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

Whereas it is expedient to regulate the [import, manufacture, distribution and sale] of drugs [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:-

LEGISLATIVE HISTORY ▼

- Repealing and Amending Act, 1949 (40 of 1949)
- Adoption of Laws Order, 1950
- Part B States (Laws) Act, 1951 (3 of 1951)
- Drugs (Amendment) Act, 1955 (11 of 1955)
- Drugs (Amendment) Act, 1960 (35 of 1960)
- Drugs (Amendment) Act, 1962 (21 of 1962)
- Drugs and Cosmetics (Amendment) Act, 1964 (13 of 1964)
- Drugs and Cosmetics (Amendment) Act, 1972 (19 of 1973)
- Drugs and Cosmetics (Amendment) Act, 1982 (68 of 1982)
- Drugs and Cosmetics (Amendment) Act, 1986 (71 of 1986)
- Finance Act, 1995 (22 of 1995)
- Drugs and Cosmetics (Amendment) Act, 2008 (26 of 2008)

FACT SHEET ▼

- "1st April, 1947, see Notification No.F. 28(10)(3) 45-H(I), dated 2.9.1946, Gazette of India, 1946, Pt.I, p.1349.
- Chapter IV came into force in the States of Delhi, Ajmer and Coorg on 1.4.1947, see Notification No.F. 28(10)(3) 45-H(I).
- Chapters III and IV came into force in the States of Himachal Pradesh, Bilaspur, Kutch, Bhopal, Tripure, Vindhya

Pradesh and Manipur on 1.4.1953 vide Notification No. S.R.O. 663, dated 30.3.1953, Gazette of India, Pt.II, Section 3, p.451.
☐ Chapter IV came into force in the Union territory of Dadra and Nagar Haveli w.e.f. 1.8.1968, see Notification No. ADM/Law/117(74), dated 20.7.1968, Gazette of India, Pt.II, Section 3, p.128."
☐ This Act has been extended to the new provinces and merges States by the Merged States (Laws) Act 59 of 1949, Section 3 and to the Union territories of Manipur and Tripura by the Union Territories (Laws) Act 30 of 1950, Section 3.
☐ Manipur and Tripura are full-fledged States now, see Act 81 of 1971; but Vindhya Pradesh to which this Act was extended now forms part of the State of Madhya Pradesh now, see Act 37 of 1956, Section 9.
☐ The Act has been extended to the Union territory of-(1) Dadra and Nagar Haveli by Regulation 6 of 1963, Section 2 and Sch.;
☐ (2) Pondicherry by Regulation 7 of 1963;
☐ (3) Goa, Daman and Diu by Regulation 2 of 1963. Goa is now a State, see Act 18 of 1987, Section 3 (w.e.f. 30.5.1987) and
☐ (4) Laccadive, Minicoy and Amindivi Islands (now known as Lakshadweep) by Regulation 8 of 1965.
☐ The Act has been extended to and enforced on 15.9.1984 in Sikkim, see S.O.529(E)/1983 and S.O.767(E)/1984.

CHAPTER I

Introductory

1. Short title, extent and commencement .(1) This Act may be called The Drugs [and Cosmetics] Act , 1940.
(2) It extends to the whole of India [- - -].
(3) It shall come into force at once; but Chapter III shall take effect only from such date 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 as the State Government may, by like notification, appoint in this behalf:
[Provided that in relation to the State of Jammu and Kashmir, Chapter III shall take effect only from such [date] 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.]

Object & Reasons▼

Statement of Objects and Reasons.-In order to give effect to the recommendations of the Drugs Enquiry Committee, insofar as they relate to matters with which the Central Government is primarily concerned, a Bill to regulate the import of drugs into British India was introduced in the Legislative Assembly in 1937. The Select Committee appointed by the Legislative Assembly was of the opinion that a more comprehensive measure providing for the uniform control of the manufacture and distribution of drugs as well as of import was desirable. The Government of India accordingly asked Provincial Governments to invite the Provincial Legislatures to pass resolutions under section 103 of the Government of India Act, 1935, empowering the Central Legislature to pass an Act for regulating such matters relating to the control of drugs as fall within the Provincial Legislative list. Such resolutions have now been passed by all Provincial Legislatures.

2. Chapter II of the Bill establishes a Board of Technical Experts to advise the Central and the Provincial Governments on technical matters.

3. Chapter III provides for the control of the import of drugs into British India. The executive power under this Chapter will accordingly be exercised by the Central Government.

4. Chapter IV relates to control of the manufacture, sale and distribution of drugs and contains the provisions which it is proposed should be enacted in exercise of the powers conferred by the resolutions under section 103 of the Government of India Act, 1935, passed by the Provincial Legislatures. The executive power under Chapter IV will be exercised by the Provincial Government.

5. The First Schedule prescribes the standards to be complied with by imported drugs and the Second Schedule prescribes the standards to be complied with the drugs manufactured, sold or distributed in India. The standards prescribed in the two Schedules are identical. The Central Government will have power to amend the First Schedule, but power to amend the Second Schedule will rest with Provincial Government.

6. The Government of India have considered to what extent provision can be made to secure the maintenance of uniformity in standards and in other important matters in which uniformity is desirable. They understand that it would be ultra vires of the Central Legislature to assign to any

authority other than the Provincial Governments authority conferred by the Bill in respect of matters falling within the Provincial Legislative field. For this reason it is not possible to assign the power to fix standards and to make rules to any single authority. In order to assure that before any action is taken due consideration is given to the desirability of maintaining uniformity, provision has been made in Chapter VI for a single Technical Advisory Board which both Central and Provincial Government will be required to consult before modifying the standards set up by the Bill or before making rules under the Bill.

Amendment Act 35 of 1960-Statement of Objects and Reasons.-We should have preferred to find included in the present legislation provisions dealing also with pharmacy, and for bringing the pharmaceutical profession under the salutary control provided for by the Bill. We have, however, received an assurance that the Central Government will take steps immediately to consult Provincial Governments with a view to undertaking such legislation as early as possible. In the meantime we have, by our amendments to sub-clause (2) of clause 5, made increased provision for the representation of the pharmaceutical profession on the Drugs Technical Advisory Board by the addition of clause (ix) providing for the nomination by the Central Government of one additional member of that profession, and we have been assured that, when the proposed legislation on pharmacy has been enacted. Government will consider the amendment of the provisions contained in this Bill relating to the constitution of the Drugs Technical Advisory Board.

The Pharmaceutical Enquiry Committee appointed by the Government of India to make a comprehensive survey of the pharmaceutical industry, trade and profession in the country unanimously recommended that Drugs Standard Control which was exercised by State Governments should be centralised for a better enforcement of the Drugs Act, 1940. On the basis of this recommendation of the Committee it is proposed to amend the Drugs Act, 1940, so as to empower the Central Government to control the manufacture of drugs, to appoint Inspectors for inspecting manufacturing premises and taking samples of drugs, to appoint Government Analysts to whom samples drawn by such Inspectors could be sent for analysis and to issue directions to State Governments for carrying into execution any of the provisions of the Act. It is further proposed to provide a

minimum punishment of one year's imprisonment and fine for the manufacture, sale, etc., of certain misbranded drugs and a minimum punishment of two years' imprisonment with fine for subsequent offences. Provision is also being made for the confiscation of sub-standard and misbranded drugs under orders of the Court after such enquiry as may be necessary.

Amendment Act 21 of 1962-Statement of Objects and Reasons.-The continual development of research and application of various organic synthetics and intermediates to the formulation of cosmetics make it necessary to ensure that nothing is used in cosmetics which may have deleterious effects on the health of the people. Contact dermatits is one of the evil effects of using certain cosmetics. Preparations which appear to be among the most frequent causes of dermatitis are deodorants, pomades, lipsticks and nail polishes. Apart from dermatitis following the use of certain cosmetics, there is also the bigger risk of the cumulative toxicity of azo and other synthetic dyes used in the manufacture of lipsticks, etc. It appears that while in well-organised and equipped units of cosmetic industry there is a fair amount of control, there are many units dispersed throughout the country where even elementary precautions for testing raw materials and observing hygienic conditions during manufacture are not taken.

The question of regulating the manufacture of cosmetics was discussed at the last meeting of the Central Council of Health held at Jaipur October, 1960. The consensus of opinion was that the manufacture of cosmetics should be regulated, if necessary, by extending the provisions of the Drugs Act, 1940, to them. It is accordingly proposed to amend the Drugs Act, 1940, suitably so as to provide for regulation of the manufacture of cosmetics and prohibition of import and sale of sub-standard and misbranded cosmetics.

Amendment Act 13 of 1964-Statement of Objects and Reasons.-The provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940), do not apply to medicines and substances exclusively used or prepared for use in accordance with the Ayurvedic or Unani systems of medicine. The preparation of Ayurvedic and Unani drug is no longer confined to Vaidyas and Hakims for their patients but has been commercialised by firms. There is a growing tendency on the part of certain manufacturers to market preparations containing partly modern drugs and partly Ayurvedic or

Unani drugs under names which simulate Ayurvedic or Unani Preparations thus making it difficult to exercise control over them under the Drugs and Cosmetics Act, 1940. The Udupa Committee's report discloses that costly raw materials such as gold, musk, pearl, saffron, etc., which are component ingredients in the various Ayurvedic and Unani preparations are either not used or substituted by imitation products. For these reasons it is proposed to bring Ayurvedic and Unani drugs also within the scope of the Act.

In order to keep a check on drugs which are contaminated with foreign matter or which are manufactured, packed or held under insanitary conditions whereby they may have been contaminated or rendered injurious to health, it is proposed to bring within the scope of the Act a separate category called adulterated drugs and to prohibit the import, manufacture, sale, etc., of such drugs.

There has been a general demand throughout the country for enhancing the penalty for the manufacture and sale of misbranded and spurious drugs. Accordingly, it is proposed to enhance the maximum penalty of imprisonment provided for such offences to ten years and also to provide for the confiscation of property, apparatus, etc., used for the manufacture of such drugs.

Amendment Act 68 of 1982-Statement of Objects and Reasons.-The Drugs and Cosmetics Act, 1940, regulates the import into, manufacture, distribution and sale of drugs and cosmetics in the country. The problems of adulteration of drugs and also of production of spurious and sub-standard drugs are posing serious threat to the health of the community. It is, therefore, considered necessary to amend the Drugs and Cosmetics Act, so as to impose more stringent penalties on the anti-social elements indulging in the manufacture or sale of adulterated or spurious drugs or drugs not of standard quality which are likely to cause death or grievous hurt to the user. This opportunity is also being availed of to incorporate certain other provisions on the other aspects of effective control on the manufacture, distribution, sale of drugs and cosmetics on the basis of experience gained in the working of the Act.

2. Some of the important proposals envisaged are set out below:-

(1)(a) Widening of the definition of the expression "cosmetics" so as to bring within its scope "toilet soaps" in order to exercise control over such soaps which may

contain harmful ingredients like hexachlorophene [vide clause 3(c)];

(b) The definition of the expression "drug" to be expanded to enable control being exercised over the components of drugs including empty gelatine capsules and also devices which are intended for internal or external use in the diagnosis or treatment of diseases in human beings or animals [vide clause 3(d)];

(c) Widening of the scope of the expression "patent or proprietary medicine" so as to include patent or proprietary medicines which relate to Ayurveda, Siddha or Unani Tibb systems of medicines but not including such medicines as are administered by parenteral (i.e. by means of injections) route [vide clause 3(f)].

(2) Incorporation of a new provision for the purpose of defining certain terms like "spurious drugs" and "spurious cosmetics" and making of suitable consequential amendments in the definitions of other expressions like "misbranded drugs", "adulterated drugs" and "misbranded cosmetics". Analogous provisions of a like nature are also to be included in respect of drugs relating to Ayurveda, Siddha or Unani Tibb systems of medicines [vide clauses 6,13 and 31].

(3) New provisions to be incorporated to empower the Central Government to prohibit import or manufacture of drugs and cosmetics in the public interest where that Government is satisfied that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or where the drug does not have any therapeutic justification [vide clauses 8 and 21].

(4) Insertion of a mandatory provision so as to make it obligatory for any person who is a holder of a license to maintain such records, registers and other documents as may be prescribed and to produce them to the concerned authority if and when required [vide clause 15].

(5) Provision to empower the Inspector to 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 the Act is being committed [vide clause 19].

(6) Enhancement of the quantum of punishment for offences relating to the manufacture or sale of adulterated, spurious drugs or drugs not of a standard quality which are likely to

cause death or grievous hurt to the user. Penalties provided in respect of other offences are to be revised on a more rational basis.

(a) The proposed scale of punishment in respect of the first offence shall be as set out below [vide clause 22];

(i) imprisonment for not less than five years which may extend to life and with fine of not less than rupees then thousand for the manufacture and sale of adulterated or spurious drugs or drugs not of standard quality which are likely to cause death or harm on the patient's body as would amount to grievous hurt;

(ii) imprisonment for not less than one year which may extend to three years and fine of not less than rupees five thousand for manufacture or sale of any adulterated drug or manufacture and sale of drugs without a valid license;

(iii) imprisonment for three years which may extend to five years and with fine of not less than rupees five thousand for manufacture or sale of spurious drugs;

(iv) imprisonment for other offences shall be not less than one year which may extend to two years and with fine.

(b) The proposed scale of punishment for subsequent offences shall be as set out below [vide clause 25]

(i) imprisonment for not less than two years which may extend to six years and with fine of not less than rupees ten thousand for manufacture and sale of any adulterated drug or manufacture and sale of drugs without a valid license;

(ii) imprisonment for not less than six years which may extend to ten years and with fine of not less than rupees ten thousand for manufacture and sale of a spurious drug;

(iii) imprisonment for a term for not less than two years which may extend to four years and with fine of not less than rupees one thousand or with both for other offences.

(7) Provision to be made in section 33-C to give representations to experts in the

Ayurvedic, Siddha and Unani systems of medicines on the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board [vide clause 30].

(8) Another proposal relates to the constitution of an Advisory Committee to be called 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 intended to secure uniformity throughout India in the administration of the Act. The Committee shall consist of two persons to be nominated by the Central Government and one each by the State Governments [vide clause 31].

(9) Punishments for manufacture, sale, etc., of Ayurvedic, Siddha or Unani drugs in contravention of the provisions of the Act are sought to be enhanced [vide clause 33].

(a) The proposed scale of punishments for the first offence shall be as set out below-

(i) imprisonment up to one year or with fine of not less than rupees one thousand for the manufacture of adulterated, Ayurvedic, Siddha and Unani drugs or its manufacture without a valid license;

(ii) imprisonment for one year which may extend to three years and fine of not less than rupees five thousand for the manufacture of spurious Ayurvedic, Siddha and Unani drugs;

(iii) imprisonment for three months and fine of not less than rupees five thousand for other offences.

(b) The proposed scale of punishment for subsequent offences shall be as set out below-

(i) imprisonment for a term which may extend to two years and with fine of not less than rupees two thousand for offences of manufacturing, sale or distribution of any Ayurvedic, Siddha or Unani drug;

(ii) imprisonment for six months and with fine of not less than rupees five thousand for manufacturing of any spurious Ayurvedic, Siddha or Unani drug or sale thereof;

(iii) imprisonment for six months and with fine of rupees one thousand for

(10) A new provision to be made to provide for summary

trial in case of offences where the penalty is not more than three years' imprisonment [vide clause 39].

3. The Bill seeks to achieve the above objects. The above apart, the other amendments sought to be effected are of a general or consequential nature.

Amendment Act 71 of 1986-Statement of Objects and Reasons.-The Drugs and Cosmetics Act, 1940 is a consumer protection legislation, which is mainly concerned with the standards and purity of drugs manufactured in this country and control of the manufacture, sale and distribution of drugs. The Act at present does not confer any power on the recognised Consumer Associations to draw legal samples and launch prosecution.

2. To promote Voluntary Consumer Movement and to ensure involvement of recognised Consumer Associations in the enforcement of this Act, it is necessary to confer powers on them so that legal action can be initiated by them in the Court on the basis of test reports given by the Government Analyst. Accordingly, it is proposed to amend suitably sections 26 and 32 of the Act to confer powers on such Consumer Associations in this regard.

3. Opportunity has been taken to explain the expression recognised Consumer Association registered under the Companies Act, 1956 or any other law for the time being in force.

Amendment Act 26 of 2008-Statement of Objects and Reasons.-The Drugs and Cosmetics Act, 1940 is a consumer protection legislation, which is mainly concerned with the standards and quality of drugs manufactured in this country and control of the import, manufacture, sale and distribution of drugs and cosmetics.

2. There have been widespread reports regarding the easy movement and harmful consequences of adulterated and spurious drugs in the country and wide ranging national concern has been expressed on these reports. The issue of adulterated or spurious drugs has serious dimensions because it involves medicinal use and can lead to serious and even fatal injury. There is also loss of revenue to the Government due to the manufacture and sale of adulterated or spurious drugs.

3. Drugs and Cosmetics Act, 1940 was amended in 1982 so as to impose more stringent penalties on the anti-social elements indulging in the manufacture or sale of adulterated or spurious drugs or drugs not of standard quality which are

likely to cause death or grievous hurt to the user. However, the penalties existing in the said Act are not found effective. One of the reasons for the existing penalties not being effective is that manufacture and sale of adulterated and spurious drugs is primarily clandestine activity which is showing increasing involvement of organised crime in recent years. Besides, offenders often obtain bail as the offences are non-cognisable and bailable under the existing provisions of the Act. The offenders remain on bail due to delay in disposal of cases for manufacture and sale of adulterated and spurious drugs. Many cases for violation are detected and investigated by the police who needs to be conferred upon the power to prosecute such cases promptly.

4. The Central Government constituted an Expert Committee under the chairmanship of Dr. R.A. Mashelkar, Director General of Council of Scientific and Industrial Research in January, 2003 to undertake a comprehensive examination of drugs regulatory issues, including the problem of spurious drugs, evaluate the extent of the problem of spurious or substandard drugs and recommend measures required to deal with the problem effectively. The Committee, inter alia, recommended for enhancement of penalties, designation of Special Court for speedy trial of spurious drugs cases, making offences relating to spurious drugs cognisable and non-bailable, authorising the police to file prosecution for offences related to spurious drugs and compounding of offences, etc. A Bill to amend the Drugs and Cosmetics Act, 1940 broadly to give effect to the recommendations of the aforesaid Committee was introduced on the 22nd December, 2003 in Lok Sabha and the Bill lapsed due to dissolution of Lok Sabha. The Central Government, inter alia, proposes to make the following amendments in the Drugs and Cosmetics Act, 1940, broadly on the lines of the earlier Bill introduced with certain modifications which relate to enhancement of punishment and doing away with the death penalty as proposed in the said Bill, namely:'-

(i) The existing provisions contained in section 27 of the aforesaid Act, inter alia, provide for scale of punishment for the first offence in respect of adulterated or spurious drugs. Clause (a) of section 27 of the aforesaid Act, provides for imprisonment for not less than five years which may extend to life and with fine of not less than rupees ten thousand for the manufacture and sale of

adulterated or spurious drugs or drugs not of standard quality which are likely to cause death of the patients or harm on the patient's body as would amount to grievous hurt. It is proposed to enhance the period of 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 of ten lakh rupees or three times the value of the drugs confiscated, whichever is more;

(ii) It is also proposed to insert two provisos in the said clause (a) so as to provide that the fine imposed on the convicted person and realised from him under the said clause shall be paid to the person who used such adulterated or spurious drugs and in case of his death, to his relative;

(iii) Clause (b) of said section 27 provides for punishment of imprisonment for not less than one year which may extend to three years and fine of not less than rupees five thousand for manufacture and sale of any adulterated drug (not being a drug referred to in section 17-A) or manufacture and sale of drugs without a valid license. It is proposed to enhance the said punishment of imprisonment being not less than three years but may extend to five years and with fine which shall not be less than one lakh rupees;

(iv) Clause (c) of aforesaid section 27 provides for punishment of imprisonment for not less than one year which may extend to three years but which may extend to five years and with fine which shall not be less than rupees five thousand for manufacture and sale of any spurious drug (not being a drug referred to in section 17-B). It is proposed to enhance the said punishment of imprisonment being not less than seven years but which may extend to imprisonment for life and with fine which shall be three lakh rupees or three times the value of the drugs seized, whichever is more;

(v) Clause (d) of aforesaid section 27 provides for punishment of imprisonment for a term which shall not be less than one year but which may extend to

two years and with fine. It is proposed to provide that the fine shall not be less than twenty thousand rupees;

(vi) It is also proposed to provide for a fine of not less than twenty thousand rupees under section 28 for non-disclosure of the name of the manufacturer and under section 28-A for not keeping documents, etc., and for non-disclosure of information;

(vii) It is also proposed to enhance punishment specified under section 30 for subsequent offences. Clause (a) of said section 30 provides for punishment for imprisonment not less than two years which may extend to six years and with fine of not less than rupees ten thousand for manufacture and sale of any adulterated drug or manufacture and sale of drugs without a valid license. It is proposed to enhance the said punishment 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. Clause (b) of aforesaid section 30 provides for punishment for imprisonment for not less than six years which may extend to ten years and with fine of not less than rupees ten thousand for manufacture and sale of a spurious drug. It is proposed to enhance the punishment of imprisonment which 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;

(viii) It is also proposed to designate one or more Court of Session as Special Court for trial of offences related to adulterated or spurious drugs;

(ix) It is also proposed to make offences relating to adulterated or spurious drugs as cognisable and non-bailable in certain cases;

(x) It is also proposed to confer powers upon the police officers not below the rank of sub-inspector of police and other officers of the Central Government or State Government authorised by it to institute the prosecution under the aforesaid Act;

(xi) It is also proposed to provide compounding of certain offences not being an offence punishable with imprisonment only or with imprisonment and also with fine.

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,

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

[(aa) the Board means

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

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

[[(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 [* * *];]

[(b) drug includes

[(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the 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 [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;]

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

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

[(c) Government Analyst means

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

[- - -]

[(e) Inspector means

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

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

[[(f)] manufacture in relation to any drug [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 [or cosmetic] with a view to its [sale or distribution] but does not include the compounding or dispensing [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 expressions means to bring into [India];

[[(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;]

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

[- - -]

[3-A. 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 State of 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 IV-A] shall be deemed to be a poisonous substance for the purpose of Chapter III or Chapter IV [or Chapter IV-A], as the case may be.

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) 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.]

(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:
[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 sub-committees for such periods, not exceeding three years, as it may decide, or temporarily for the consideration of particular matters, persons who are not members of the Board.
(6) The functions of the Board may be exercised notwithstanding any vacancy therein.
(7) The 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 [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 [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;

[- - -]

(d) the procedure for the submission to the said Laboratory under [Chapter IV or Chapter IV-A] of samples of drugs [or cosmetics] for analysis or test, the forms of the Laboratorys 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 its application to the State of Uttar Pradesh, in Section 6(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 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.U.P. Act 47 of 1975, Section 5 (w.e.f. 5-9-1975).

[West Bengal] .In its application to the State of West Bengal, in Section 6(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.W.B. Act 42 of 1973, Section 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 [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.

[7-A. Sections 5 and 7 not to apply to [Ayurvedic, Siddha or Unani] drugs.] Nothing contained in section sections 5 and 7 shall apply to [Ayurvedic , Siddha or Unani Drugs.

CHAPTER III

[Import of Drugs and Cosmetics]

8. Standards of quality .[(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 [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 [the Second Schedule], for the purposes of this Chapter, and thereupon [the Second Schedule] shall be deemed to be amended accordingly.

[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.]

[9-A. 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.

9-B. 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.

9-C. 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.

9-D. 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 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;

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

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

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

[(d) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof [the true formula or list of 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 for 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.

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> ***FACT SHEET ▼***
> The dates are 1.4.1947, for clauses (a), (b), (c), (e) and (f) and 1.4.1949, for Cl.(d), see Notification No. 18.12.46-D-I, dated 11.2.1947, Gazette of India, 1947, Pt.I,p.189 as amended by Notification No. F-1-2/48-D(I), dated 29.9.1948. 1.4.1953, for the States of Himachal Pradesh, Bilaspur, Kutch, Bhopal, Tripura, Vindhya Pradesh and Manipur vide Notification No.S.R.O.666, dated 30.3.1953, Gazette of India, 1953, Pt.II, Section 3, p.451.">

[10-A. 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)] shall, subject to the provisions of section 13 of this Act, apply in respect of drugs [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 [Commissioner of Customs] and other officers of Customs, shall have the same powers in respect of such drugs [and cosmetics] as they have for the time being in respect of such goods as aforesaid.

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

12. Power of Central Government to make rules .(1) The Central Government may, [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 the 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 [or cosmetics or classes of cosmetics] for the import of which a license is required, [and prescribe the form and conditions of such licenses, the authority empowered to issue the same, the fees payable therefor and provide for the cancellation, or suspension of such license 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 license is issued is not complied with];

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

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

[(cc) prescribe under clause (d) of [section 9-A] 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 [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 [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 [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 [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 [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, [India];

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

(l) regulate the mode of labelling drugs [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;

(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 [or cosmetics or class of cosmetics].

[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 9-B or any spurious cosmetic referred to in section 9-D 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 10-A, shall be punishable with imprisonment for a term which may extend to three years, or with fine which may extend to five thousand rupees, or with both.

(2) Whoever having been convicted of an offence

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

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

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

Form of Charge ▼

Form of Charge under section 13 read with section 9

I ,..... .....(name and office of the Magistrate, etc.), hereby charge you..... .....(name of the accused) as follows:

That you, on or about the..... .....day of....., at....., imported a misbranded drug, to wit,.....and as such drug or cosmetic was an imitation of.....or substitute for or resembled or resembled in a manner likely to deceive, another drug, to wit,.....or, bore upon it or upon its label or container the name of another drug, namely,.....or it purported to be a product of a place or country, to wit,.....of which it was not truly a product or it was imported under a name which belonged to another drug, to wit,..... or it was so coloured, coated, powered or polished that damage was concealed or it was made to appear of better or greater the repeutic value than it really was or that it was not labelled in a prescribed manner or its label or container bore a statement, design or device, to wit,.....which made a false claim that.....(specify claim) which was false or misleading or the label or container bore the name of individual or company, namely,.....,purporting to be the manufacturer or producer of the drug and which

individual company was fictitious and did not exist and thereby committed an offence punishable under section 13 read with section 9 of the Drugs and Cosmetics Act, 1940, and within my cognizance.

And I hereby direct that you be tried by this Court on the said charge

Form of Charge ▼

Form of Charge under section 13 read with section 9-A Adulterated Drugs

I ,..... .....(name and office of the Magistrate, etc.), hereby charge you.....(name of the accused) as follows:

That you, on or about the..... .....day of....., at....., imported a misbranded cosmetics drug, to wit,.....as it was an imitation of or substitute for or resembled in a manner likely to deceive another cosmetic, namely,.....or it purported to be a product of a place or country.....(name the place or country) of which it was not truly a product or it contained a colour.....(specify the colour) which was not prescribed or it was imported under a name which belonged to another cosmetic..... .....(specify the cosmetic) or it was not labelled in the prescribed manner or its label or container bore the name of an individual or company.....(specify the name of such individual or company purporting to be the manufacturer or producer of the cosmetic) and such individual or company was fictitious and not did exist or the label or container of the cosmetic bore a statement, to wit,.....(specify the statement) which was false and misleading and thereby committed an offence punishable under section 13 read with section 9-A of the Drugs and Cosmetics Act, 1940, and within my cognizance.

And I hereby direct that you be tried by this Court on the said charge.

Form of Charge ▼

Form of Charge under section 13 read with section 9-B Spurious Drugs

I ,.....(name and office of the Magistrate, etc.), hereby charge you.....(name of the accused) as follows:

That you, on or about the..... ....day of....., at....., you imported adulterated drug as it consisted in whole (or part) of a filthy (or putrid or decomposed) substance, to wit,.....or it had been prepared (or

packed or stored) under insanitary conditions, whereby if may have been contaminated with filthy (or rendered injurious to health) or its container was composed of.....a poisonous (or deleterious) substance, which rendered its contents, injurious to health or, it bore or, contained..... .....colour which was other than the colour prescribed or the substance, to wit,.....had been mixed and packed therewith so as to reduce its quality or strength or that the said substance had been substituted wholly (or in part) therefore and thereby committed an offence punishable under section 13 read with section 9-B of the Drugs and Cosmetics Act, 1940, and within my cognizance.

And I hereby direct that you be tried by this Court on the said charge.

Form of Charge ▼

Form of Charge under section 13 read with section 10Prohibition of import of certain drugs

I ,.....(name and office of the Magistrate, etc.), hereby charge you.....(name of the accused) as follows:

That you, on or about the..... .....day of....., at....., you imported a drug (or cosmetic), to wit,.....which was not of standard quality, or a drug.....(name the drug) or cosmetic,.....(name the cosmetic) for the import of which a licence was prescribed, otherwise than under, and in accordance with, such licence or a patent (or propriety) medicine, to wit,..... without displaying in the prescribed manner on the label or container thereof the true formula (or a list of ingredients contained in it) in a manner readily intelligible to the member of the medical profession or a drug or cosmetic, namely,.....containing an ingredient, to wit,..... .....which rendered it unsafe or harmful for use under directions indicated of recommended or a drug, namely,.....the import of which was prohibited by rules and thereby committed an offence punishable under section 13 read with section 10 of the Drugs and Cosmetics Act, 1940, and within my cognizance.

And I hereby direct that you be tried by this Court on the said charge.

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

15. Jurisdiction .No Court inferior to that [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 [Drugs and Cosmetics]

16. Standards of quality .[(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 [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 [the Second Schedule] for the purposes of this Chapter, and thereupon [the Second Schedule] shall be deemed to be amended accordingly.

[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.

17-A. 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.

17-B. 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.

17-C. 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.

17-D. 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.]

[17-E. 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

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

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

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

[(iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof [the true formula or list of 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 [to prevent, cure or mitigate] any such disease or ailment, or to have any such other effect as may be prescribed;

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

(c) [manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale,] or distribute any drug [or cosmetic], except under, and in accordance with the conditions of, a license 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 [Central Government] may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the [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.

[- - -]

[18-A. 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.]

[18-B. Maintenance of records and furnishing of information .Every person holding a license 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) [For the purposes of section 18 a drug shall not be deemed to be misbranded or [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.

[(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 AMENDMENTS ▼

[Uttar Pradesh] .In its application to the State of Uttar Pradesh, after Section 19, insert the following section, namely:

19-A. Burden of proof.When any drug or cosmetic is seized from any person under clause (c) of section 22 by an Inspector 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.U.P. Act 47 of 1975, Section 5 (w.e.f. 15-9-1975).

[West Bengal] .In its application to the State of West Bengal, after Section 19, insert the following section, namely:

19-A. 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.W.B. Act 42 of 1973, Section 5 (w.e.f. 29-4-1974).

[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 [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 [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.

[(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.]

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 [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 [, having the prescribed qualifications,] as the Government appointing him may specify in this behalf.]

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

[(a) inspect,

(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;]

[(cc) examine any record, register, document or any other material object found [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;]

[(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 [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 [section 94] of the said Code.

[(2-A) 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 produced 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 [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 acquire 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 [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 [or cosmetic]; and

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

(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 [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.

[(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 [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 [and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18- A], 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 [or the person whose name, address and other particulars have been disclosed under section 18-A] 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 Analysts 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 [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 [or cosmetic] enabled to obtain test or analysis .Any person [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 [or cosmetic] [purchased by him or it] and to receive a report of such test or analysis signed by the Government Analyst.

[*Explanation* .For the purposes of this section and section 32, recognised consumer association means a voluntary consumer association registered under the Companies Act, 1956 (1 of 1956) or any other law for the time being in force.]

[26-A. Powers of Central Government to [regulate, restrict or 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] prohibit the manufacture, sale or distribution of such drug or cosmetic.]

[26-B. 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, be

notification in the Official Gazette, regulate or restrict the manufacture, sale or distribution of such drug.]

[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 17-A or spurious under section [17-B 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 [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:]

[Provided that the fine imposed on and released from, the person convicted under this clause shall be paid, by way of compensation, to the 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 17-A, but not being a drug referred to in clause (a), or

(ii) without a valid license 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]:

Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of [less than three years and of fine of less than one lakh rupees];

(c) any drug deemed to be spurious under section 17-B, but not being a drug referred to in clause (a) shall be punishable with imprisonment for a term which shall not less than seven years but which may extend to imprisonment for life and with fine which shall not be 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 [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 [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.

STATE AMENDMENTS ▼

[Uttar Pradesh] .In its application to the State of Uttar Pradesh, for Section 27, substitute the following section, namely:

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, sells, stocks or exhibits for sale or distributes

(a) any drug

(i) deemed to be misbranded under clause (a), clause (b), clause (c), clause (d), clause (f) or clause (2) of section 17 or adulterated under section 17-B, or

(ii) without a valid license as required under clause (c) of section 18; or

(b) any drug other than a drug referred to in clause (a) in contravention of any of the provisions of this Chapter or any rule made thereunder, shall be punished with imprisonment for life:

Provided that the Court may, for any special reasons to be recorded in writing, impose a sentence of imprisonment which is less than imprisonment for life.U.P. Act 47 of 1975, Section 5 (w.e.f. 15-9-1975).

[West Bengal] .In its application to the State of West Bengal, in Cl. (a) of Section 27, for the words for a term which shall not be less than one year but which may extend to ten years, substitute for life; in the proviso, for the words imprisonment of less than one year, substitute less than imprisonment for life; and in Cl. (b), for the words for a term which may extend to three years substitute for life.W.B. Act 42 of 1973, Section 5 (w.e.f. 29-4-1974).

Form of Charge ▼

Form of charge under section 27 read with section 17

I ,.....(*name and office of the Court of Session*), *hereby charge you*.....(*name of the accused*) *as follows*:

That you, on or about the.....day of....., at....., manufactured for sale (sold, stocked or exhibited for sale or distributed) either yourself or through another person (name the person if known or say an unknown person) on your behalf a misbranded drugs, namely,.....and such drug or cosmetic was an imitation of.....(or substitute for or resembled in a manner likely to deceive) another drug, to wit,.....or bore upon it or upon its label or container the name of another drug, to wit,.....(or it purported to be a product of a place or country, namely,.....of which it was not truly a product) or it was manufactured sold, etc., under a name which belonged to another drug, namely,.....or it was so coloured, coated, powered or

polished that damage was concealed or it was made to appear of better or greater the repeutic value that it really was or that it was not labelled in a prescribed manner or its label or container bore a statement, design or device, to wit,.....which made a false claim that.....(specify claim) which was false (or misleading) or the label or container bore the name of individual or company, namely,.....purporting to be the manufacturer or producer of the drug and which individual company was fictitious and did not exist and thereby committed an offence punishable under section 27 read with section 17 of the Drugs and Cosmetics Act, 1940, and within my cognizance.

And I hereby direct that you be tried by this Court on the said charge.

Form of Charge ▼

Form of Charge under section 27 read with section 17-A

I ,.....(name and office of the Court of Session), hereby charge you.....(name of the accused) as follows:

That you, on or about the.....day of....., at....., manufactured for sale (stocked or exhibited for sale, or distributed) either yourself or through another person..... on your behalf misbranded cosmetics, to wit, a manner likely to deceive another cosmetic, to wit,.....or it purported to be a product of a place or country (name the place or country) of which it was not truly a product or, it contained a colour (specify the colour) which was not prescribed (or it was manufactured, sold, etc., under a name which belonged to another cosmetic.....(specify the cosmetic) or, it was not labelled in the prescribed manner or its label or container bore the name of an individual or company.....(specify the name of such individual or company) purporting to be the manufacturer or producer of the cosmetic and such individual or company was fictitious and did not exist or the label or container of the cosmetic bore a statement, to wit,.....(specify the statement) which was false and misleading and thereby committed an offence punishable under section 27 read with section 17-A of the Drugs and Cosmetics Act, 1940, and within my cognizance.

And I hereby direct that you be tried by this Court on the said charge.

Form of Charge ▼

Form of Charge under section 27 read with section 17-B

I ,.....(name and office of the Magistrate, etc.), hereby charge you.....(name of the accused) as follows:

That you, on or about the.....day of....., at....., manufactured for sale, (sold, stocked, exhibited or sale for distributed) either yourself or through another person, to wit,.....on your behalf adulterated drugs as it consisted in whole (or in part) of a filthy (or putrid or decomposed) substance, to wit,.....or it had been prepared (or packed or stored), under insanitary conditions, whereby it may have been contaminated with fifth (or rendered injurious to health) or its container was composed or.....a poisonous (or deleterious) substances which rendered its contents, injurious to health or it bore or contained..... colour which was other than the colour prescribed or, the substance.....had been missed and packed therewith so as to reduce its quality or strength or the said substance had been substituted wholly (or in part), therefore, and thereby committed an offence punishable under section 27 read with section 17-B of the Drugs and Cosmetics Act, 1940, and within my cognizance.

And I hereby direct that you be tried by this Court on the said charge.

Form of Charge ▼

Form of Charge under section 27 read with section 18

I ,.....(name and office of the Magistrate, etc.), hereby charge you.....(name of the accused) as follows:

That you, on or about the.....day of....., at....., manufactured for sale (sold, stocked, exhibited for sale or distributed) either yourself or through another person on your behalf (name the person, if known or say an unknown person), to wit,.....a drug or cosmetic, namely,.....which was not of standard quality, or a drug.....(name the drug) or cosmetic.....(name the cosmetic) for the import of which a licence was prescribed, otherwise than under, and in accordance with, such licence (or a patent or property) medicine, to wit,.....without displaying in the prescribed manner on the label or container thereof, the true formula or a list of ingredients contained in it in a manner readily intelligible to the members of the medical profession or, a drug or cosmetic, to wit,.....containing an ingredient, to

wit,.....which rendered unsafe or harmful for use under the directions indicated or recommended or a drug, to wit,.....the import of which was prohibited by rules and thereby committed an offence punishable under section 27 read with section 18 of the Drugs and Cosmetics Act, 1940, and within my cognizance.
And I hereby direct that you be tried by this Court on the said charge.

27-A. 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

[(i) any cosmetic deemed to be spurious under section 17-D or adulterated under section 17-E 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 the 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.]

STATE AMENDMENTS ▼

[Uttar Pradesh] .In its application to the State of Uttar Pradesh, for Section 27-A, substitute the following section, namely:

27-A. 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, sells, stocks or exhibits for sale, or distributes any cosmetics in contravention of any of the provisions of this Chapter or any rule made thereunder, shall be punishable with imprisonment for life and shall also be liable to fine:

Provided that the Court may, for adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment which is less than imprisonment for life.U.P. Act 47 of 1975, Section 5 (w.e.f. 15-9-1975).

[West Bengal] .In its application to the State of West Bengal, in Section 27-A, for the words a term which may extend to one year, or with fine which may extend to five hundred rupees, substitute life or with fineW.B. Act 42 of 1973, Section 5 (w.e.f. 29-4-1974)

Form of Charge ▼

Form of Charge under section 27-A read with section 18
(U.P. and West Bengal State Amendments)
I ,.....(*name and office of the Court of Session*), *hereby charge you*.....(*name of the accused*) *as follows*:
That you, on or about the.....day of....., at....., manufactured for sale (sold, stocked or exhibited for sale or distributed) either yourself or through another person, namely,.....on your behalf a cosmetic.....which was misbranded, adultered or without a valid licence (specify the manner of misbranding or adulteration) and thereby committed an offence punishable under section 27-A read with section 18 of the Drugs and Cosmetics Act, 1940, and within my cognizance.
And I hereby direct that you be tried by this Court on the said charge.

[28. Penalty for non-disclosure of the name of the manufacturer, etc .Whoever contravenes the provisions of section 18-A [or section 24] shall be punishable with imprisonment for a term which may extend to one year, or [with fine which shall not be less than twenty thousand rupees or with both].]

[28-A. Penalty for not keeping documents, etc., and for non-disclosure of information .Whoever without reasonable cause or excuse, contravenes the provisions of section 18-B shall be punishable with imprisonment for a term which may extend to one year or [with fine which shall not be less than twenty thousand rupees or with both].]

28-B. Penalty for manufacture, etc., of drugs or cosmetics in contravention of section 26-A .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 26-A, 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 Analysts 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 [or cosmetic], shall be punishable with fine which may extend to [five thousand rupees].

[30. Penalty for subsequent offences .[(1)] Whoever having been convicted of an offence,

(a) under clause (b) of section 27 is again convicted of an offence under that clause, shall be punishable with 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 [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 [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 [fifty thousand rupees], or with both.]

[(1-A) Whoever, having been convicted of an offence under section 27-A 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 [two thousand rupees], or with both.]

(2) Whoever, having been convicted of an offence under [two years, or with fine which shall not be less than ten thousand rupees or with both.]

STATE AMENDMENTS ▼

[Uttar Pradesh] .In its application to the State of Uttar Pradesh, for Section 30, substitute the following section, namely:

30. All offences punishable under this Chapter shall be cognisable and non-bailable.U.P. Act 47 of 1975, Section 5 (w.e.f. 15-9-1975).

[West Bengal] .In its application to the State of West Bengal, Section 30,

(a) in sub-S. (1), Cl. (a), for the words ten years, substitute imprisonment for life;

(b) in sub-S. (1), Cl. (b), for the words may extend to ten years, or with fine, or with both, substitute 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-S. (1-A), for the words may extend to two years, or with fine which may extend to one thousand rupees, or with both, substitute shall not be less than two years but which may extend to imprisonment for life and shall also be liable to fine.W.B. Act 42 of 1973, Section 5 (w.e.f. 29-4-1974).

31. Confiscation .[(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 [or cosmetic] in respect of which the contravention has been made shall be liable to confiscation [and if such contravention is in respect of

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

(ii) [manufacture for sale, or for distribution, sale, or stocking or exhibiting or offering for sale,] or distribution of any drug without a valid license 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].

[(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 [or is a [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.]

[31-A. 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 AMENDMENTS ▼

[Haryana] .Same as that of Punjab.Punjab Act 25 of 1964 read with Haryana A.L.O., 1968.

[Punjab] .In its application to the State of Punjab, in sub-S. (2), for the words a Magistrate, substitute a Judicial Magistrate.Punjab Act 25 of 1964, Section 2 and Sch. (w.e.f. 2-10-1964).

[West Bengal] .In its application to the State of 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 credible information has been received of his having been concerned in any of the offences punishable under this Act.W.B. Act 42 of 1973, Section 5 (w.e.f. 29-4-1974).

[32-A. 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 [in sub-sections (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.]

[32-B. 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 28-A 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.]

33. Power of Central Government to make rules .[(1) The Central Government may [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 drugs [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 [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 [section 17-A] the colour or colours which a drug may bear or contain for the purposes of colouring;]

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

(e) prescribe the forms of licenses [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 [or of cosmetics or any specified cosmetic or class of cosmetics], the form of application for such licenses, the conditions subject to which such licenses may be issued, the authority empowered to issue the same [the qualifications of such authority] and the fees payable therefor; [and provide for the cancellation or suspension of such licenses 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];

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

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

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

(f) specify the diseases or ailments which a drug may not purport or claim [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 [or cosmetics], [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;

(l) 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;

[- - -]

(n) prescribe the powers and duties of Inspectors [and the qualifications of the authority to which such Inspectors shall be subordinate] and [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;

[(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; [*]

(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 [or cosmetic or class of cosmetics]; [and]

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

[* * *]

STATE AMENDMENTS ▼

[Maharashtra]

.In its application to the State of Maharashtra, in Section 33,

(1) in sub-S. (2),

(a) in Cl. (e), the words and the fees payable therefor shall be deleted;

(b) Cl. (eea) shall be deleted; and

(c) in Cl. (o), the words and the fees payable therefor shall be deleted.Maharashtra Act 31 of 1989, Section 2 (w.e.f. 4-10-1989).

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

33-1A. 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 drugs 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.Maharashtra Act 31 of 1989, Section 3 (w.e.f. 4-10-1989).

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

[CHAPTER IV-A]

Provisions Relating To [Ayurvedic, Siddha And Unani] Drugs

33-B. Application of Chapter IV-A .This Chapter shall apply only to [Ayurvedic, Siddha and Unani] drugs.

33-C. Ayurvedic, Siddha and Unani Drugs Technical Advisory Board .(1) The Central Government shall, by notification in the Official Gazette and with effect from such date as may be specified therein, constitute a Board (to be called the [Ayurvedic, 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 33-F, to be nominated by the Central Government;

(vi) one Pharmacognocist to be nominated by the Central Government;

(vii) one Phyto-chemist to be nominated by the Central Government;

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

(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;

[(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.

[33-D. 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 insofar 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.

33-E. 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.]

33-EE. 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.

33-EEA. 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.

33-EEB. 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.

33-EEC. 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 license 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.

33-EED. 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.

33-F. 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.

[(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.]

33-G. 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 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.

33-H. 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 [Ayurvedic, Siddha or Unani] drug.

[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

[(a) any Ayurvedic, Siddha or Unani drug

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

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

(iii) without a valid license or in violation of any of the conditions thereof, as required under section 33-EEC, 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 33-EEA, 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 [fifty thousand rupees or three times the value of the drugs confiscated, whichever is more]; or

[(c) any Ayurvedic, Siddha or Unani drug in contravention of the provisions of any notification issued under section 33-EED 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 33-H 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].

33-J. Penalty for subsequent offences .Whoever having been convicted of an offence,

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

(c) under sub-section (2) of section 33-I is again convicted of an offence under that sub-section, shall be punishable with imprisonment for a term which may extend to [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].

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

[33-KA. 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.

33-KB. Maintenance of records and furnishing of information .Every person, holding a license under clause (c) of section 33-EEC 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.]

33-L. Application of provisions to Government departments .The provisions of this Chapter except those contained in section 33-K shall apply in relation to the manufacture for sale, sale or distribution of any [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.

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

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

33-N. Power of Central Government to make rules .(1) The Central Government may, [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;

(d) specify any substance as a poisonous substance;

(e) prescribe the forms of licenses for the manufacture for sale of [Ayurvedic, Siddha or Unani] drugs, [and for sale of processed Ayurvedic, Siddha or Unani] drugs, the form of application for such licenses, the conditions subject to which such licenses may be issued, the authority empowered to issue the same and the fees payable therefor; [and provide for the cancellation or suspension of such licenses 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];

[(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 not be included in such labels;]

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

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

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

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

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

STATE AMENDMENTS ▼

[Maharashtra] .In its application to the State of Maharashtra, in Section 33-N,

(1) in sub-S. (2), in Cl. (e), the words and the fees payable therefor shall be deleted;

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

33-N-1. Power of 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 any Ayurvedic, Siddha or Unani drug by Government Analyst; and

(d) any other matter for which fees may be prescribed under this Chapter.Maharashtra Act 31 of 1989, Section 4 (w.e.f. 4-10-1989).

33-O. 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

[[33-P.] 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.

[34-A. Offences by Government departments .Where an offence under Chapter IV or Chapter IV-A 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 IV-A, 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.]

[34-AA. 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, [the Court before which the conviction takes place shall, on application made to it by the Inspector, cause] the offenders name, place of residence, the offence of which he has been convicted and the penalty which has been inflicted upon him, to be published at the expense of such person in such newspapers or in such other manner as the Court may direct.

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

36. Magistrates power to impose enhanced penalties .Notwithstanding anything contained in [- - -] [the Code of Criminal Procedure, 1973 (2 of 1974)], it shall be lawful for [any Metropolitan Magistrate or any Judicial

Magistrate of the first class] to pass any sentence authorised by this Act in excess of his powers under [- - -] the said Code.

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

[36-AB. 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 28-A, section 28-B and clause (b) of sub-section (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.

36-AC. Offences to be cognisable 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 28-A, section 28-B and sub-sections (1) and (2) of section 30 and other offences relating to adulterated drugs or spurious drugs, shall be cognisable.

(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 section 27, section 28, section 28-A, section 28-B 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 36-AB.

36-AD. 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.

36-AE. 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 proceedings shall lie against any person for anything which is in good faith done or intended to be done under this Act.

[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, [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 AMENDMENTS ▼

<=”” p=”” style="box-sizing: border-box; border-radius: 0px !important; padding: 0in 5.4pt; border-top: none; border-right: none; border-bottom: none; border-image: initial; border-left: 6pt solid rgb(84, 141, 212); font-size: 11pt;">(1) in Section 38, for the words Every rule made, substitute 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 the 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 aforesaid, 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.Maharashtra Act 31 of 1989, Section 7 (w.e.f. 4-10-1989).

[THE FIRST SCHEDULE]

[See section 3(a)]

[A. -AYURVEDIC AND SIDDHA SYSTEMS]

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.	Brihat Bhaishajya Ratnakara
11.	Bhava Prakasha
12.	Brihat Nighantu Ratnakara
13.	Charaka Samihita
14.	Chakra Datta
15.	Gada Nigraha
16.	Kupi Pakva Rasayana
17.	Nighantu Ratnakara
18.	Rasa Chandanshu
19.	Rasa Raja Sundara
20.	Rasaratna Samuchaya
21.	[Rasatantra Sara Va Siddha Prayoga Sangraha-Part 1]
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.	Sidha Yoga Samgraha
34.	Sushruta Samhita
35.	Vaidya Chintamani
36.	Vaidyaka Shabda Sindu
37.	Vaidyaka Chikitsa Sara
38.	Vidya Jiwan
39.	Vasava Rajeeyam
40.	Yoga Ratnakara
41.	Yoga Tarangini
42.	Yoga Chintamani
43.	Kashyapasamhita
44.	Bhelasamhita
45.	Vishwanathachikitsa
46.	Vrindachikitsa
47.	Ayurvedachintamani
48.	Abhinavachintamani
49.	Ayurveda-Ratnakara
50.	Yogaratnasangraha
51.	Rasamrita
52.	Dravyagunanighantu
53.	Rasamanijari
54.	Banagasena
[54-A.]	Ayurvedic Formulary of India [***]
54-B.	Ayurveda Sara Samgraha
[54-C.	Ayurvedic Pharmacopoeia of India

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.	Agasshiyar Rathna Chrukkam
67.	Therayar Karisal (300)
68.	Veeramamuni Nasa Kandam
69.	Agasthiyar (600)
70.	Agasthiyar Kanma Soothiram
71.	18 Siddar's Chillarai Kovai
72.	Yog 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
[84.]	Siddha Formulary of India (Part I)
[B.-UNANI TIBB SYSTEM]	
1.	Karabadin Qadri
2.	Karabadin Kabir
3.	Karabadin Azam

4.	Ilaj-ul-Amraz
5.	Al Karabadin
6.	Biaz Kabir Vol. II
7.	Karabadin Jadid
8.	Kithalf-ul-Taklis
9.	Sanat-ul-Taklis
10.	Mifta-ul-Khazain
11.	Madan-ul-Aksir
12.	Makhzan-ul-murabhat
13.	National Formulary of Unani Medicine [***]
14.	Unani Pharmacopoeia of India.

THE SECOND SCHEDULE

(See sections 8 and 16)

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

Class of drug	**Standard to be complied with**
1. Patent or proprietary medicines [other than Homoeopathic medicines]	The formula of list of ingredients displayed in the prescribed manner on the label or container and such other standards as may be prescribed.
2. Substances commonly known as vaccines, sera toxins, toxoids, antitoxins and antigens and biological products of such nature for human use or for veterinary use.	The standards maintained at the International Laboratory for Biological Standards, Stantans Serum Institute, Copenhagen and at the Central Veterinary Laboratory, Weybridge Surrey, U.K. and such other laboratories recognized by the World Health Organization from time to time, and such further standards of strength, quality and purity, as may be prescribed.
[* * *]	
4.Substances (other than food) intended to affect the structure or	Such standards may be prescribed.

any function of the human body or intended to be used for the destruction or vermin or insect which cause disease in human beings or animals.	
4-A. Homoeopathic Medicines :	Standards of identity, purity and strength specified in the edition of the Homoeopathic Pharmacopoeia of the India for the time being and such other standards as may be prescribed.
(a) Drugs included in the Homoeopathic Pharmacopacia of India.	
(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.	Standards of identity, purity and strength prescribed for the drug in the edition of such Pharmacopoeia for the time being in which they are given and such other standards as may be prescribed.
(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.	The formula of 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.
5. Other drugs :	
(a) Drugs included in the Indian Pharmacopoeia.	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.
	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.
(b) Drugs not included in the Indian Pharmacopoeia but not included in the official Pharmacopoeia of any other country.	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 the official Pharmacopoeia for the time being in force but are specified in the edition immediately preceding, the standards of identity, purity and strength shall be those occurring in such immediately preceding edition of the official Pharmacopoeia and such other standards as may be prescribed.