# THE DRUGS AND COSMETICS ACT, 1940
## (23 of 1940)[1]

*[10th April, 1940]*

An Act to regulate the import, manufacture, distribution and sale of drugs [2][and cosmetics].

Whereas it is expedient to regulate the [3][import, manufacture, distribution and sale] of drugs [2][and cosmetics];

And whereas the Legislatures of all the Provinces have passed resolutions in terms of section 103 of the Government of India Act, 1935 in relation to such of the above-mentioned matters and matters ancillary thereto as are enumerated in List II of the Seventh Schedule to the said Act;

It is hereby enacted as follows:—

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## CHAPTER I
## INTRODUCTORY

**1. Short title, extent and commencement.—(1)** This Act may be called the Drugs [4][and Cosmetics] Act, 1940.

(2) It extends to the whole of India [5][***].

(3) It shall come into force at once, but Chapter III shall take effect only from such date[6] as the Central Government may, by notification in the Official Gazette, appoint in this behalf, and Chapter IV shall take effect in a particular State only from such date[6] as the State Government may, by like notification, appoint in this behalf:

[7][Provided that in relation to the State of Jammu and Kashmir, Chapter III shall take effect only from such date[6] after the commencement of the Drugs and Cosmetics (Amendment) Act, 1972 (19 of 1972), as the Central Government may, by notification in the Official Gazette, appoint in this behalf.]

**2. Application of other laws not barred.**—The provisions of this Act shall be in addition to, and not in derogation of, the Dangerous Drugs Act, 1930 (2 of 1930), and any other law for the time being in force.

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

[1][([a]) "[7]*l*Ayurvedic, Siddha or Unani] drug" includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of [8][disease or disorder in human beings or animals, and manufactured] exclusively in accordance with the formulae described in, the authoritative books of [9][Ayurvedic, Siddha and Unani Tibb systems of medicine], specified in the First Schedule;]

[5][(aa) "the Board" means—

(i) in relation to [2][Ayurvedic, Siddha or Unani] drug, the [6][Ayurvedic, Siddha 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;]

[5][[7][(aaa)] "cosmetic" means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic [10][***];]

[9][(b) "drug" includes—

[10][(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;]

(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 [11] [vermin] 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;] [2][(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

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animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;]

[3][(c) "Government Analyst" means—

(i) in relation to [12][Ayurvedic, 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;]

[6][(e) "Inspector" means—

(i) in relation to [13][Ayurvedic, 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**;]**

[7][(f) "manufacture" in relation to any drug [14][or cosmetic] includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug [8][or cosmetic] with a view to its [15][sale or distribution] but does not include the compounding or dispensing [10][of any drug, or the packing of any drug or cosmetic,] in the ordinary course of retail business; and "to manufacture" shall be construed accordingly;]

'[(g)] "to import", with its grammatical variations and cognate expressionsmeans to bring into [16][India];

[3][(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][(i) "prescribed" means prescribed by rules made under this Act.]

[6]**[3A. Construction of references to any law not in force or any functionary not in existence in the State of Jammu and Kashmir.**—Any reference in this Act to any law which is not in force, or any functionary not in existence, in the Stateof Jammu and Kashmir, shall, in relation to that State, be construed as a reference to the corresponding law in force, or to the corresponding functionary in existence, in that State.]

**4. Presumption as to poisonous substances.—**Any substance specified as poisonous by rule made under Chapter III or Chapter IV '[or Chapter IVA] shall be deemed to be a poisonous substance for the purpose of Chapter III or Chapter IV [!][or Chapter IVA], as the case may be.

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## CHAPTER II

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

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

[2][(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.]

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(3) The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election:

[1][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.]

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

(5) The Board may constitute sub-committees and may appoint to such subcommittees for such periods, not exceeding three years, as it may decide, or temporarily for the consideration of particular matters, persons who are not members of the Board.

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

(7) The 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.

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

Provided that, if the Central Government so prescribes, the functions of the Central Drugs Laboratory in respect of any drug or class of drugs [17][or cosmetic or class of cosmetics] shall be carried out at the Central Research Institute, Kasauli, or at any other prescribed Laboratory and the functions of the Director of the Central Drugs Laboratory in respect of such drug or class of drugs [2][or such cosmetic or class of cosmetics] shall be exercised by the Director of that Institute or of that other Laboratory, as the case may be.

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

(a) the functions of the Central Drugs Laboratory;
(b)[***]
(c) [***]
(d) the procedure for the submission of the said Laboratory [18][under Chapter IV or Chapter IVA] of samples of drugs [2][or cosmetics] for analysis or test, the forms of the Laboratory's reports thereon and the fees payable in respect of such reports;
(e) such other matters as may be necessary or expedient to enable the said Laboratory to carry out its functions;
(f) the matters necessary to be prescribed for the purposes of the proviso to sub-section (1).

## STATE AMENDMENTS

**Uttar Pradesh.**—In section 6, in sub-section (1), after the existing proviso, insert the following proviso, namely.—

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"Provided further that the State Government may, with the prior approval of the Central Government, direct that the functions of the Central Drugs Laboratory and of the Director may be carried out in Uttar Pradesh by such authority and such officer respectively as may be specified by the State Government by notification in the Official Gazette, and any reference in this Act to the Central Drugs Laboratory or the Director shall then be construed as a reference to such Authority or officer, as the case may be."

*[Vide* Uttar Pradesh Act 47 of 1975, sec. 5 (w.e.f. 5-9-1975).]

**West Bengal.**—In section 6, in sub-section (1), after the existing proviso, insert the following proviso, namely:—

"Provided further that the State Government may, with the prior approval of the Central Government direct that the functions of the Central Drugs Laboratory and of the Director may be carried out in West Bengal by such Authority and such Officer respectively as may be specified by the State Government by notification in the Official Gazette, and any reference in this Act to the Central Drugs Laboratory or the Director shall then be construed to mean such Authority or officer, as the case may be."

*[Vide* West Bengal Act 42 of 1973, sec. 5 (w.e.f. 29-4-1974).]

7. **The Drugs Consultative Committee.**—(1) The Central Government may constitute an advisory committee to be called "the Drugs Consultative Committee" to advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout [19] [India] in the administration of this Act.

(2) The Drugs Consultative Committee shall consist of two representatives of the Central Government to be nominated by that Government and one representative of each State Government to be nominated by the State Government concerned.

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

[2][**7A. Sections 5 and 7 not to apply to Ayurvedic, Siddha or Unani drugs.—**Nothing contained in sections 5 and 7 shall apply to [20][Ayurvedic, Siddha or Unani] drugs.]

## CHAPTER III
## IMPORT OF DRUGS AND COSMETICS

**8. Standards of quality.—**[21]**[(1)** For the purposes of this Chapter, the expression "standard quality" means—

(a) in relation to a drug, that the drug complies with the standard set out in [22][the Second Schedule], and

(b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.]

(2) 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 [3][the Second Schedule], for the purposes of this Chapter, and thereupon [3][the Second Schedule] shall be deemed to be amended accordingly.

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[4]**[9. Misbranded drugs.**—For the purposes of this Chapter, a 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.]

[5]**[9A. Adulterated drugs.**—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 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.]

[1][**9B. Spurious drugs.**—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.]

[2][**9C. Misbranded cosmetics.**—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.]

[2][**9D. Spurious cosmetics.**—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.]

**10. Prohibition of import of certain drugs or cosmetics.**—From such date[23] as may be fixed by the Central Government by notification in the Official Gazette in this behalf, no person shall import—

(a) any drug '[or cosmetic] which is not of standard quality;

[2][(b) any misbranded drug [24][or misbranded or spurious cosmetic];]

[4][(bb) any [25][adulterated or spurious] drug;]

(c) any drug '[or cosmetic] for the import of which a licence is prescribed, otherwise than under, and in accordance with, such licence;

[6][(d) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof [26][the true formula or list of active ingredients contained in it together with the quantities thereof];]

(e) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;

'[(ee) any cosmetic containing any ingredient which may render it unsafe or harmful or use under the directions indicated or recommended;]

(f) any drug '[or cosmetic] the import of which is prohibited by rule made under this Chapter:

Provided that nothing in this section shall apply to the import, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis or for personal use:

Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the import of any drug or class of drugs not being of standard quality.

[9][**10A. Power of Central Government to prohibit import of drugs and cosmetics in public interest.**—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.]

**11. Application of law relating to sea customs and powers of Customs Officers.**—(1) The law for the time being in force relating to sea customs and to goods, the import of which is prohibited by section 18 of the Sea Customs Act, 1878 (8 of 1878)[27] shall, subject to the provisions of section 13 of this Act, apply in respect of drugs [28][and cosmetics] the import of which is prohibited under this Chapter, and officers of Customs and officers empowered under that Act to perform the duties imposed thereby on a [29][Commissioner of Customs] and other officers of Customs, shall have the same powers in respect of such drugs [2][and cosmetics] as they have for the time being in respect of such goods as aforesaid.

[4][(2) Without prejudice to the provisions of sub-section (1), the [3][Commissioner of Customs] 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 [2][or cosmetic] 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 [2][or cosmetic] found therein to the Central Drugs Laboratory.]

**12. Power of Central Government to make rules.—(1)** The Central Government may, [30][after consultation with or on the recommendation of 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) specify the drugs or classes of drugs [31][or cosmetics or classes of cosmetics] for the import of which a licence is required, [32][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];

(b) prescribe the methods of test or analysis to be employed in determining whether a drug [2][or cosmetic] is of standard quality;

(c) prescribe, in respect of biological and organometallic compounds, the units or methods of standardisation;

[4][(cc) prescribe under clause (d) of [33][section 9A] the colour or colours which a drug may bear or contain for purposes of colouring;]

(d) specify the diseases or ailments which an imported drug may not purport or claim [34][to prevent, cure or mitigate] and such other effects which such drug may not purport or claim to have;

(e) prescribe the conditions subject to which small quantities of drugs, the import of which is otherwise prohibited under this Chapter, may be imported for the purpose of examination, test or analysis or for personal use;

(f) prescribe the places at which drugs [2][or cosmetics] may be imported, and prohibit their import at any other place;

(g) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label or container of any specified imported drug or class of such drug, and prohibit the import of the said drug or class of drug after the expiry of a specified period from the date of manufacture;

(h) regulate the submission by importers, and the securing, of samples of drugs [2][or cosmetics] for examination, test or analysis by the Central Drugs Laboratory, and prescribe the fees, if any, payable for such examination, test or analysis;

(i) prescribe the evidence to be supplied, whether by accompanying documents or otherwise, of the quality of drugs [35] [or cosmetics] sought to be imported, the procedure of officers of Customs in dealing with such evidence, and the manner of storage at places of import of drugs [x][or cosmetics] detained pending admission;

(j) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter and the rules made thereunder of drugs *[or cosmetics] imported for the purpose only of transport through, and export from, [36][India];

(k) prescribe the conditions to be observed in the packing in bottles, packages or other containers, of imported drugs [37][or cosmetics] [3][including the use of packing material which comes into direct contact with the drugs];

(1) regulate the mode of labelling drugs [J][or cosmetics] imported for sale in packages, and prescribe the matters which shall or shall not be included in such labels;

(m) prescribe the maximum proportion of any poisonous substance which may be added to or contained in any imported drug, prohibit the import of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder;

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(n) require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the label or wrapper of any imported, patent or proprietary medicine containing such drug;

(o) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder of any specified drug or class of drugs [L][or cosmetics or class of cosmetics].

[4][**13. Offences.**—(1) Whoever himself or by any other person on his behalf imports,—

(a) any drug deemed to be adulterated under section 9 A 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.

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(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.]

**14. Confiscation.**—Where any offence punishable under section 13 has been committed, the consignment of the drugs [1][or cosmetics] in respect of which the offence has been committed shall be liable to confiscation.

**15. Jurisdiction.**—No Court inferior to that [38][of a Metropolitan Magistrate or of a Judicial Magistrate of the first class] shall try an offence punishable under section 13.

## CHAPTER IV
## MANUFACTURE, SALE AND DISTRIBUTION OF [39][DRUGS AND COSMETICS]

**16. Standards of quality.**— [40][(1) For the purposes of this Chapter, the expression "standard quality" means—

(a) in relation to a drug, that the drug complies with the standard set out in [41][the Second Schedule], and

(b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.]

(2) The [42][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 [1] [the Second Schedule] for the purposes of this Chapter, and thereupon [1] [ the Second Schedule] shall be deemed to be amended accordingly.

[2][**17. Misbranded drugs.**—For the purposes of this Chapter, a 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.]

[3][17A. **Adulterated drugs.**—For the purposes of this Chapter, a drug shall be adeemed 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 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.]

[4][17B. **Spurious drugs.**—For the purposes of this Chapter, a drug shall be deemed to be spurious,—

(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.]

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[1][17C. **Misbranded cosmetics.**—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.]

[1][17D. **Spurious cosmetics.**—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.]

[2][17E. **Adulterated cosmetics.**—For the purposes of this Chapter, a cosmetic 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

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(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.]

**18. Prohibition of manufacture and sale of certain drugs and cosmetics.—**

From such date[43] 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—

(a) [44][manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale,] or distribute—

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

[4][(ii) any cosmetic which is not of a standard quality, or is misbranded, adulterated or spurious;]]

[5][(iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof [45][the true formula or list of active ingredients contained in it together with the quantities, thereof];]

(iv) any drug which by means of any statement design or device accompanying it or by any other means, purports or claims [46][to prevent, cure or mitigate] any such disease or ailment, or to have any such other effect as may be prescribed;

[8][(v) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(vi) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;]

"/(b) [47][sell, or stock or exhibit or offer for sale,] or distribute any drug [48][or cosmetic] which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

(c) [49][manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale,] or distribute any drug [2][or cosmetic], except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter:

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

Provided further that the [50][Central Government] may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the [51][manufacture for sale or for distribution, sale, stocking or exhibiting or offering for sale] or distribution of any drug or class of drugs not being of standard quality.

[7]**[18A. Disclosure of the name of the manufacturer, etc.**—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.]

[8]**[18B. Maintenance of records and furnishing of information.**—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.]

**19. Pleas.**—**(1)** Save as hereinafter provided in this section, it shall be no defence in a prosecution under this Chapter to prove merely that the accused was ignorant of the nature, substance or quality of the drug '[or cosmetic] in respect of which the offence has been committed or of the circumstances of its manufacture or import, or that a purchaser, having bought only for the purpose of test or analysis, has not been prejudiced by the sale.

(2) [2][For the purposes of section 18 a drug shall not be deemed to be misbranded or [3][adulterated or spurious] or to be below standard quality nor

shall a cosmetic be deemed to be misbranded or to be below standard quality] only by reason of the fact that—

(a) there has been added thereto some innocuous substance or ingredient because the same is required for the manufacture or preparation of the drug ’[or cosmetic] as an article of commerce in a state fit for carriage or consumption, and not to increase the bulk, weight or measure of the drug ’[or cosmetic] or to conceal its inferior quality or other defects; or

(b) in the process of manufacture, preparation or conveyance some extraneous substance has unavoidably become intermixed with it: provided that this clause shall not apply in relation to any sale or distribution of the drug ’[or cosmetic] occurring after the vendor or distributor became aware of such intermixture.

[5][(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.]

## STATE AMENDMENT

**West Bengal.**—After section 19, insert the following section, namely.—

*"19A. Burden of proof.*—When any drug or cosmetic is seized from any person in the reasonable belief that such drug or cosmetic is misbranded or adulterated, the burden of proving that such drug or cosmetic is not misbranded or adulterated shall be on the person from whose possession such drug or cosmetic was seized."

*[Vide* West Bengal Act 42 of 1973, sec. 5 (w.e.f. 29-4-1974).]

[1]**[20. Government Analysts.**—(1) The 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 in the State and in respect of such drugs or [52][classes of drugs or such cosmetics or classes of cosmetics] as may be specified in the notifications.

(2) The Central Government may also, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts in respect of such drugs or [53][classes of drugs or such cosmetics or classes of cosmetics] as may be specified in the notification.

(3) Notwithstanding anything contained in sub-section (1) or sub-section (2), 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.]

[3][(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.]

[4]**[21. Inspectors.**—(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.

(2) The powers which may be exercised by an Inspector and the duties which may be performed by him, the drugs or [54][classes of drugs or cosmetics or classes of cosmetics] in relation to which 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 import, manufacture or sale of drugs or cosmetics] 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 (45 of 1860), and shall be

officially subordinate to such authority [2][, having the prescribed qualifications,] as the Government appointing him may specify in this behalf.]

[4][**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,—

[4][(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;]

[1][(cc) examine any record, register, document or any other material object found [55][with any person, or in any place, vehicle, vessel or other conveyance referred to in clause (c)], and seize the same if he has reason to believe that it may

furnish evidence of the commission of an offence punishable under this Act or the Rules made thereunder;]

[3][(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;]

(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 [56][the Code of Criminal Procedure, 1973 (2 of 1974)] 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 [57][section 94] of the said Code.

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[3][(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.]

(3) If any person wilfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this Chapter [6][or refuses to produce any record, register or other document when so required under clause (cca) of sub-section(1),] he shall be punishable with imprisonment which may extend to three years, or with fine, or with both.]

23. **Procedure of Inspectors.**—(1) Where an Inspector takes any sample of a drug '[or cosmetic] under this Chapter, he shall tender the fair price thereof and may require a written acknowledgement therefor.

(2) Where the price tendered under sub-section (1) is refused or where the Inspector seizes the stock of any drug '[or cosmetic] under clause (c) of section 22, he shall tender a receipt therefor in the prescribed form.

(3) Where an Inspector takes a sample of a drug '[or cosmetic] for the purpose of test or analysis, he shall intimate such purpose in writing in the

prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked:

Provided that where the sample is taken from premises whereon the drug '[or cosmetic] is being manufactured, it shall be necessary to divide the sample into three portions only:

Provided further that where the drug [J][or cosmetic] is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug *[or cosmetic] be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them.

(4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows:—

(i) one portion or container he shall forthwith send to the Government Analyst for test or analysis;

(ii) the second he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug [58][or cosmetic]; and

[2][(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.]

(5) Where an Inspector takes any action under clause (c) of section 22,—

(a) he shall use all despatch in ascertaining whether or not the drug '[or cosmetic] contravenes any of the provisions of section 18 and, if it is ascertained that the drug *[or cosmetic] does not so contravene forthwith revoke the order passed under the said clause or, as the case may be, take such action as may be necessary for the return of the stock seized;

(b) if he seizes the stock of the drug '[or cosmetic], he shall as soon as may be, inform [59][a Judicial Magistrate] and take his orders as to the custody thereof;

(c) without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the drug '[or cosmetic], he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.

[3][(6) Where an Inspector seizes any record, register, document or any other material object under clause (cc) of sub-section (1) of section 22, he shall, as soon as may be, inform [2][a Judicial Magistrate] and take his orders as to the custody thereof.]

**24. Persons bound to disclose place where drugs or cosmetics are manufactured or kept.**—Every person for the time being in charge of any premises whereon any drug '[or cosmetic] is being manufactured or is kept for sale or distribution shall, on being required by any Inspector so to do, be legally bound to disclose to the Inspector the place where the drug '[or cosmetic] is being manufactured or is kept, as the case may be.

**25. Reports of Government Analysts.—(1)** The Government Analyst to whom a sample of any drug '[or cosmetic] has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.

(2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken [60][and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A], and shall retain the third copy for use in any prosecution in respect of the sample.

(3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken [1][or the person whose name, address and other particulars have been disclosed under section 18A] has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

(4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's

report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused: cause the sample of the drug [1][or cosmetic] produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.

(5) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct.

**26. Purchaser of drug [61][or cosmetic] enabled to obtain test or analysis.—**

Any person [62][or any recognised consumer association, whether such person is a member of that association or not] shall, on application in the prescribed manner and on payment of the prescribed fee, be entitled to submit for test or analysis to a Government Analyst any drug [2][or cosmetic] [63][purchased by him or it] and to receive a report of such test or analysis signed by the Government Analyst.

[5]*[Explanation*.—For the purposes of this section and section 32, "recognised consumer association" means a voluntary consumer association registered under the Companies Act, 1956 or any other law for the time being in force.]

[6]***[26A*. Powers of Central Government to prohibit manufacture, etc., of drug and cosmetic in public interest.**—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, ^regulate, restrict or prohibit] the manufacture, sale or distribution of such drug or cosmetic.]

[2]**[26B. Power of Central Government to regulate or restrict, manufacture, etc., of drug in public interest.**—Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that a

drug is essential to meet the requirements of an emergency arising due to epidemic or natural calamities and that in the public interest, it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate or restrict the manufacture, sale or distribution of such drug.]

[3][**27. Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter.**—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 [4][17B and 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 (45 of 1860), solely on account of such drug being adulterated or spurious or not of standard quality, as the case may be, shall be [5][punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more:]

[6][Provided that the fine imposed on and released from, the person convicted under this clause shall be paid, by way of compensation, tothe person who had used the adulterated or spurious drugs referred to in this clause:

Provided further that where the use of the adulterated or spurious drugs referred to in this clause has caused the death of a person who used such drugs, the fine imposed on and realised from, the person convicted under this clause, shall be paid to the relative of the person who had died due to the use of the adulterated or spurious drugs referred to in this clause.

*Explanation*.—For the purposes of the second proviso, the expression "relative" means—

(i) spouse of the deceased person; or
(ii) a minor legitimate son, and unmarried legitimate daughter and a widowed mother; or
(iii) parent of the minor victim; or

(iv) if wholly dependent on the earnings of the deceased person at the time of his death, a son or a daughter who has attained the age of eighteen years; or

(v) any person, if wholly or in part, dependent on the earnings of the deceased person at the time of his death,—

(a) the parent; or

(b) a minor brother or an unmarried sister; or

(c) a widowed daughter-in-law; or

(d) a widowed sister; or

(e) a minor child of a pre-deceased son; or

(f) a minor child of a pre-deceased daughter where no parent of the child is alive; or

(g) the paternal grandparent if no parent of the member is alive;]

(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 three years but which may extend to five years and with fine which shall not be less than one lakh rupees or three times the value of the drugs confiscated, whichever is more];

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Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence ofimprisonment for a term of [64][less than three years and of fine of less than one lakh 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 [65][not be less than seven years but which may extend to imprisonment for life and with fine which shall not be less than three lakh rupees or three times the value of the drugs confiscated, whichever is more]:

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 [66][less than seven years but not less than three years and of fine of less than one lakh rupees];

(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 [67][and with fine which shall not be less than twenty 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.

[5]**[27A. Penalty for manufacture, sale, etc., of cosmetics in contravention of this Chapter.**—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—

[1][(i) any cosmetic deemed to be spurious under section 17D or adulterated under section 17E shall be punishable with imprisonment for a term which may extend to three years and with fine which shall not be less than fifty thousand rupees or three times to value of the cosmetics confiscated, whichever is more;

(ii) any cosmetic other than a cosmetic referred to in clause (i) 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 twenty thousand rupees, or with both.]

[2]**[28. Penalty for non-disclosure of the name of the manufacturer, etc.—**

Whoever contravenes the provisions of section 18A [3][or section 24] shall be punishable with imprisonment for a term which may extend to one year, or [4][with fine which shall not be less than twenty thousand rupees or with both.]

[5]**[28A. Penalty for not keeping documents, etc., and for non-disclosure of information.—**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 [6][with fine which shall not be less than twenty thousand rupees or with both].]

[7]**[28B. Penalty for manufacture, etc., of drugs or cosmetics in contravention of section 26A.—**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.]

29. Penalty for use of Government Analyst's report for advertising.—

Whoever uses any report of a test or analysis made by the Central Drugs Laboratory or by a Government Analyst, or any extract from such report, for the purpose of advertising any drug [8][or cosmetic], shall be punishable with fine which may extend to [9][five thousand rupees].

**[10][30. Penalty for subsequent offences.—**[n][(l) 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 imprisonment for a term which shall '[not be less than seven years but which may extend to ten years and with fine which shall not be less than two lakh 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 [68][less than seven years and of fine of less than one lakh 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 [3][shall not be less than ten years but which may extend to imprisonment for life and with fine which shall not be less than three lakh 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 [69][fifty thousand rupees], or with both.]

[5][(1A) Whoever, having been convicted of an offence under section 27A is again convicted under that section, shall be punishable with imprisonment for a term which may extend to two years, or with fine which may extend to [70][two thousand rupees], or with both.]

(2) Whoever, having been convicted of an offence under [71][***] section 29 is again convicted of an offence under the same section, shall be punishable with imprisonment which may extend to [72][two years, or with fine which shall not be less than ten thousand rupees or with both].

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## STATE AMENDMENTS

**Uttar Pradesh.**—For section 30, substitute the following section, namely.—

"30. All offences punishable tinder this chapter shall be cognizable and non-bailable"

*[Vide* Uttar Pradesh Act 47 of 1975, sec. 5 (w.e.f. 15-9-1975).]

**West Bengal.**—In section 30,—

(a) in sub-section (1), in clause (a), for the words "ten years", substitute the words "imprisonment for life";

(b) in sub-section (1), in clause (b), for the words "may extent to ten years, or with fine, or with both", substitute the words "shall not be less than two years but which may extend to imprisonment for life and shall also be liable to fine";

(c) in sub-section (1A), for the words "may extend to two years, or with fine which me extend to one thousand rupees, or with both", substitute the words "shall not be less than two years but which may extend to imprisonment for life and shall also be liable to fine".

*[Vide* West Bengal Act 42 of 1975, sec. 5 (w.e.f. 29-4-1974).]

*Ed.* This State Amendment relates to section 30, prior to its amendments made by the Central Act 26 of 2008, sec. 11 (w.e.f. 10-8-2009) and Central Act 68 of 1982, sec. 25 (w.e.f. 1-2-1983).

**31. Confiscation.**—[73]**[(1)]** Where any person has been convicted under this Chapter for contravening any such provision of this Chapter or any rule made thereunder as may be specified by rule made in this behalf, the stock of the drug [2][or cosmetic] in respect of which the contravention has been made shall be liable to confiscation [74][and if such contravention is in respect of—

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

(ii) [75][manufacture for sale, or for distribution, sale, or stocking or exhibiting or offering 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].

[6][(2) Without prejudice to the provisions contained in sub-section (1) where the Court is satisfied, on the application of an Inspector or otherwise and after

such inquiry as may be necessary that the drug or cosmetic is not of standard quality [76][or is a [77][misbranded, adulterated or spurious drug or misbranded or spurious cosmetic,]] such drug or, as the case may be, such cosmetic shall be liable to confiscation.]

[9][**31A. Application of provisions to Government departments.**—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.]

**32. Cognizance of offences.**—'[(1) No prosecution under this Chapter shall be instituted except by—

(a) an Inspector; or

(b) any gazetted officer of the Central Government or a State Government authorised in writing in this behalf by the Central Government or a State Government by a general or special order made in this behalf by that Government; or

(c) the person aggrieved; or

(d) a recognised consumer association whether such person is a member of that association or not.

(2) Save as otherwise provided in this Act, no court inferior to that of a Court of Session shall try an offence punishable under this Chapter.]

(3) Nothing contained in this Chapter shall be deemed to prevent any person from being prosecuted under any other law for any act or omission which constitutes an offence against this Chapter.

## STATE AMENDMENT

**West Bengal.**—For section 32, substitute the following section, namely:—

"32. *Cognizance of offences and arrest without warrant.*—(1) All offences punishable under this Act shall be cognizable and non-bailable.

(2) Any police officer not below the rank of a sub-inspector of Police may arrest without warrant any person against whom a reasonable complaint has been made or Creditable information has been received of his having been concerned in any of the offences punishable under this Act."

*[Vide* West Bengal Act 42 of 1973, sec. 5 (w.e.f. 29-4-1974).]

[2]**[32A. Power of Court to implead the manufacturer, etc.**—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 [3][in subsections (1), (2) and (3) of section 319 of the Code of Criminal Procedure, 1973 (2 of 1974)], proceed against him as though a prosecution had been instituted against him under section 32.]

[1]**[32B. Compounding of certain offences.**—**(1)** Notwithstanding anything contained in the Code of Criminal Procedure, 1973 (2 of 1974), any offence punishable under clause (b) of sub-section (1) of section 13, section 28 and section 28A of this Act (whether committed by a company or any officer thereof), not being an offence punishable with imprisonment only, or with imprisonment and also with fine, may, either before or after the institution of any prosecution, be compounded by the Central Government or by any State Government or any officer authorised in this behalf by the Central Government or a State Government, on payment for credit to that Government of such sum as that Government may, by rules made in this behalf, specify:

Provided that such sum shall not, in any case, exceed the maximum amount of the fine which may be imposed under this Act for the offence so compounded:

Provided further that in cases of subsequent offences, the same shall not be compoundable.

(2) When the accused has been committed for trial or when he has been convicted and an appeal is pending, no composition for the offence shall be allowed without the leave of the court to which he is committed or, as the case may be, before which the appeal is to be heard.

(3) Where an offence is compounded under sub-section (1), no proceeding or further proceeding, as the case may be, shall be taken against the offender in respect of the offence so compounded and the offender, if in custody, shall be released forthwith.]

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**33. Power of Central Government to make rules.**—[78][(1) The Central Government may [79][after consultation with, or on the recommendation of, the Board] and after previous publication by notification in the Official Gazette, make rules for the purposes 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 drugs [80][or cosmetics];

(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 a drug [4][or cosmetic] is of standard quality;

(d) prescribe, in respect of biological and organometallic compounds, the units or methods of standardisation;

[:][(dd) prescribe under clause (d) of [81][section 17A] the colour or colours which a drug may bear or contain for purposes of colouring;]

[3][(dda) prescribe under clause (d) of section 17E the colour or colours which a cosmetic may bear or contain for the purposes of colouring;]

(e) prescribe the forms of licences [82][for the manufacture for sale or for distribution], for the sale and for the distribution of drugs or any specified drug or class of drugs [83][or of cosmetics or any specified cosmetic or class of cosmetics], the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same [84][the qualifications of such authority] and the fees payable therefor; [6][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];

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

[6][(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;]

[6][(eeb) prescribe the manner in which copies are to be certified under subsection (2A) of section 22;]

(f) specify the diseases or ailments which a drug may not purport or claim [85][to prevent, cure or mitigate] and such other effects which a drug may not purport or claim to have;

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

(h) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label or container of any specified drug or class of drugs, and prohibit the sale, stocking or exhibition for sale, or distribution of the said drug or class of drugs after the expiry of a specified period from the date of manufacture or after the expiry of the date of potency;

(i) prescribe the conditions to be observed in the packing in bottles, packages, and other containers of drugs [5][or cosmetics], [6][including the use of packing material which comes into direct contact with the drugs] and prohibit the sale, stocking or exhibition for sale, or distribution of drugs '[or cosmetics] packed in contravention of such conditions;

(j) regulate the mode of labelling packed drugs ’[or cosmetics], and prescribe the matters which shall or shall not be included in such labels;

(k) prescribe the maximum proportion of any poisonous substance which may be added to or contained in any drug, prohibit the manufacture, sale or stocking or exhibition for sale, or distribution of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder;

(1) require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the label or wrapper of any patent or proprietary medicine containing such drug;

[3][(n) prescribe the powers and duties of Inspectors [86][and the qualifications of the authority to which such Inspectors shall be subordinate] and [5][specify the drugs or classes of drugs or cosmetics or classes of cosmetics] in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed;]

(o) prescribe the forms of report to be given by Government Analysts, and the manner of application for test or analysis under section 26 and the fees payable therefor;

[6][(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; [87][***]]

(q) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder, of any specified drug or class of drugs [J][or cosmetic or class of cosmetics]; [8][and]

[9][(r) sum which may be specified by the Central Government under section 32B.]

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## STATE AMENDMENT

**Maharashtra.**—In section 33,—

(1) in sub-section (2),—

(a) in clause (e), omit the words "and the fees payable";

(b) omit clause (ee);

(c) in clause (o), omit the words "and the fees payable therefor"

*[Vide* Maharashtra Act 31 of 1989, sec. 2 (w.e.f. 4-10-1989.]

(2) after section 33, insert the following section, namely:—

*"33A. Power of State Government to make rules.*—The State Government may, by notification in the Official Gazette and subject to the condition of previous publication, make rules to prescribe the fees payable for the following purposes of this chapter, namely:—

(a) grant or renewal of a license for the manufacture for sale or distribution for the sale and for the distribution of drugs or any specified drugs or class of drug or of cosmetics or any specified cosmetics or class of cosmetics;

(b) inspection (for the purposes of grant or renewal of licenses) or premises, wherein any drug or cosmetic is being or is proposed to be manufactured;

(c) test or analysis of any drug or cosmetic by Government Analyst; and

(d) any other matter for which fees may be prescribed under this Chapter."

*[Vide* Maharashtra Act 31 of 1989, sec. 3 (w.e.f. 4-10-1989).]

[1][**33A. Chapter not to apply to** [88][**Ayurvedic, Siddha or Unani] drugs.**—Save as otherwise provided in this Act, nothing contained in this Chapter shall apply to [2][Ayurvedic, Siddha or Unani] drugs.]

## [3][CHAPTER IVA
## PROVISIONS RELATING TO [2][AYURVEDIC, SIDDHA AND UNANI] DRUGS

**33B. Application of Chapter IVA.**—This Chapter shall apply only to [2][Ayurvedic, Siddha and Unani] drugs.

**33C. Ayurvedic and Unani Drugs Technical Advisory Board.—(1)** TheCentral 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 [4][Ayurvedic, Siddha 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.

(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 principal officer dealing with Indian systems of medicine in the 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;

[2][(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 Unani Pharmacopoeia Committee and one from amongst the members of the Siddha Pharmacopoeia Committee;]

(ix) one teacher in Darvyaguna and Bhaishajya Kalpana, to be nominated by the Central Government;

(x) one teacher in Ilm-ul-Advia and Taklis-Wa-Dawa-Sazi, to be nominated by the Central Government;

[3][(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 amongst the practitioners of Ayurvedic, Siddha and Unani Tibb 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 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.

[!][**33D. The Ayurvedic, Siddha and Unani Drugs Consultative Committee.**—(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.]

[1][**33E. Misbranded drugs.**—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.]

[1][**33EE. Adulterated drugs.**—For the purposes of this Chapter, an Ayurvedic, Siddha or Unani 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 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.]

[1][**33EEA. Spurious drugs.**—For the purposes of this Chapter, an Ayurvedic, Siddha or Unani drug shall be deemed to be spurious—

(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.]

[1][**33EEB. Regulation of manufacture for sale of Ayurvedic, Siddha and Unani drugs.**—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.]

**H33EEC. Prohibition of manufacture and sale of certain Ayurvedic, Siddha and Unani drugs.**—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.]

[1][**33EED. Power of Central Government to prohibit manufacture, etc., of Ayurvedic, Siddha or Unani drugs in public interest.**—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.]

**33F. Government Analysts.**—(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.

(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.

[2][(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.]

**33G. Inspectors.**—(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.

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(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 (45 of 1860) and shall be officially subordinate to such authority as the Government appointing him may specify in this behalf.

**33H. Application of provisions of sections 22, 23, 24 and 25.**—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 [89] [Ayurvedic, Siddha or Unani] drug.

[2][**33-I. Penalty for manufacture, sale, etc., of Ayurvedic, Siddha or Unani drug in contravention of this Chapter.**—Whoever himself or by any other person on his behalf—

(1) manufactures for sale or for distribution—

[3][(a) any Ayurvedic, Siddha or Unani drug—

(i) deemed to be misbranded under section 33E,

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

(iii) without a valid licence or in violation of any of the conditions thereof, as required under 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 twenty thousand rupees or three times the value of the drugs confiscated, whichever is more;]

(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 [fifty thousand rupees or three times the value of the drugs confiscated, whichever is more]:

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 [90][fifty thousand rupees or three times the value of the drugs confiscated, whichever is more]; or

[5][(c) any Ayurvedic, Siddha or Unani drug in contravention of the provisions of any notification issued under section 33EED shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to fifty thousand rupees or three times the value of the drugs confiscated, whichever is more.]

(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 ’[six months and with fine which shall not be less than ten thousand rupees].

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[2]**[33J. Penalty for subsequent offences.**—Whoever having been convicted of an offence,—

(a) under clause (a) of sub-section (1) of section 33-1 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 [91][fifty thousand rupees or three times the value of the drugs confiscated, whichever is more];

(b) under clause (b) of sub-section (1) of section 33-1 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 [92][one lakh rupees or three times the value of the drugs confiscated, whichever is more]:

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 [4][one lakh rupees or three times the value of the drugs confiscated, whichever is more];

(c) under sub-section (2) of section 33-1 is again convicted of an offence under that sub-section, shall be punishable with imprisonment for a term which may extend to [93][one year and with fine which shall not be less than twenty thousand rupees or three times the value of the drugs confiscated, whichever is more].

**33K. Confiscation.**—Where any person has been convicted under this Chapter, the stock of the [94][Ayurvedic, Siddha or Unani] drug, in respect of which the contravention has been made, shall be liable to confiscation.

[3]**[33KA. Disclosure of name of manufacturer, etc.**—Every person, not being the manufacturer of any Ayurvedic, Siddha or Unani drug 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 Ayurvedic, Siddha or Unani drug.]

[7]**[33KB. Maintenance of records and furnishing of information.**—Every person holding a licence under clause (c) of section 33EEC 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

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function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act.]

**33L. Application of provisions to Government departments.**—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 [95] [Ayurvedic, 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.

**33M. Cognizance of offences.**—(1) No prosecution under this Chapter shall be instituted except by an Inspector [96][with the previous sanction of the authority specified under sub-section (4) of section 33G].

(2) No Court inferior to that [97][of a Metropolitan Magistrate or of a Judicial Magistrate of the first class] shall try an offence punishable under this Chapter.

**33N. Power of Central Government to make rules.**—(1) The Central Government may, [98][after consultation with, or on the recommendation of, 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, 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, Siddha or Unani] drug is labelled with the true list of the ingredients which it is purported to contain;

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(d) specify any substance as a poisonous substance;

(e) prescribe the forms of licences for the manufacture for sale of ’[Ayurvedic, Siddha or Unani] drugs, [99][and for sale of processed Ayurvedic, 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; [J][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];

[2][(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;]

(g) prescribe the conditions subject to which small quantities of [1] [Ayurvedic, Siddha or Unani] drugs may be manufactured for the purpose of examination, test or analysis; and

[1][(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;]

[1] [ (gga) prescribe the standards for Ayurvedic, Siddha or Unani drugs under section 33EEB [100][***];]

[4][(ggb) prescribe the records, registers or other documents to be kept and maintained under section 33KB; and]

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

## STATE AMENDMENT

**Maharashtra.—In section** 33N,—

(1) in sub-section (2), in clause (e), omit the words "and the fees payable therefore";

(2) after section 33N, insert the following section, namely:—

*"33N-1. Power of State government to make roles*.—The State Government may, by notification in the Official Gazette and subject to the condition of previous publication, make rules to prescribe the fees payable for the following purposes of this chapter, namely.—

(a) grant or renewal of a license for the manufacture for sale of Ayurvedic, Siddha or Unani drugs, and for sale of processed Ayurvedic, Siddha or Unani drugs;

(b) inspection (for the purpose of grant or removal of licenses) of premises, wherein any Ayurvedic, Siddha or Unani drug is being or is proposed to be manufactured;

(c) test or analysis of Ayurvedic, Siddha or Unani drug by Government Analyst; and

(d) any other matter for which fees may be prescribed under this chapter."

*[Vide* Maharashtra Act 31 of 1989, sec. 4 (w.e.f. 4-10-1989).]

**33-0. Power to amend First Schedule.**—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.]

## CHAPTER V
## MISCELLANEOUS

[2][[101]**[33P.] Power to give directions.**—The Central Government may give such directions to any State Government as may appear to the Central Government to be necessary for carrying into execution in the State any of the provisions of this Act or of any rule or order made thereunder.]

**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.

[4][**34A. Offences by Government departments.**—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.]

[1][34AA. **Penalty for vexatious search or seizure.**—Any Inspector exercising powers under this Act or the rules made thereunder, who,—

(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.]

**35. Publication of sentences passed under this Act.**—(1) If any person is convicted of an offence under this Act, [102][the Court before which the conviction takes place shall, on application made to it by the Inspector, 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.

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**36. Magistrate's power to impose enhanced penalties.**—Notwithstanding anything contained in [103][***] [104][the Code of Criminal Procedure, 1973 (2 of 1974)], it shall be lawful for [105][any Metropolitan Magistrate or any Judicial Magistrate of the first class] to pass any sentence authorized by this Act in excess of his powers under [3][***] the said Code.

[1][**36A. Certain offences to be tried summarily.**—Notwithstanding anything contained in the Code of Criminal Procedure, 1973 (2 of 1974), [106][all offences (except the offences triable by the Special Court under section 36AB or Court of Session) 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:

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 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.]

[3][**36AB. Special Courts.**—(1) The Central Government, or the State Government, in consultation with the Chief Justice of the High Court, shall, for trial of offences relating to adulterated drugs or spurious drugs and punishable under clauses (a) and (b) of section 13, sub-section (3) of section 22, clauses (a) and (c) of section 27, section 28, section 28A, section 28B and clause (b) of subsection (1) of section 30 and other offences relating to adulterated drugs or spurious drugs, by notification, designate one or more Courts of Session as a Special Court or Special Courts for such area or areas or for such case or class or group of cases as may be specified in the notification.

*Explanation*.—In this sub-section, "High Court" means the High Court of the State in which a Court of Session designated as Special Court was functioning immediately before such designation.

(2) While trying an offence under this Act, a Special Court shall also try an offence, other than an offence referred to in sub-section (1), with which the accused may, under the Code of Criminal Procedure, 1973 (2 of 1974), be charged at the same trial.]

[3][**36AC. Offences to be cognizable and non-bailable in certain cases.—(1)**Notwithstanding anything contained in the Code of Criminal Procedure, 1973 (2 of 1974),—

(a) every offence, relating to adulterated or spurious drug and punishable under clauses (a) and (c) of sub-section (1) of section 13, clause (a) of sub-section (2) of section 13, sub-section (3) of section 22, clauses (a) and (c) of section 27, section 28, section 28A, section 28B and sub-sections (1) and (2) of section 30 and other offences relating to adulterated drugs or spurious drugs, shall be cognizable.

(b) no person accused, of an offence punishable under clauses (a) and

(c) of sub-section (1) of section 13, clause (a) of sub-section (2) of section 13, sub-section (3) of section 22, clauses (a) and (c) of section27, section 28, section 28A, section 28B and sub-sections (1) and (2) of section 30 and other offences relating to adulterated drugs or spurious drugs, shall be released on bail or on his own bond unless—

(i) the Public Prosecutor has been given an opportunity to oppose the application for such release; and

(ii) where the Public Prosecutor opposes the application, the Court is satisfied that there are reasonable grounds for believing that he is not guilty of such offence and that he is not likely to commit any offence while on bail:

Provided that a person, who, is under the age of sixteen years, or is a woman or is sick or infirm, may be released on bail, if the Special Court so directs.

(2) The limitation on granting of bail specified in clause (b) of sub-section (1) is in addition to the limitations under the Code of Criminal Procedure, 1973 (2 of 1974) or any other law for the time being in force on granting of bail.

(3) Nothing contained in this section shall be deemed to affect the special powers of the High Court regarding bail under section 439 of the Code of Criminal Procedure, 1973 (2 of 1974) and the High Court may exercise such powers including the power under clause (b) of sub-section (1) of that section as if the reference to "Magistrate" in that section includes also a reference to a "Special Court" designated under section 36AB.]

[1][**36AD. Application of Code of Criminal Procedure, 1973 to proceedings before Special Court.**—(1) Save as otherwise provided in this Act, the provisions of the Code of Criminal Procedure, 1973 (2 of 1974) (including the provisions as to bails or bonds), shall apply to the proceedings before a Special Court and for the purposes of the said provisions, the Special Court shall be deemed to be a Court of Session and the person conducting the prosecution before the Special Court, shall be deemed to be a Public Prosecutor:

Provided that the Central Government or the State Government may also appoint, for any case or class or group of cases, a Special Public Prosecutor.

(2) A person shall not be qualified to be appointed as a Public Prosecutor or a Special Public Prosecutor under this section unless he has been in practice as an advocate for not less than seven years, under the Union or a State, requiring special knowledge of law.

(3) Every person appointed as a Public Prosecutor or a Special Public Prosecutor under this section shall be deemed to be a Public Prosecutor within the meaning of clause (u) of section 2 of the Code of Criminal Procedure, 1973 (2 of 1974) and the provisions of that Code shall have effect accordingly.]

[1][**36AE. Appeal and revision.**—The High Court may exercise, so far as may be applicable, all the powers conferred by Chapter XXIX or Chapter XXX of the Code of Criminal Procedure, 1973 (2 of 1974), on a High Court, as if a Special Court within the local limits of the jurisdiction of the High Court were a Court of Session trying cases within the local limits of the jurisdiction of the High Court.]

**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.]

[2][**38. Rules to be laid before Parliament.**—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, [107][and if, before the expiry of the session immediately following the session 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.]

## STATE AMENDMENT

**Maharashtra.**—(1) In section 38, for the words "Every rule made", substitute the words "Every rule made by the Central Government".

(2) After section 38, insert the following section, namely.—

*"39. Rules to be laid before State Legislature.*—Every rule made by State Government under this Act shall be laid, as soon as may be after it is made, before each House of the State Legislature, 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 immediately following the session or the successive sessions afore said, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, and notify such decision in the Official Gazette, the rule shall from the date of publication of such notification 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 or omitted to be done under that rule."

*[Vide* Maharashtra Act 31 of 1989, sec. 7 (w.e.f. 4-10-1989).]

## *'[THE FIRST SCHEDULE [See* section 3(a)]

## [2][A.—AYURVEDIC AND SIDDHA SYSTEMS]

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| Serial No. | Name of book |
|---|---|
| | *Ayurveda* |
| *1.* | Arogya Kalpadruma |
| 2. | Arka Prakasha |
| 3. | Arya Bhishak |
| 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 |

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| 14. | Chakra Datta |
| 15. | Gada Nigraha |
| 16. | Kupi Pakva Rasayana |
| 17. | Nighantu Ratnakara |
| 18. | Rasa Chandanshu |
| 19. | Rasa Raja Sundara |
| 20. | Rasaratna Samuchaya |
| 21. | [3][Rasatantra Sara Va Siddha Prayoga Samgraha - Part I] |
| [4][21(a). | Rastantra Sara Va Siddha Prayog Samgraha - Part II (Edition 2006).] |
| 22. | Rasa Tarangini |
| 23. | Rasa Yoga Sagara |
| 24. | Rasa Yoga Ratnakara |
| 25. | Rasa Yoga Samgraha |
| 26. | Rasendra Sara Samgraha |
| 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 |

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| 43. | Kashyapasamhita |
| 44. | Bhelasamhita |
| 45. | Vishwanathachikitsa |
| 46. | Vrindachikitsa |
| 47. | Ayurvedachintamani |
| 48. | Abhinavachintamani |
| 49. | Ayurveda-ratnakar |
| 50. | Yogara tnasangraha |
| 51, | Rasamrita |
| 52. | Dravyagunanighantu |
| 53. | Rasamanijari |
| 54. | Bangasena |
| [1][54A. | [2][Ayurvedic Formulary of India and its Parts] |
| [1][54B. | Ayurveda Sara Sangraha] |
| [3][54C. | Ayurvedic Pharmacopoeia of India] |
| [4][54D. | Ayurvedic Pharmacopoeia of India and its Parts]] |
| | *Siddha* |
| 55. | Siddha Vaidya Thirattu |
| 56. | Therayar Maha Karisal |
| 57. | Brahma Muni Karukkadai (300) |
| 58. | Bhogar (700) |
| 59. | Pulippani (500) |
| 60. | Agasthiyar Paripuranam (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 |

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| 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 |
| [1][84. | Siddha Formulary of Unani Medicine (Part I)] |
| [2] [85. | Sidha Pharmacopoeia of India and its Parts] |
| | [3]**[B.—UNANI TIBB SYSTEM]** |
| 1. | Karabadin Qadri |
| 2. | Karabadin Kabir |
| 3. | Karabadin Azam |
| 4. | Ilaj-ul-Amraz |
| 5. | A1 Karabadin |
| 6. | Biaz Kabir Vol. II |
| 7. | Karabadin Jadid |
| 8. | Kitalf-ul-Taklis |
| 9. | Sanat-ul-Taklis |
| 10. | Mifta-ul-Khazain |
| 11. | Madan-ul-Aksir |
| 12. | Makhzan-ul-Murabbat |
| M13. | National Formulary of Unani Medicine [4][***][ |

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| [5][14. | Unani Pharmacopoeia of India]] |

## [6][*THE SECOND SCHEDULE*

*(See* sections 8 and 16)

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

| Class of drug | Standard to be complied with |
|---|---|
| 1. Patent or proprietary medicines [7][other than Homoeopathic medicines].<br><br>[8][2. Substances commonly known as vaccines, sera, toxine, toxoids, antitoxins, and antigens and biological products of like nature for human use or for veterinary use. | The formula or list of ingredients displayed in the prescribed manner on the label or container and such other standards as may be prescribed. The standards maintained at the International Laboratory for Biological Standards, Stantans Seruminstitute, Copenhagen, and at the Central Veterinary Laboratory, Weybridge Surrey, UK and such other laboratories recognised by the World Health Organisation from time to time, such further standards of strength, quality and purity, as may be prescribed.] |

| Class of drug | Standard to be complied with |
|---|---|
| 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.<br><br>[2][4A. Homoeopathic Medicines—<br><br>(a) Drugs included in the | Such standards as may be prescribed.<br><br>Standards of identity, purity and strength specified in the edition of the Homoeopathic Pharmacopoeia of India for the time being and such other standards as may be prescribed. Standards of identity, purity and strength prescribed for the Drugs in the edition of such Pharmacopoeia for the time being in which they are given and |

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| Homoeopathic Pharmacopoeia of India.<br><br>(b) Drugs not included in the Homoeopathic Pharmacopoeia of India but which are included in the Homoeopathic Pharmacopoeia of United States of America or the United Kingdom or the German Homoeopathic Pharmacopoeia.<br><br>(c) Drugs not included in the Homoeopathic Pharmacopoeia of India or the United States of America, or the United Kingdom or the German Homoeopathic Pharmacopoeia.<br><br>[3][5. Other drugs—<br><br>(a) Drugs included in the Indian Pharmacopoeia.<br><br>(b) Drugs not included in the Indian Pharmacopoeia but which are included in the official Pharmacopoeia of any other country. | such other standards as may be prescribed.<br><br>The formula or list of ingredients displayed in the prescribed manner on the label of the container and such other standards as may be prescribed by the Central Government.]<br><br>Standards of identity, purity and strength specified in the edition of the Indian Pharmacopoeia for the time being in force and such other standards as may be prescribed.<br><br>In case the standards of identity, purity and strength for drugs are not specified in the edition of the Indian Pharmacopoeia for the time being in force but are specified in the edition of the Indian Pharmacopoeia immediately preceding the standards of identity, purity and strength shall be those occurring in such immediately preceding edition of the Indian Pharmacopoeia and such other standards as may be prescribed. Standards of identity, purity and strength specified for drugs in the edition of such official Pharmacopoeia of any other country for the time being in force and such other standards as may be prescribed. In case the standards of identity, purity and strength for drugs are not specified in the edition of such official Pharmacopoeia for the time being in force, but are specified in the edition immediately preceding the standards of |

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| | identity, purity and strength shall be those occurring in such immediately preceding edition of such official Pharmacopoeia and such other standards as may be prescribed.]] |

# REFERENCES

1 For Statement of Objects and Reasons, *see* Gazette of India, 1940, Pt. V, p. 34; for the Report of the Select Committee, *see* Gazette of India, 1940, Pt. V. p. 143.The Act has been applied to all the partially excluded areas in the State of Orissa, *see* Orissa Government Notification No. 3358-LSG, dated 25th August, 1941.

2 Ins. by Act 21 of 1962, sec. 2 (w.e.f. 27-7-1964).

3 Subs, by the A.O. 1950, for certain words.

4 Ins. by Act 21 of 1962, sec. 3 (w.e.f. 27-7-1964).

5 The words "except the State of Jammu and Kashmir" omitted by Act 19 of 1972, sec. 2 (w.e.f. 31-5-1972).

6 24th August, 1974, *vide* Notification No. S.O. 2185, dated 9th August, 1974, published in the Gazette of India, 1974, Pt. II, Sec. 3(ii), p. 2331.

7 Subs, by Act 68 of 1982, sec. *2*, for "Ayurvedic (including Siddha) or Unani" (w.e.f. 1-2-1983).

8 Subs, by Act 68 of 1982, sec. 3, for "disease in human beings, mentioned in, and processed and manufactured" (w.e.f. 1-2-1983).

9 Subs, by Act 68 of 1982, sec. 3, for "Ayurvedic (including Siddha) and Unani (Tibb) system of medicine" (w.e.f. 1-2-1983).

10 The words ", but does not include soap" omitted by Act 68 of 1982, sec. 3 (w.e.f. 1-2-1983).

11 Subs, by Act 13 of 1964, sec. 2, for "vermins" (w.e.f. 15-9-1964).

12 Subs, by Act 68 of 1982, sec. 2, for "Ayurvedic (including Siddha) or Unani" (w.e.f. 1-2-1983).

13 Clause (d) omitted by Act 19 of 1972, sec. 3 (w.e.f. 31-5-1972).

14 Ins. by Act 21 of 1962, sec. 4 (w.e.f. 27-7-1964).

15 Subs, by Act 68 of 1982, sec. 3, for "sale and distribution" (w.e.f. 1-2-1983)

16 Subs, by Act 3 of 1951, sec. 3 and Sch., for "the States".

17 Subs, by Act 13 of 1964, sec. 4, for sub-section (2) (w.e.f. 15-9-1964).

18 Subs, by Act 13 of 1964, sec. 5, for "under Chapter IV" (w.e.f. 15-9-1964).

19Ins. by Act 3 of 1951, sec. 3 and Sch., for "the States" (w.e.f. 1-4-1951).

20 Subs, by Act 68 of 1982, sec. 2, for "Ayurvedic (including Siddha) or Unani" (w.e.f. 1-2-1983).

21 Subs, by Act 21 of 1962, sec. 6, for sub-section (1) (w.e.f. 27-7-1964).

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22 Subs, by Act 13 of 1964, sec. 7, for "the Schedule" (w.e.f. 15-9-1964).

23*Contd. from Previous page*
1st April, 1953, for the States of Himachal Pradesh, Bilaspur, Kutch, Bhopal, Tripura, Vindhya Pradesh and Manipur *vide* Notification No. S.R.O. 666, dated 30th March, 1953, Gazette of India, 1953, Pt. II. Sec. 3, p. 451.

24 Subs, by Act 68 of 1982, sec. 7, for "or misbranded cosmetic" (w.e.f. 1-2-1983).

25 Subs, by Act 68 of 1982, sec. 7, for "adulterated" (w.e.f. 1-2-1983).
26 Subs, by Act 68 of 1982, sec. 7, for certain words (w.e.f. 1-2-1983).

27 Now *see* the Customs Act, 1962 (52 of 1962).

28 Ins. by Act 21 of 1962, sec. 9 (w.e.f. 27-7-1964).

29 Subs, by Act 22 of 1995, sec. 83, for "Customs Collector" (w.e.f. 26-5-1995).

30 Subs, by Act 68 of 1982, sec. 9, for "after consultation with the Board" (w.e.f. 1-2-1983).

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31 Ins. by Act 21 of 1962, sec. 10 (w.e.f. 27-7-1964).

32 Subs, by Act 68 of 1982, sec. 9, for certain words (w.e.f. 1-2-1983).

33 Subs, by Act 68 of 1982, sec. 9 for "section 9B" (w.e.f. 1-2-1983).

34 Subs, by Act 11 of 1955, sec. 7, for "to cure or mitigate" (w.e.f. 15-4-1955).

35 Ins. by Act 21 of 1962, sec. 10 (w.e.f. 27-7-1964).

36 Subs, by Act 3 of 1951, sec. 3 and Sch., for "the States" (w.e.f. 1-4-1951).

37 Subs, by Act 68 of 1982, sec. 10, for section 13 (w.e.f. 1-2-1983).

38 Subs, by Act 68 of 1982, sec. 11, for certain words (w.e.f. 1-2-1983).

39 Subs, by Act 68 of 1982, sec. 12, for **"DRUGS"** (w.e.f. 1-2-1983).

40 Subs, by Act 21 of 1962, sec. 12, for sub-section (1) (w.e.f. 27-7-1964).

41 Subs, by Act 13 of 1964, sec. 11, for "the Schedule" (w.e.f. 15-9-1964).

42 Subs, by Act 11 of 1955, sec. 8, for "State Government" (w.e.f. 15-4-1955).

43Ins. by Act 68 of 1982, sec. 13 (w.e.f. 1-2-1983).

44Ins. by Act 26 of 2008, sec. 2 (w.e.f. 10-8-2009).

45 Subs, by Act 68 of 1982, sec. 14, for certain words (w.e.f. 1-2-1983).

46 Subs, by Act 11 of 1955, sec. 9, for "to cure or mitigate" (w.e.f. 15-4-1955).

47 Subs, by Act 68 of 1982, sec. 14, for "sell, or stock or exhibit for sale" (w.e.f. 1-2-1983).

48 Ins. by Act 21 of 1962, sec. 14 (w.e.f. 27-7-1964).

49 Subs, by Act 68 of 1982, sec. 14, for certain words (w.e.f. 1-2-1983).

50 Subs, by Act 11 of 1955, sec. 9, for "State Government" (w.e.f. 15-4-1955).

51 Subs, by Act 68 of 1982, sec. 14, for "manufacture for sale, sale" (w.e.f. 1-2-1983).

52 Subs, by Act 21 of 1962, sec. 16, for "class of drugs" (w.e.f. 27-7-1964).

53 Ins. by Act 68 of 1982, sec. 17 (w.e.f. 1-2-1983).

54 Subs, by Act 21 of 1962, sec. 17 for "class of drugs" (w.e.f. 27-7-1964).

55 Subs, by Act 68 of 1982, sec. 19, for "in any place mentioned in clause (c)" (w.e.f. 1-2-1983).

56 Subs, by Act 68 of 1982, sec. 19, for "the Code of Criminal Procedure, 1898 (5 of 1898)" (w.e.f.1-2-1983).

57 Subs, by Act 68 of 1982, sec. 19, for "section 98" (w.e.f. 1-2-1983).

58 Ins. by Act 21 of 1962, sec. 15 (w.e.f. 27-7-1964).

59 Subs, by Act 13 of 1964, sec. 16, for clause (iii) (w.e.f. 15-9-1964).

60 Subs, by Act 13 of 1964, sec. 17, for certain words (w.e.f. 15-9-1964).

61 Ins. by Act 21 of 1962, sec. 15 (w.e.f. 27-7-1964).

62 Ins. by Act 71 of 1986, sec. 2 (w.e.f. 15-9-1987).

63 Subs, by Act 71 of 1986, sec. 2, for "purchased by him" (w.e.f. 15-9-1987).

64 Subs, by Act 26 of 2008, sec. 6(ii)(B), for "less than one year and of fine of less than five thousand rupees" (w.e.f. 10-8-2009).

65 Subs, by Act 26 of 2008, sec. 6(iii)(A), for "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" (w.e.f. 10-8-2009).

66Subs, by Act 26 of 2008, sec. 6(iii)(B), for "less than three years but not less than one year" (w.e.f. 10-8-2009).

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67 Subs, by Act 26 of 2008, sec. 6(iv), for "and with fine" (w.e.f. 10-8-2009).

68 Subs, by Act 26 of 2008, sec. ll(a)(i)(B), for "less than two years and of fine of less than ten thousand rupees;" (w.e.f. 10-8-2009).

69 Subs, by Act 26 of 2008, sec. ll(a)(iii), for "five thousand rupees" (w.e.f. 10-8-2009).

70Subs, by Act 68 of 1982, sec. 25, for "one thousand rupees" (w.e.f. 1-2-1983).

71 The words "section 28 or" omitted by Act 13 of 1964, sec. 20 (w.e.f. 15-9-1964).

72 Subs, by Act 26 of 2008, sec. 11(b), for "ten years, or with fine, or with both" (w.e.f. 10-8-2009).

73 Section 31 re-numbered as sub-section (1) of that section by Act 35 of 1960, sec. 9 (w.e.f. 16-3-1961).

74 Added by Act 13 of 1964, sec. 21 (w.e.f. 15-9-1964).

75 Subs, by Act 68 of 1982, sec. 26, for certain words (w.e.f. 1-2-1983).

76 Subs, by Act 13 of 1964, sec. 21, for "or is a misbranded drug" (w.e.f. 15-9-1964).

77 Subs, by Act 68 of 1982, sec. 26, for "misbranded or adulterated drug, or misbranded cosmetic" (w.e.f. 1-2-1983).

78 Ins. by Act 13 of 1964, sec. 23 (w.e.f. 15-9-1964).

79 Subs, by Act 68 of 1982, sec. 28, for "in sub-section (1) of section 351 of the Code of Criminal Procedure, 1898 (5 of 1898)" (w.e.f. 1-2-1983).

80 Ins. by Act 21 of 1962, sec. 22 (w.e.f. 27-7-1964).

81 Subs, by Act 68 of 1982, sec. 29, for "section 17B" (w.e.f. 1-2-1983).

82 Subs, by Act 68 of 1982, sec. 29, for "for the manufacture for sale" (w.e.f. 1-2-1983)

83Ins. by Act 21 of 1962, sec. 22 (w.e.f. 27-7-1964).

84Ins. by Act 68 of 1982, sec. 29 (w.e.f. 1-2-1983).

85 Subs, by Act 11 of 1955, sec. 15, for "to cure or mitigate" (w.e.f. 15-4-1955).

86 Ins. by Act 68 of 1982, sec. 29 (w.e.f. 1-2-1983).

87 The word "and" omitted by Act 26 of 2008, sec. 14(ii) (w.e.f. 10-8-2009).

88 Subs, by Act 68 of 1982, sec. 2, for "Ayurvedic (including Siddha) or Unani" (w.e.f. 1-2-1983).

89 Subs, by Act 68 of 1982, sec. 31, for sections 33D and 33E (w.e.f. 1-2-1983).

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

90 Subs, by Act 26 of 2008, sec. 15(a)(ii), for "five thousand rupees" (w.e.f. 10-8-2009).

91 Subs, by Act 26 of 2008, sec. 16(a), for "two thousand rupees" (w.e.f. 10-8-2009).

92 Subs, by Act 26 of 2008, sec. 16(b), for "five thousand rupees" (w.e.f. 10-8-2009).

93 Subs, by Act 26 of 2008, sec. 16(c), for "six months and with fine which shall not be less thanone thousand rupees." (w.e.f. 10-8-2009).

94 Subs, by Act 68 of 1982, sec. 2, for "Ayurvedic (including Siddha) or Unani" (w.e.f. 1-2-1983).

95 Subs, by Act 68 of 1982, sec. 2, for "Ayurvedic (including Siddha) or Unani" (w.e.f. 1-2-1983).

96 Ins. by Act 68 of 1982, sec. 34 (w.e.f. 1-2-1983).

97 Subs, by Act 68 of 1982, sec. 34, for "of a Presidency Magistrate or of a Magistrate of the first class" (w.e.f. 1-2-1983).

98 Subs, by Act 68 of 1982, sec. 35, for "after consultation with the Board" (w.e.f. 1-2-1983).

99 Ins. by Act 68 of 1982, sec. 35 (w.e.f. 1-2-1983).

100 The word "and" omitted by Act 26 of 2008, sec. 18(i) (w.e.f. 10-8-2009).

101 Section 33A re-numbered as section 33P by Act 13 of 1964, sec. 27 (w.e.f. 15-9-1964).

102 Subs, by Act 68 of 1982, sec. 37, for certain words (w.e.f. 1-2-1983).

103 The words "section 32 of" omitted by Act 13 of 1964, sec. 29 (w.e.f. 15-9-1964).

104 Subs, by Act 68 of 1982, sec. 38, for "the Code of Criminal Procedure, 1898 (5 of 1898)" (w.e.f. 1-2-1983).

105 Subs, by Act 68 of 1982, sec. 38, for "any Presidency Magistrate or any Magistrate of the first class" (w.e.f. 1-2-1983).

106 Subs, by Act 26 of 2008, sec. 19, for "all offences under this Act" (w.e.f. 10-8-2009).

107 Subs, by Act 68 of 1982, sec. 40, for certain words (w.e.f. 1-2-1983).

*** End ***

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

भारतीय भेषजी परिषद्
(स्वास्थ्य एवं परिवार कल्याण मंत्रालय के अंतर्गत सांविधिक निकाय)
भारत सरकार
एन बी सी सी सेन्टर, तृतीय तल, प्लॉट नम्बर 2,
कॉमुन्युटी सेन्टर, मां आनन्दमयी मार्ग,
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PHARMACY COUNCIL OF INDIA
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Government of India
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**CIRCULAR**

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To

1. **All the State Governments**
2. **All State Pharmacy Councils**
3. **All Approved Institutions -**
   **a) u/s 12 of the Pharmacy Act, 1948**
   **b) conduct of course**

**Sub: The Jan Vishwas (Amendment in Provisions) Act, 2023 – reg.**

Sir

With reference to the subject cited above, please find attached herewith the Jan Vishwas (Amendment of Provisions) Act, 2023 issued by the Ministry of Law and Justice (legislative department) in the Gazette of India (Extraordinary) No. 21, Part-II, Section 1 dt. 11th August,2023 as **Annexure-I** .

All the State Governments and State Pharmacy Councils are requested to kindly implement the same.

This is for your strict compliance.

Yours faithfully

(ANIL MITTAL)
**Registrar-cum-Secretary**

रजिस्ट्री सं० डी० एल०—(एन)04/0007/2003—20 REGISTERED NO. DL—(N)04/0007/2003—21

# भारत का राजपत्र
# The Gazette of India

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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
Separate paging is given to this Part in order that it may be filed as a separate compilation.

## MINISTRY OF LAW AND JUSTICE
## (Legislative Department)

*New Delhi, the* 11*th August,* 2023/*Sravana* 20, 1945 (*Saka*)

The following Act of Parliament received the assent of the President on the 11th August, 2023 and is hereby published for general information:—

## THE *JAN VISHWAS* (AMENDMENT OF PROVISIONS) ACT, 2023

No. 18 OF 2023

[11*th August,* 2023.]

An Act to amend certain enactments for decriminalising and rationalising offences to further enhance trust-based governance for ease of living and doing business.

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

Short title and commencement.

**1.** (*1*) This Act may be called the *Jan Vishwas* (Amendment of Provisions) Act, 2023.

(*2*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint; and different dates may be appointed for amendments relating to different enactments mentioned in the Schedule.

Amendment of certain enactments.

**2.** The enactments mentioned in column (4) of the Schedule are hereby amended to the extent and in the manner mentioned in column (5) thereof.

Revision of fines and penalties.

**3.** The fines and penalties provided under various provisions in the enactments mentioned in the Schedule shall be increased by ten per cent. of the minimum amount of fine or penalty, as the case may be, prescribed therefor, after the expiry of every three years from the date of commencement of this Act.

| (1) | (2) | (3) | (4) | (5) |
|---|---|---|---|---|
| 6. | 1940 | 23 | The Drugs and Cosmetics Act, 1940 | (*A*) In section 29, for the words "punishable with fine which may extend to five thousand rupees", the words "liable to penalty which may extend to one lakh rupees" shall be substituted.<br><br>(*B*) In section 30, in sub-section (*2*), for the words "imprisonment which may extend to two years, or with fine which shall not be less than ten thousand rupees, or with both", the words "fine which shall not be less than five lakh rupees" shall be substituted.<br><br>(*C*) In section 32B, in sub-section (*1*), after the words and figures "of section 13,", the words, brackets, letters and figures "clause (*d*) of section 27 and clause (*ii*) of section 27A," shall be inserted. |
| 7. | 1944 | 18 | The Public Debt Act, 1944 | Section 27 shall be omitted. |
| 8. | 1947 | 24 | The Rubber Act, 1947 | (*A*) In section 11, in sub-section (*3*), for the words "imprisonment for a term which may extend to one year or with fine or with both", the words and figures "penalty which may extend to one lakh rupees or cancellation of licence issued under section 14, or with both" shall be substituted.<br><br>(*B*) In section 13, sub-section (*3*) shall be omitted.<br><br>(*C*) In section 25, in sub-section (*2*), after clause (*xxiii*), the following clauses shall be inserted, namely:—<br><br>"(*xxiiia*) the manner of holding inquiry and imposing penalty under sub-section (*1*) of section 26B;<br><br>(*xxiiib*) the form and manner of preferring appeal under sub-section (*2*) of section 26B;".<br><br>(*D*) In section 26, in sub-section (*1*), in the long line, for the words "punishable with imprisonment for a term which may extend to one year, or with fine which may extend to five thousand rupees, or with both", the words "liable to penalty which may extend to fifty thousand rupees" shall be substituted.<br><br>(*E*) After section 26A, the following section shall be inserted, namely:<br><br>"26B. Adjudication of penalties.—(*1*) For the purposes of adjudging the penalties under sub-section (*3*) of section 11 and section 26, the Executive Director shall appoint the Secretary to the Board or any other officer authorised by the Central Government, as the case may be, to be an adjudicating officer for holding an inquiry |