drug.”

32. In section 33F of the principal Act, after sub-section (2), the following sub-section shall be inserted, namely:—

“(3) No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be a Government Analyst under this section.”

Amendment of section 33F.

33. For sections 33-I and 33J of the principal Act, the following sections shall be substituted, namely:—

Substitution of new sections for sections 33-I and 33J.

“33-I. Whoever himself or by any other person on his behalf—

(1) manufactures for sale or for distribution,—

(a) any Ayurvedic, Siddha or Unani drug—

(i) deemed to be adulterated under section 33EE, or

(ii) without a valid licence as required under clause

(c) of section 33EEC,

shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than two thousand rupees;

(b) any Ayurvedic, Siddha or Unani drug deemed to be spurious under section 33EEA, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and with fine which shall not be less than five thousand rupees:

Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than one year and of fine of less than five thousand rupees; or

(2) contravenes any other provisions of this Chapter or of section 24 as applied by section 33H or any rule made under this Chapter, shall be punishable with imprisonment for a term which may extend to three months and with fine which shall not be less than five hundred rupees.

33J. Whoever having been convicted of an offence,—

(a) under clause (a) of sub-section (1) of section 33-I is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to two years and with fine which shall not be less than two thousand rupees;

(b) under clause (b) of sub-section (1) of section 33-I is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to six years and with fine which shall not be less than five thousand rupees:

Penalty for manufacture, sale, etc., of Ayurvedic, Siddha or Unani drug in contravention of this Chapter.

Penalty for subsequent offences.

Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than two years and of fine of less than five thousand rupees;

(c) under sub-section (2) of section 33-I is again convicted of an offence under that sub-section, shall be punishable with imprisonment for a term which may extend to six months and with fine which shall not be less than one thousand rupees.”.

Amend-  
ment of  
section  
33M.

34. In section 33M of the principal Act,—

(a) in sub-section (1), the words, brackets, figures and letter “with the previous sanction of the authority specified under sub-section (4) of section 33G” shall be inserted at the end;

(b) in sub-section (2), for the words “of a Presidency Magistrate or of a Magistrate of the first class”, the words “of a Metropolitan Magistrate or of a Judicial Magistrate of the first class” shall be substituted.

Amend-  
ment of  
section  
33N.

35. In section 33N of the principal Act,—

(a) in sub-section (1), in the opening portion, for the words “after consultation with the Board”, the words “after consultation with, or on the recommendation of, the Board” shall be substituted;

(b) in sub-section (2),—

(1) in clause (e),—

(i) after the words “or Unani drugs”, the words “and for sale of processed Ayurvedic, Siddha or Unani drugs,” shall be inserted;

(ii) the words “and provide for the cancellation or suspension of such licences in any case where any provision of this Chapter or rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with” shall be inserted at the end;

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

“(f) prescribe the conditions to be observed in the packing of Ayurvedic, Siddha and Unani drugs including the use of packing material which comes into direct contact with the drugs, regulate the mode of labelling packed drugs and prescribe the matters which shall or shall not be included in such labels;”;

(3) after clause (g), the following clauses shall be inserted, namely:—

“(gg) prescribe under clause (d) of section 33EE the colour or colours which an Ayurvedic, Siddha or Unani drug may bear or contain for purposes of colouring;

(gga) prescribe the standards for Ayurvedic, Siddha or Unani drugs under section 33EEB;”.

36. After section 34A of the principal Act, the following section shall be inserted, namely:—

Insertion of new section 34AA.

“34AA. Any Inspector exercising powers under this Act or the rules made thereunder, who,—

Penalty for vexatious search or seizure.

(a) without reasonable ground of suspicion searches any place, vehicle, vessel or other conveyance; or

(b) vexatiously and unnecessarily searches any person; or

(c) vexatiously and unnecessarily seizes any drug or cosmetic, or any substance or article, or any record, register, document or other material object; or

(d) commits, as such Inspector, any other act, to the injury of any person without having reason to believe that such act is required for the execution of his duty,

shall be punishable with fine which may extend to one thousand rupees.”

37. In section 35 of the principal Act, in sub-section (1), for the words “it shall be lawful for the Court before which the conviction takes place to cause”, the words “the Court before which the conviction takes place shall, on application made to it by the Inspector, cause” shall be substituted.

Amendment of section 35.

38. In section 36 of the principal Act,—

(a) for the words and figures “the Code of Criminal Procedure, 1898”, the words and figures “the Code of Criminal Procedure, 1973” shall be substituted;

(b) for the words “any Presidency Magistrate or any Magistrate of the first class”, the words “any Metropolitan Magistrate or any Judicial Magistrate of the first class” shall be substituted.

Amendment of section 36.

39. After section 36 of the principal Act, the following section shall be inserted, namely:—

Insertion of new section 36A.

“36A. Notwithstanding anything contained in the Code of Criminal Procedure, 1973, all offences under this Act, punishable with imprisonment for a term not exceeding three years, other than an offence under clause (b) of sub-section (1) of section 33-I, shall be tried in a summary way by a Judicial Magistrate of the first class specially empowered in this behalf by the State Government or by a Metropolitan Magistrate and the provisions of sections 262 to 265 (both inclusive) of the said Code shall, as far as may be, apply to such trial:

Certain offences to be tried summarily.

Provided that, in the case of any conviction in a summary trial under this section, it shall be lawful for the Magistrate to pass a sentence of imprisonment for a term not exceeding one year:

Provided further that when at the commencement of, or in the course of, a summary trial under this section it appears to the Magistrate that the nature of the case is such that a sentence of

5 of 1898.  
2 of 1974.

2 of 1974.

imprisonment for a term exceeding one year may have to be passed or that it is, for any other reason, undesirable to try the case summarily, the Magistrate shall, after hearing the parties, record an order to that effect and thereafter recall any witness who has been examined and proceed to hear or rehear the case in the manner provided by the said Code.”.

Amend-  
ment of  
section  
38.

40. In section 38 of the principal Act, for the words “and if before the expiry of the session in which it is so laid or the successive sessions aforesaid”, the words “and if, before the expiry of the session immediately following the session or the successive sessions aforesaid” shall be substituted.

Amend-  
ment of  
First  
Sche-  
dule.

41. In the First Schedule to the principal Act,—

(a) for the heading “A.—AYURVEDIC (INCLUDING SIDDHA) SYSTEM”, the heading “A.—AYURVEDIC AND SIDDHA SYSTEMS” shall be substituted;

(b) for the heading “B.—UNANI (TIBB) SYSTEM”, the heading “B.—UNANI TIBB SYSTEM” shall be substituted.

Transi-  
tory pro-  
vision.

42. (1) Until the constitution of the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board in accordance with the provisions of the principal Act, as amended by this Act, the Ayurvedic and Unani Drugs Technical Advisory Board constituted in accordance with the provisions of the principal Act and functioning immediately before the commencement of this Act shall be deemed to be the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board constituted in accordance with the provisions of the principal Act as amended by this Act and shall continue to function as if this Act had not been passed.

(2) On the constitution of the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board in accordance with the provisions of the principal Act, as amended by this Act, every person nominated as a member of the Ayurvedic and Unani Drugs Technical Advisory Board, in accordance with the provisions of the principal Act, and holding office as such member immediately before such constitution shall be deemed to have vacated his office.