

Rep. by Act... 56 of 1974, s. 22 Sch. I

THE DRUGS AND COSMETICS (AMENDMENT)
ACT, 1964

No. 13 OF 1964

[12th May, 1964]

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

BE it enacted by Parliament in the Fifteenth Year of the Republic of India as follows:—

1. (1) This Act may be called the Drugs and Cosmetics (Amendment) Act, 1964. Short title and commencement.

(2) It shall come into force on such date¹ as the Central Government may, by notification in the Official Gazette, appoint, and different dates may be appointed for different provisions of this Act.

23 of 1940.

2. In section 3 of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the principal Act),— Amendment of section 3.

(a) clauses (a) and (aa) shall be re-lettered as clauses (aa) and (aaa) respectively, and—

(i) before clause (aa) as so re-lettered, the following clause shall be inserted, namely:—

“(a) “Ayurvedic (including Siddha) or Unani drug” includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings, mentioned in, and processed and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic (including Siddha) and Unani (Tibb) systems of medicine, specified in the First Schedule;”;

(ii) for clause (aa) as so re-lettered, the following clause shall be substituted, namely:—

“(aa) “the Board” means—

¹The provisions of this Act except sections 25 and 26 and Sch. I referred to in section 31, shall come into force on 15-9-1964: Vide S. O. 3404, dated 3-9-1964, Gazette of India, Pt. II, Sec. 3(ii), p. 3911.

2. Provisions of sections 25, 26¹³⁵ and Sch. I, referred to in section 31, shall come into force on 1-2-1969: vide S.O. 325 dated 16-1-69, Gaz. of India, Pt. II, section 3(ii), p. 380.

(i) in relation to Ayurvedic (including Siddha) or Unani drug, the Ayurvedic and Unani Drugs Technical Advisory Board constituted under section 33C; and

(ii) in relation to any other drug or cosmetic, the Drugs Technical Advisory Board constituted under section 5;';

(b) in clause (b),—

(i) in sub-clause (i), the words "other than medicines and substances exclusively used or prepared for use in accordance with the Ayurvedic or Unani systems of medicine" shall be omitted;

(ii) in sub-clause (ii), for the word "vermins", the word "vermin" shall be substituted;

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

'(c) "Government Analyst" means—

(i) in relation to Ayurvedic (including Siddha) or Unani drug, a Government Analyst appointed by the Central Government or a State Government under section 33F; and

(ii) in relation to any other drug or cosmetic, a Government Analyst appointed by the Central Government or a State Government under section 20;';

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

'(e) "Inspector" means—

(i) in relation to Ayurvedic (including Siddha) or Unani drug, an Inspector appointed by the Central Government or a State Government under section 33G; and

(ii) in relation to any other drug or cosmetic, an Inspector appointed by the Central Government or a State Government under section 21;';

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

'(h) "patent or proprietary medicine" means 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 in any other pharmacopoeia authorised in this behalf by the Central Government after consultation with the Board;.

3. In section 4 of the principal Act, after the word and figures "Chapter IV" wherever they occur, the words, figures and letter "or Chapter IVA" shall be inserted. Amendment of section 4.

4. In section 5 of the principal Act,—

Amendment of section 5.

(a) for sub-section (2), the following sub-section shall be substituted, namely:—

"(2) The Board shall consist of the following members, namely:—

(i) the Director General of Health Services, *ex officio*, who shall be Chairman;

(ii) the Drugs Controller, India, *ex officio*;

(iii) the Director of the Central Drugs Laboratory, Calcutta, *ex officio*;

(iv) the Director of the Central Research Institute, Kasauli, *ex officio*;

(v) the Director of the Indian Veterinary Research Institute, Izatnagar, *ex officio*;

(vi) the President of the Medical Council of India, *ex officio*;

(vii) the President of the Pharmacy Council of India, *ex officio*;

(viii) the Director of the Central Drug Research Institute, Lucknow, *ex officio*;

(ix) two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States;

(x) one person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or

pharmacognosy on the staff of an Indian University or a college affiliated thereto;

(xi) one person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto;

(xii) one person to be nominated by the Central Government from the pharmaceutical industry;

(xiii) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;

(xiv) one person to be elected by the Central Council of the Indian Medical Association;

(xv) one person to be elected by the Council of the Indian Pharmaceutical Association;

(xvi) two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government;"

(b) in sub-section (3), for the proviso, the following proviso shall be substituted, namely:—

"Provided that the person nominated or elected, as the case may be, under clause (ix) or clause (x) or clause (xi) or clause (xvi) of sub-section (2) shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the Board."

Amend-
ment of
section 6.

5. In section 6 of the principal Act, in clause (d) of sub-section (2), for the words and figures "under Chapter IV", the words, figures and letter "under Chapter IV or Chapter IVA" shall be substituted.

Insertion
of new
section 7A.

6. In Chapter II of the principal Act, after section 7, the following section shall be inserted, namely:—

"7A. Nothing contained in sections 5 and 7 shall apply to Ayurvedic (including Siddha) or Unani drugs."

Sections 5
and 7 not
to apply to
Ayurvedic
(including
Siddha)
or Unani
drugs.

7. In section 8 of the principal Act, for the words "the Schedule" wherever they occur, the words "the Second Schedule" shall be substituted. Amendment of section 8.

8. After section 9A of the principal Act, the following section shall be inserted, namely:— Insertion of new section 9B.

"9B. 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 any substance has been—

(i) mixed or packed therewith so as to reduce its quality or strength; or

(ii) substituted wholly or in part therefor.

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 within the period, if any, specified on the label of the drug within which the drug is to be used:

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

9. In section 10 of the principal Act, after clause (b), the following clause shall be inserted, namely:— Amendment of section 10.

"(bb) any adulterated drug;"

Amend-
ment of
section 12.

10. In section 12 of the principal Act, in sub-section (2), after clause (c), the following clause shall be inserted, namely:—

“(cc) prescribe under clause (d) of section 9B the colour or colours which a drug may bear or contain for purposes of colouring;”.

Amend-
ment of
section 16.

11. In section 16 of the principal Act, for the words “the Schedule” wherever they occur, the words “the Second Schedule” shall be substituted.

Insertion
of new
section
17B.

12. After section 17A of the principal Act, the following section shall be inserted, namely:—

Adultera-
ted drugs.

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

(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 any substance has been—

(i) mixed or packed therewith so as to reduce its quality or strength; or

(ii) substituted wholly or in part therefor.

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 within the period, if any, specified on the label of the drug within which the drug is to be used:

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.”.

Amend-
ment of
section 18.

13. In section 18 of the principal Act, in clause (a), after sub-clause (ii), the following sub-clause shall be inserted, namely:—

“(iia) any adulterated drug;”.

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

Insertion
of new
section
18A.

“18A. Every person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic.”

Disclosure
of the
name of
the manu-
facturer,
etc.

15. In section 19 of the principal Act,—

Amend-
ment of
section 19.

(a) in sub-section (2),—

(i) for the words and figures “For the purposes of section 18 a drug or cosmetic shall not be deemed to be misbranded or to be below standard quality”, the words and figures “For the purposes of section 18 a drug shall not be deemed to be misbranded or adulterated or to be below standard quality nor shall a cosmetic be deemed to be misbranded or to be below standard quality” shall be substituted;

(ii) clause (aa) shall be omitted;

(b) for sub-section (3), the following sub-section shall be substituted, namely:—

“(3) A person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall not be liable for a contravention of section 18 if he proves—

(a) that he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer thereof;

(b) that he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of that section; and

(c) that the drug or cosmetic, while in his possession, was properly stored and remained in the same state as when he acquired it.”

16. In section 23 of the principal Act, for clause (iii) of sub-section (4), the following clause shall be substituted, namely:—

Amend-
ment of
section 23.

“(iii) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A.”

Amend-
ment of
section 25.

17. In section 25 of the principal Act,—

(a) in sub-section (2), for the words, brackets and figures “and another copy to the warrantor, if any, named under the proviso to sub-section (3) of section 19”, the words, figures and letter “and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A” shall be substituted;

(b) in sub-section (3), for the words “or the said warrantor”, the words, figures and letter “or the person whose name, address and other particulars have been disclosed under section 18A” shall be substituted.

Substitu-
tion of
section 27.

18. For section 27 of the principal Act, the following section shall be substituted, namely:—

Penalty
for manu-
facture,
sale, etc.,
of drugs
in contra-
vention
of this
Chapter.

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

(a) any drug—

(i) deemed to be misbranded under clause (a), clause (b), clause (c), clause (d), clause (f) or clause (g) of section 17 or adulterated under section 17B; 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 ten years and shall also be liable to fine:

Provided that the Court may, for any special reasons to be recorded in writing, impose a sentence of imprisonment of less than one year;

(b) any drug other than a drug referred to in clause (a) in contravention of any of the provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to three years, or with fine, or with both.”

Substitu-
tion of
section 28.

19. For section 28 of the principal Act, the following section shall be substituted, namely:—

Penalty
for non-
disclosure
of the
name of
the manu-
facturer,
etc.

“28. Whoever contravenes the provisions of section 18A shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to five hundred rupees, or with both.”

20. In section 30 of the principal Act,—

Amend-
ment of
section 30.

(a) in sub-section (1), for the words "five years" wherever they occur, the words "ten years" shall be substituted;

(b) in sub-section (2),—

(i) the words and figures "section 28 or" shall be omitted;

(ii) for the words "two years", the words "ten years" shall be substituted.

21. In section 31 of the principal Act,—

Amend-
ment of
section 31.

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

"and if such contravention is in respect of—

(i) manufacture of any drug deemed to be misbranded under clause (a), clause (b), clause (c), clause (d), clause (f) or clause (g) of section 17 or adulterated under section 17B; or

(ii) manufacture for sale, or sale, or stocking or exhibiting for sale, or distribution of any drug without a valid licence as required under clause (c) of section 18,

any implements or machinery used in such manufacture, sale or distribution and any receptacles, packages or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances used in carrying such drug shall also be liable to confiscation";

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

22. After section 31 of the principal Act, the following section shall be inserted, namely:—

Insertion
of new
section
31A.

"31A. The provisions of this Chapter except those contained in section 31 shall apply in relation to the manufacture, sale or distribution of drugs by any department of Government as they apply in relation to the manufacture, sale or distribution of drugs by any other person."

Applica-
tion of
provi-
sions to
Govern-
ment
depart-
ments.

Insertion
of new
section
32A.

Power of
Court to
implead
the manu-
facturer,
etc.

23. After section 32 of the principal Act, the following section shall be inserted, namely:—

“32A. Where, at any time during the trial of any offence under this Chapter alleged to have been committed by any person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, the Court is satisfied, on the evidence adduced before it, that such manufacturer or agent is also concerned in that offence, then, the Court may, notwithstanding anything contained in sub-section (1) of section 351 of the Code of Criminal Procedure, 1898, proceed against him as if 5 of 1898. though a prosecution had been instituted against him under section 32.”

Amend-
ment of
section 33.

24. In section 33 of the principal Act,—

(i) in sub-section (2),—

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

“(dd) prescribe under clause (d) of section 17B the colour or colours which a drug may bear or contain for purposes of colouring;”;

(b) clause (m) shall be omitted;

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

“(p) specify the offences against this Chapter or any rule made thereunder in relation to which an order of confiscation may be made under section 31; and”;

(ii) sub-section (3) shall be omitted.

Insertion
of new
section
33A.

25. In Chapter IV of the principal Act, after section 33, the following section shall be inserted, namely:—

Chapter
not to
apply to
Ayurvedic
(including
Siddha)
or Unani
drugs.

“33A. Save as otherwise provided in this Act, nothing contained in this Chapter shall apply to Ayurvedic (including Siddha) or Unani drugs.”

26. After Chapter IV of the principal Act, the following Chapter shall be inserted, namely:—

Insertion
of new
Chapter
IVA.

‘CHAPTER IVA

PROVISIONS RELATING TO AYURVEDIC (INCLUDING SIDDHA) AND UNANI
DRUGS

33B. This Chapter shall apply only to Ayurvedic (including Siddha) and Unani drugs.

Applica-
tion of
Chapter
IVA.

33C. (1) The Central Government shall, by notification in the Official Gazette and with effect from such date as may be specified therein, constitute a Board (to be called the Ayurvedic and Unani Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of this Chapter and to carry out the other functions assigned to it by this Chapter.

Ayurvedic
and Unani
Drugs
Technical
Advisory
Board.

(2) The Board shall consist of the following members, namely:—

- (i) the Director General of Health Services, *ex officio*;
- (ii) the Drugs Controller, India, *ex officio*;
- (iii) the Adviser in indigenous systems of medicine, Ministry of Health, *ex officio*;
- (iv) the Director of the Central Drugs Laboratory, Calcutta, *ex officio*;
- (v) one person holding the appointment of Government Analyst under section 33F, to be nominated by the Central Government;
- (vi) one Pharmacognocist to be nominated by the Central Government;
- (vii) one Phyto-chemist to be nominated by the Central Government;
- (viii) two persons to be nominated by the Central Government from among members of the Central Council of Ayurvedic Research;
- (ix) one teacher in Dravyaguna and Bhaishajya Kalpana, to be nominated by the Central Government;
- (x) one teacher in IL-MUL-ADVIA and TAKLIS-WA-DAWASAZI, to be nominated by the Central Government;

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

(xii) two persons, one each from among the practitioners of Ayurvedic (including Siddha) and Unani systems of medicine, to be nominated by the Central Government.

(3) The Central Government shall appoint a member of the Board as its Chairman.

(4) The nominated members of the Board shall hold office for three years but shall be eligible for renomination.

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

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

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

Prohibition
of manu-
facture for
sale of
Ayurvedic
(including
Siddha)
and Unani
drugs.

33D. From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf, manufacture for sale any Ayurvedic (including Siddha) or Unani, drug—

(a) except under prescribed hygienic conditions;

(b) except under the supervision of a person having the prescribed qualifications;

(c) except under and in accordance with the conditions of a licence issued for such purpose under this Chapter;

(d) unless the raw materials used in the preparation of such drug are genuine and are properly identified;

(e) unless such drug is labelled with the true list of all the ingredients contained in it and with such other particulars as may be prescribed; and

(f) in contravention of any of the provisions of this Chapter or any rule made thereunder:

Provided that nothing in this section shall apply to Vaidyas and Hakims who manufacture such drugs for the use of their own patients:

Provided further that nothing in clauses (a), (b) and (c) shall apply to the manufacture, subject to prescribed conditions, of small quantities of any such drug for the purpose of examination, test or analysis.

33E. From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf, sell, or stock or exhibit for sale, or distribute, any Ayurvedic (including Siddha) or Unani drug other than that manufactured by a manufacturer licensed under this Chapter.

Restriction on sale, etc., of Ayurvedic (including Siddha) and Unani drugs.

33F. (1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

Government Analysts.

(2) Notwithstanding anything contained in sub-section (1), neither the Central Government nor a State Government shall appoint as a Government Analyst any official not serving under it without the previous consent of the Government under which he is serving.

33G. (1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

Inspectors.

(2) The powers which may be exercised by an Inspector and the duties which may be performed by him and the conditions, limitations or restrictions subject to which such powers and duties may be exercised or performed shall be such as may be prescribed.

(3) No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be an Inspector under this section.

(4) Every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code and shall be officially subordinate to such authority as the Government appointing him may specify in this behalf.

Applica-
tion of
provi-
sions of
sections
22, 23, 24
and 25.

33H. The provisions of sections 22, 23, 24 and 25 and the rules, if any, made thereunder shall, so far as may be, apply in relation to an Inspector and a Government Analyst appointed under this Chapter as they apply in relation to an Inspector and a Government Analyst appointed under Chapter IV, subject to the modification that the references to "drug" in the said sections, shall be construed as references to "Ayurvedic (including Siddha) or Unani drug".

Penalty
for manu-
facture,
sale, etc.,
of Ayur-
vedic
(includ-
ing
Siddha)
and Unani
drugs in
contra-
vention
of this
Chapter.

33I. Whoever contravenes the provisions of section 33D or section 33E or 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, or with fine which may extend to five hundred rupees, or with both.

Penalty
for sub-
sequent
offences.

33J. Whoever, having been convicted of an offence under section 33D or section 33E is again convicted of an offence under the said section shall be punishable with imprisonment for a term which may extend to six months, or with fine which may extend to one thousand rupees, or with both.

Confisca-
tion.

33K. Where any person has been convicted under this Chapter, the stock of the Ayurvedic (including Siddha) or Unani drug, in respect of which the contravention has been made, shall be liable to confiscation.

Applica-
tion of
provi-
sions to
Govern-
ment
depart-
ments.

33L. The provisions of this Chapter except those contained in section 33K shall apply in relation to the manufacture for sale, sale, or distribution of any Ayurvedic (including Siddha) or Unani drug by any department of Government as they apply in relation to the manufacture for sale, sale, or distribution of such drug by any other person.

Cogniz-
ance of
offences.

33M. (1) No prosecution under this Chapter shall be instituted except by an Inspector.

(2) No Court inferior to that of a Presidency Magistrate or of a Magistrate of the first class shall try an offence punishable under this Chapter.

Power of
Central
Govern-
ment to
make
rules.

33N. (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.

(2) Without prejudice to the generality of the foregoing power, such rules may,—

(a) provide for the establishment of laboratories for testing and analysing Ayurvedic (including Siddha) or Unani drugs;

(b) prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;

(c) prescribe the methods of test or analysis to be employed in determining whether any Ayurvedic (including Siddha) or Unani drug is labelled with the true list of the ingredients which it is purported to contain;

(d) specify any substance as a poisonous substance;

(e) prescribe the forms of licences for the manufacture for sale of Ayurvedic (including Siddha) or Unani drugs, the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same and the fees payable therefor;

(f) regulate the mode of labelling packed Ayurvedic (including Siddha) or Unani drugs and prescribe the matters which shall or shall not be included in such labels;

(g) prescribe the conditions subject to which small quantities of Ayurvedic (including Siddha) or Unani drugs may be manufactured for the purpose of examination, test or analysis; and

(h) any other matter which is to be or may be prescribed under this Chapter.

330. The Central 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 First Schedule for the purposes of this Chapter and thereupon the said Schedule shall be deemed to be amended accordingly.

Power to
amend
First
Schedule.

Amendment of section 33A.

27. Section 33A of the principal Act shall be re-numbered as section 33P.

Insertion of new section 34A.

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

Offences by Government departments.

“34A. Where an offence under Chapter IV or Chapter IVA has been committed by any department of Government, such authority as is specified by the Central Government to be in-charge of manufacture, sale or distribution of drugs or where no authority is specified, the head of the department, 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 section shall render any such authority or person liable to any punishment provided in Chapter IV or Chapter IVA, as the case may be, if such authority or person proves that the offence was committed without its or his knowledge or that such authority or person exercised all due diligence to prevent the commission of such offence.”.

Amendment of section 36.

29. In section 36 of the principal Act, the words and figures “section 32 of” shall be omitted.

Insertion of new section 38.

30. After section 37 of the principal Act, the following section shall be inserted, namely:—

Rules to be laid before Parliament.

“38. Every rule made under this Act shall be laid as soon as may be after it is made before each House of Parliament while it is in session for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if before the expiry of the session in which it is so laid or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so however that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.”.

31. For the Schedule to the principal Act, the following Schedules shall be substituted, namely:—

Substitution of Schedule.

“THE FIRST SCHEDULE

[See section 3(a)]

A.—AYURVEDIC (INCLUDING SIDDHA) SYSTEM

Serial No.	Name of book
<i>Ayurveda</i>	
1.	Arogya Kalpadruma
2.	Arka Prakasha
3.	Arya Bhashak
4.	Ashtanga Hridaya
5.	Ashtanga Samgraha
6.	Ayurveda Kalpadruma
7.	Ayurveda Prakasha
8.	Ayurveda Samgraha
9.	Bhaishajya Ratnavali
10.	Bharat Bhaishajya Ratnakara
11.	Bhava Prakasha
12.	Brihat Nighantu Ratnakara
13.	Charaka Samhita
14.	Chakra Datta
15.	Gada Nigraha
16.	Kupi Pakva Rasayana
17.	Nighantu Ratnakara
18.	Rasa Chandanshu
19.	Rasa Raja Sundara
20.	Rasaratna Samuchaya
21.	Rasatantra Sara Siddha Prayoga Samgraha
22.	Rasa Tarangini
23.	Rasa Yoga Sagara
24.	Rasa Yoga Ratnakara
25.	Rasa Yoga Samgraha
26.	Rasendra Sara Samgraha

Serial No.	Name of book
27.	Rasa Pradipika
28.	Sahasrayoga
29.	Sarvaroga Chikitsa Ratnam
30.	Sarvayoga Chikitsa Ratnam
31.	Sharangadhara Samhita
32.	Siddha Bhaishajya Manimala
33.	Siddha Yoga Samgraha
34.	Sushruta Samhita
35.	Vaidya Chintamani
36.	Vaidyaka Shabda Sindu
37.	Vaidyaka Chikitsa Sara
38.	Vaidya Jiwan
39.	Basava Rajeeyam
40.	Yoga Ratnakara
41.	Yoga Tarangini
42.	Yoga Chintamani
43.	Kashyapasamhita
44.	Bhelasamhita
45.	Vishwanathachikitsa
46.	Vrindachikitsa
47.	Ayurvedachintamani
48.	Abhinavachintamani
49.	Ayurveda-ratnakar
50.	Yogaratanasangraha
51.	Rasamrita
52.	Dravyagunanighantu
53.	Rasamanjari
54.	Bangasena
<i>Siddha</i>	
55.	Siddha Vaidya Thirattu
56.	Therayar Maha Karisal
57.	Brahma Muni Karukkadai (300)
58.	Bhogar (700)
59.	Pulippani (500)

Serial No.	Name of book
60.	Agasthiyar Paripuramam (400)
61.	Therayar Yamagam
62.	Agasthiyar Chenduram (300)
63.	Agasthiyar (1500)
64.	Athmarakshamrutham
65.	Agasthiyar Pin (80)
66.	Agasthiyar Rathna Churukkam
67.	Therayar Karisal (300)
68.	Veeramamuni Nasa Kandam
69.	Agasthiyar (600)
70.	Agasthiyar Kanma Soothiram
71.	18 Siddhar's Chillarai Kovai
72.	Yogi Vatha Kaviyam
73.	Therayar Tharu
74.	Agasthiyar Vaidya Kaviyam (1500)
75.	Bala Vagadam
76.	Chimittu Rathna (Rathna) Churukkam
77.	Nagamuni (200)
78.	Agasthiyar Chillarai Kovai
79.	Chikicha Rathna Deepam
80.	Agasthiyar Nayana Vidhi
81.	Yugi Karisal (151)
82.	Agasthiyar Vallathi (600)
83.	Therayar Thaila Varkam

B.—UNANI (TIBB) SYSTEM

Serial No.	Name of book
1.	Karabadin Qadri
2.	Karabadin Kabir
3.	Karabadin Azam
4.	Ilaj-ul-Amraz
5.	Al Karabadin
6.	Biaz Kabir Vol. II
7.	Karabadin Jadid
8.	Kitab-ul-Taklis
9.	Sanat-ul-Taklis
10.	Mifta-ul-Khazain
11.	Madan-ul-Aksir
12.	Makhzan-ul-murabbat.

THE SECOND SCHEDULE

(See sections 8 and 18)

STANDARDS TO BE COMPLIED WITH BY IMPORTED DRUGS AND BY DRUGS MANUFACTURED FOR SALE, SOLD, STOCKED OR EXHIBITED FOR SALE OR DISTRIBUTED.

Class of drug	Standard to be complied with
1. Patent or proprietary medicines.	The formula or list of ingredients displayed in the prescribed manner on the label or container and such other standards as may be prescribed.
2. Substances commonly known as vaccines, sera, toxine, toxoids, antitoxins, and antigens and biological products of such nature.	The standards maintained at the International Laboratory for Biological Standards, Stantans Seruminstitut, Copenhagen and such further standards of strength, quality and purity as may be prescribed.
3. Vitamins, hormones and analogous products.	The standards maintained at the International Laboratory for Biological Standards, National Institute for Medical Research, London, and such further standards of strength, quality and purity as may be prescribed.
4. 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 vermin or insects which cause disease in human beings or animals.	Such standards as may be prescribed.
5. Other drugs:	Standards of identity, purity and strength specified in the edition of the Indian Pharmacopoeia for the time being and such other standards as may be prescribed.
(a) Drugs included in the Indian Pharmacopoeia.	
(b) Drugs not included in the Indian Pharmacopoeia but which are included in any Pharmacopoeia of any other country.	Standards of identity, purity and strength specified for the drugs in the edition of such pharmacopoeia for the time being and such other standards as may be prescribed."

32. Until the constitution of the Drugs Technical Advisory Board under section 5 of the principal Act as amended by this Act, the Drugs Technical Advisory Board constituted under section 5 of the principal Act and functioning immediately before the commencement of this Act shall be deemed to be the Drugs Technical Advisory Board constituted under section 5 of the principal Act as amended by this Act and shall continue to function as if this Act had not been passed.

Transitory
provision.