THE DRUGS AND COSMETICS ACT, 1940

[Act 23 of 1940, dt. 10-4-1940]

(As amended by the Jan Vishwas (Amendment of Provisions) Act, 2026 (No. 8 of 2026), dt. 7-4-2026)

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:—

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, as the Central Government may, by notification in the Official Gazette, appoint in this behalf.

2. Application of other laws not barred

The provisions of this Act shall be in addition to, and not in derogation of, the Dangerous Drugs Act, 1930 and any other law for the time being in force.

COMMENTS

The expression "any other law for the time being in force" takes in its ambit any future law also and it cannot be confined to any law in force at a point of time when this Act came to be applied—*AIR 1964 AP 430.* The Act being in addition to and not in derogation of any law in force for the time being, any rule framed in derogation of any other valid law cannot be countenanced in view of this section—*(1985) 2 FAJ 195.* The offences regarding drugs are not confined to the provisions of this Act, but also to those of the Dangerous Drugs Act and all other laws for the time being in force.

Scope

The Drugs Act is mainly concerned with standard and quality of drugs manufactured in this country and therefore control the manufacture, sale and distribution of drugs. It has nothing to do with duties of excise and with their imposition on narcotics and narcotics drugs.—*Indian Chemical and Pharmaceutical Works v. State of Andhra Pradesh AIR 1966 SC 713*

Coca derivative : Meaning of

The expression 'coca derivative' means crude cocaine ecgonine and all preparations containing more than 1% of cocaine.—*Sadhu v. Emperor AIR 1934 All 374*

"Human blood is drug"

Human blood is Drug within the meaning of section 3(b) of the Drugs Act.—*Subodh S. Shah v. Director Food and Drugs, Ahmedabad AIR 1997 Guj. 83*

Distilled water is drug

Distilled water to be used for dissolving other medicines for injection, is a drug within the sections.—*Ram Chandra Sundarka v. State of West Bengal 1971 Cr. LJ 1369 (Cal)*

Director of Central Laboratory is Government analyst

Section 3(c)(2) is defined as meaning analyst of drugs and cosmetics who are appointed by the Central Government or State Government in appropriate cases to appoint persons possessing the required qualification as prescribed to be the Government Analysts. The Director of Central Laboratory is also a Government Analyst, is not disputed.—*Ram Shanker Misra v. State of UP AIR 1979 SC 727*

Under Section 2 of the Drugs and Cosmetics Act, it has been stated that the provisions of Drugs Act shall be in addition to and not in derogation of the Dangerous Drugs Act, 1930 and any other law for the time being in force.—*State of Bihar v. Shree Baidyanath Ayurved Bhawan (P) Ltd., AIR 2005 SC 932 : 2005(2) SCC 762*

3. Definitions

In this Act, unless there is anything repugnant in the subject or context,—

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

(aa) "the Board" means—

(i) in relation to [1][Ayurvedic, Siddha or Unani] drug, the [1][Ayurvedic, Siddha and Unani Drugs Technical Advisory Board] constituted under section 33C; and

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

(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 [2][xxx];

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1 Substituted by Act 68 of 1982, w.e.f. 1-2-1983.

2 Words ", but does not include soap" omitted, ibid.

(b) "drug" includes—

[1][(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;

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

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or 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 [1][Ayurvedic, Siddha or Unani] drug, a Government Analyst appointed by the Central Government or a State Government under section 33F; and

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

(d) [*Omitted by Act 19 of 1972, w.e.f. 31-5-1972*]

(e) "Inspector" means—

(i) in relation to [1][Ayurvedic, Siddha or Unani] drug, an Inspector appointed by the Central Government or a State Government under section 33G; and

(ii) in relation to any other drug or cosmetic, an Inspector appointed by the Central Government or 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 [3][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;

[1][(h) "patent or proprietary medicine" means,—

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1 Substituted by Act 68 of 1982, w.e.f. 1-2-1983.
2 Inserted, ibid.
3 Substituted for "sale and distribution", ibid.

(i) in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine of 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 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.

COMMENTS

Under section 3(a) of the Act, an ayurvedic drug is to be manufactured strictly in accordance with the formulae given in the ancient texts forming part of Schedule I of the Act.—*Hemma Herbs Pvt. Ltd. v. Union of India 2011 (100) AIC 370 (Himachal Pradesh H.C.)*

The definition of term "manufacture" as defined under section 3(f), which includes any process or part of process of packing of a "drug" with a view to sale, would fall within the ambit of the term "manufacture".—*Dr. C. Anbarasu v. Union of India 2010(2) Drugs Cases (DC) 327 (Madras H.C.)*

Section 3(h) deals with patent and proprietary medicine.—*Hemma Herbs Pvt. Ltd. v. Union of India 2011 (100) AIC 370 (Himachal Pradesh H.C.)*

Drugs : Under s. 2(b) of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, "drug" includes (i) a medicine for the internal or external use of human beings or animals; (ii) any substance intended to be used for or in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals; (iii) any article, other than food, intended to affect or influence in any way the structure or any organic function of the body of human beings or animals; (iv) any article intended for use as a component of any medicine, substance or article, referred to in sub-cls. (i), (ii) and (iii). The definition of "drug" is comprehensive enough to take in not only medicines but also substances intended to be used for or in the treatment of diseases of human beings or animals. The expression "substances" means something other than medicines but which are used for treatment.

Drug is an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and any article other than food intended to affect the structure or any function of the body of man or other animals. It is the general name of substances used in medicine, any substance, vegetable, animal, used in the composition or preparation of medicines, or any substance used as a medicine.

Whether certain articles can be classified as drugs and medicines is to be decided by the statutory authorities on the basis how they are understood and treated in the market, and the High Court in its writ jurisdiction cannot permit the statutory authorities by-passed.—*State of Goa v. Leukoplast (India) Ltd. (1997) 105 STC 318 (SC)*

Cosmetic : Cosmetic is a preparation to be applied to human body for the purpose of beautifying, preserving or cleaning.—*Legal Glossary 1992.*

Sec. 3(f)—Where a tender form for supply of drugs to government establishments imposed a condition about possession of three years of manufacturing experience by the tenderer, the imposition of condition was held, *ultra vires.* The definition of the word 'manufacturer' under s. 3(f)

of Drugs and Cosmetics Act, 1940 in relation to drug includes the process of making, altering, ornamenting, finishing, packing, labelling, etc. with a view to its sale and distribution.

Applicability of word 'Drug'

The definition of 'drug' would show that it took within its fold 'medicines' as well as 'substances' used for treatment, mitigation or prevention of disorder in human being as well as in animals. Under clause (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 are drugs. Thus it is used for mitigation or prevention of any disease or disorder in human beings and is a 'drug' notwithstanding the fact that it is not a 'medicine' which is to be applied for diagnosis or treatment of diseases. It is also relevant to note that a preparation applied on human body for the purpose of repelling insects like mosquitoes is also drug under clause (i). Under clause (ii) 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 Gazette is also a 'drug'. Under clause (iii) all substances intended for use as components of a drug including empty gelatin capsules is a 'drug' and as per clause (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 Gazette after consultation with the Board are also 'drug'. Thus it is clear that the definition of 'drug' is wide enough to comprehend all medicines and substances for external or internal use of human beings or animals for diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or in animals except food.—*Cadila Pharmaceuticals Ltd. v. State of Kerala AIR 2002 Ker. 357*

The definition of 'drugs' in section 3(b) of the Drugs and Cosmetics Act, 1940, is comprehensive enough to take in not only medicines but also substances intended to be used for in the treatment of human beings or animals. This artificial definition introduces a distinction between medicines and substances which are not medicines strictly so called. The expression 'substances' therefore, must be something other than medicines but which are used for treatment. However, the appropriate meaning of the expression 'substances' in section is things. Hence, absorbent cotton wool, rolled bandages and guage are 'substances' within the meaning of the said expression. These things are used for or in treatment. The Legislature designedly extended the definition of 'drug' so as to take in substances which are necessary aids for treatment; surgical or other cases.—*Chamanlal Jagjivan Das Seth v. State of Maharashtra AIR 1963 SC 665*

Amended section 3(h) not violative of Constitution

Section 3(h) as amended by Act 60 of 1982 is not unconstitutional and not arbitrary and violative of Articles 14 and 19(1)(g) of the Constitution.—*Pratap Pharma (P) Ltd. v. Union of India AIR 1997 SC 2648*

Protein not drug

Protein cannot be held to be a drug.—*State of Maharashtra v. Pravin Krishna Das Shah (1984) 2 FAC 119 (Bom.)*

What constitutes 'patent or proprietary' medicine?

Ayurvedic drugs manufactured for animals and their ingredients used in drugs were mentioned in formulae used in authoritative books but parties were not using any formulation included in authoritative books. These medicines were not given by parenteral route. They would be termed as patent or proprietary medicines within the meaning of section 3(h) of the Drugs and Cosmetics Act.—*M/s Cattle Remedies v. Licensing Authority, Lucknow AIR 2007 (NOC) 1270 (All.): 2007 (2) ALJ 514 (DB)*

Section 3(a) defines 'Ayurvedic or Unani drug' to include all medicines intended for diagnosis, treatment, mitigation or prevention of diseases manufactured exclusively in accordance with the formulae described in authoritative books consisting Ayurvedic or Unani System of medicines, specified in the First Schedule.—*State of Bihar v. Shree Baidyanath Ayurved Bhawan (P) Ltd. AIR 2005 SC 932 : 2005 (2) SCC 762*

Section 3(b) defines 'a drug' to include all medicines and all substances intended to be used for diagnosis, treatment, mitigation or prevention of any disease.—*State of Bihar v. Shree Baidyanath Ayurved Bhawan (P) Ltd. AIR 2005 SC 932 : 2005(2) SCC 762*

Human blood is 'drug'

By bare reading of section 3(b) of the Drugs and Cosmetics Act it can be seen that, all substances intended to be used for treatment of any disease in human beings or animals will fall within the ambit of the definition of "drug". Human blood is a 'substance' and it is intended to be used in treatment of diseases in human beings and accordingly, it falls within the broad language of statutory definition of 'drug'. Hence, its collection, storage and transfusion could be regulated under the provisions of the Act.—*Adarsha Hospital v. Union of India AIR 2005 Karnataka 416*

3A. Construction of references to any law not in force or any functionary not in existence in the State of Jammu and Kashmir

Any reference in this Act to any law which is not in force, or any functionary not in existence, in the 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

(1) Any substance specified as poisonous by rule made under Chapter III or Chapter IV or Chapter IVA shall be deemed to be a poisonous substance for the purpose of Chapter III or Chapter IV or Chapter IVA, as the case may be.

COMMENTS

Argemone Maxicana is poison

Argemone Maxicana seed commonly known as Bhat Ghaliya is notified as a poison under the Poisons Act.—*Laxmi Narayan v. State AIR 1953 All. 713*

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 Drugs Technical Advisory Board) to advise the Central Government and the State Government 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 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.

COMMENTS

Object of setting up of CDTAB

Section 5 authorises constitution of a Central Drugs Technical Advisory Board as also a State Board for each State. The object of setting up of such Boards is to advice the respective Governments on technical matters arising out of the administration of the Act and to carry out such other functions as are assigned to the Boards by the Act.—*Vincent Parkurlangara v. Union of India AIR 1987 SC 990*

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;

(b) [*Omitted by Act 11 of 1955, w.e.f. 15-4-1955*]

(c) [*Omitted by Act 11 of 1955, w.e.f. 15-4-1955*]

(d) the procedure for the submission of the said Laboratory under Chapter IV or Chapter IVA of samples of drugs or cosmetics for analysis or test, the forms of the Laboratory's reports thereon and the fees payable in respect of such reports;

(e) such other matters as may be necessary or expedient to enable the said Laboratory to carry out its functions;

(f) the matters necessary to be prescribed for the purposes of the proviso to sub-section (1).

COMMENTS

Regional Drug Laboratories should be set up

The Central Government should set up Regional Drug Laboratories in addition to the Central Laboratory as provided under section 6 of the Act to facilitate and promote research and co-ordinate activity in that regard.—*Vincent v. Union of India AIR 1987 SC 990*

Authorisation of Bacteriologist Central Drug Laboratory, Kolkata

S.O. 2662(E), dt. 31-10-2012—In exercise of the powers conferred by section 6 of the Drugs and Cosmetics Act, 1940 (23 of 1940), and rule 8 of the Drugs and Cosmetics Rules, 1945, the Central Government hereby authorises Shri C. Hariharan, Bacteriologist, Central Drug Laboratory, Kolkata to sign statutory certificates of test and analysis on the samples of drugs and cosmetics sent by the Courts of Law under sub-section (4) of section 25 of the said Act and in Form I of the said Rules as the Director in-charge of the Central Drug Laboratory, Kolkata for the whole of India with effect from the date of his assumption of additional charge of that post, that is 1-11-2012 (FN) till the regularly appointed person takes charge of the post or until further orders, whichever is earlier, in respect of all classes of drugs, except the classes of drugs mentioned below, namely:—

(1) Sera

(2) Solution of Serum Proteins intended for injection

(3) Vaccines

(4) Toxins

(5) Antigens

(6) Anti-toxins

(7) Sterilized surgical ligature and sterilized suture

(8) Bacteriophages

(9) Anti-Sera for Veterinary use

(10) Vaccines for Veterinary use

(11) Toxoids for Veterinary use

(12) Diagnostic Antigens for Veterinary use

(13) VDRL Antigen

(14) Intra-Uterine Devices and Falope Rings

(15) Human Blood and Human Blood Products

(16) Blood Grouping reagents and diagnostics kits for Human Immunodeficiency Virus, Hepatitis B Surface Antigen and Hepatitis C Virus

(17) Condoms

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.

7A. Sections 5 and 7 not to apply to [1][Ayurvedic, Siddha or Unani] Drugs

Nothing contained in sections 5 and 7 shall apply to [1][Ayurvedic, Siddha or Unani] drugs.

CHAPTER III

[2][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.

COMMENTS

Notification not violative

The notification in question is issued in furtherance of the Act 21 of 1954 and on the directions issued by the Government of India with a view to control the advertisements of drugs in certain cases and to provide for drugs for matters connected with the Central Act of 1954. The provisions

1 Substituted by Act 68 of 1982, w.e.f. 1-2-1983.
2 Substituted for "IMPORT OF DRUGS", ibid.

of the Act, as also the object of the notification clearly indicate that the Government of Andhra Pradesh has issued this notification empowering all its Drugs Inspectors appointed under section 21 of the Drugs Act to exercise the power under section 8 of the Central Act of 1954 for the purpose mentioned therein throughout the State of Andhra Pradesh and an inadvertent reference to the Telangana area in the preliminary part of the said notification would not in any manner restrict the operation of this notification in other parts of Andhra Pradesh.—*Bharat Damodar Kale v. State of Andhra Pradesh AIR 2003 SC 4560*

[1]**[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 drugs bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.]

COMMENTS

Goods which are misbranded

Where a level attached to goods declares that firm A was the manufacturer of those goods when, in fact, the firm A was not a firm of manufacturer and in fact the 'real manufacturers were some other company' firm A took up a fictitious role and therefore, the name of the manufacturer given in no label was fictitious. The goods were, therefore, misbranded within the meaning of section 9(g) or 17(g).—*Dharam Deo Gupta v. State AIR 1958 All. 865*

[1]**[9A. Adulterated Drugs**

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

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

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

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

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

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

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

9B. Spurious drugs

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

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

(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously

1 Substituted by Act 68 of 1982, w.e.f. 1-2-1983.

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.]

[1][**9C. Misbranded cosmetics**

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

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

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

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

9D. Spurious cosmetics

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

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

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

(c) if the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetics 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 [2][or misbranded or spurious cosmetic];

(bb) any [3][adulterated or spurious] drug;

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

(d) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof [4][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;

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1 Inserted by Act 68 of 1982, w.e.f. 1-2-1983.
2 Substituted for "or misbranded cosmetic", ibid.
3 Substituted for "adulterated", ibid.
4 Substituted, ibid.

(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.

[1][x x x]

[2][**10A. Power of Central Government to prohibit import of drugs and cosmetics in public interest**

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

COMMENTS

Scope of

The branch of health care of citizens involves an ever changing challenge. The problem is a shifting one and one cannot have a fixed process to deal with the situations that would arise from time to time. The Central Government on the basis of the expert advice can indeed adopt an approved national policy and prescribe an adequate number of formulations which would on the whole meet the requirement of the people at large. Obviously, instant attention has to be bestowed to keep abreast of the changing situations and make proper and timely amends. While laying the guidelines on this score, injurious drugs should be totally eliminated from the market. Great care in this regard has to be taken. Such drugs as are found necessary should be manufactured in abundance and availability to satisfy every demand should be ensured. Undue competition in the matter of production of drugs by allowing too many substitutes should be reduced as it introduces unhealthy practice and ultimately tends to affect quality.

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)[3] 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 [4][Commissioner of Customs] Collector 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.

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1 Explanation omitted by Act 68 of 1982, w.e.f. 1-2-1983.
2 Inserted, ibid.
3 Now the Customs Act, 1962 (52 of 1962).
4 Substituted for "Customs Collector" by Act 22 of 1995, w.e.f. 26-5-1995.

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

12. Power of Central Government to make rules

(1) The Central Government may, [2][after consultation with or on the recommendation of the Board] and after previous publication by notification in the Official Gazette, make rules, for the purpose of giving effect to the provisions of this Chapter:

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

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

(a) specify the drugs or classes of drugs or cosmetics or classes of cosmetics for the import of which a licence is required, [3][and prescribe the form and conditions of such licences, the authority empowered to issue the same, the fees payable therefor and provide for the cancellation, or suspension of such licence in any case where any provision of this Chapter or the rules made thereunder is contravened or any of the conditions subject to which the licence is issued is not complied with];

(b) prescribe the methods of test or analysis to be employed in determining whether a drug 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 [4][section 9A] the colour or colours which a drug may bear or contain for purposes of colouring;

(d) specify the diseases or ailments which an imported drugs 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 drug, 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

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1 Substituted for "Customs Collector" by Act 22 of 1995, w.e.f. 26-5-1995.
2 Substituted for "after consultation with the Board" by Act 68 of 1982, w.e.f. 1-2-1983.
3 Substituted, ibid.
4 Substituted for "section 9B", ibid.

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 [1][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 drugs 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 cosmetic or class of cosmetics.

[2]**[13. Offences**

(1) Whoever himself or by any other person on his behalf imports—

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

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1 Inserted by Act 68 of 1982, w.e.f. 1-2-1983.
2 Substituted, ibid.

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

(2) Whoever having been convicted of an offence—

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

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

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

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 [1][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 [2][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.

COMMENTS

Drugs to comply with standards of quality

The Second Schedule lays down that the drug included in the Indian Pharmacopoeia should comply with 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—*Manager, Medico Pharmaceutical Processors v. State of HP 1983 Cr. LJ 67.*

[3]**[17. Misbranded drugs**

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

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1 Inserted by Act 68 of 1982, w.e.f. 1-2-1983.
2 Substituted for "DRUGS", ibid.
3 Substituted, ibid.

(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.]

COMMENTS

A drug shall be deemed to be misbranded, if its label or container bears any statement, which makes any false claim for the drug, which is false or misleading in any particular.—*Dr. C. Anbarasu v. Union of India 2010(2) Drugs Cases (DC) 327 (Madras H.C.)*

Scope

Under section 17(c) of the Act, a drug is to be deemed misbranded if it is not labelled in the prescribed manner.—*Public Prosecutor (A) v. Mahaveer Prasad 1972 FAC 438*

Imitation to deceive regarded as spurious drug

The Supreme Court observed that keeping in view the provisions of section 17B of the Drugs and Cosmetics Act, 1940, which *inter alia* indicates as imitation or resemblance of another drug in a manner likely to deceive being regarded as a spurious drug, it is but proper that before granting permission to manufacture a drug under a brand name, the authority under that Act is satisfied that there will be no confusion or deception in the market. The authorities should consider requiring such an applicant to submit an official search report from the Trade Mark office in question which will enable the drug authority to arrive at a correct conclusion.—*Cadila Health Care Ltd. v. Cadila Pharmaceuticals Ltd. AIR 2001 SC 1952*

[1]**[17A. Adulterated drugs**

For the proposes 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.

COMMENT

As per section 17A(f), a drug shall be deemed to be adulterated, if any substance has been mixed therewith so as to reduce its quality or strength.—*Dr. C. Anbarasu v. Union of India 2010(2) Drugs Cases (DC) 327 (Madras H.C.)*

17B. Spurious drugs

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

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

1 Substituted by Act 68 of 1982, w.e.f. 1-2-1983.

(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.]

[1][**17C. Misbranded cosmetics**

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

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

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

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

17D. Spurious cosmetics

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

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

(b) if it is an imitation of, or 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.]

[2][**17E. Adulterated cosmetics**

For the purposes of this Chapter, a costmetic 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.]

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1 Inserted by Act 68 of 1982, w.e.f. 1-2-1983.

2 Inserted by Act No. 26 of 2008, dt. 5-12-2008, w.e.f. 10-8-2009 vide SO 2076(E), dt. 10-8-2009.

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

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

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

(iii) any patent or proprietary medicine, unless displayed in the prescribed manner on the label or container thereof [1][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) [1][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) [1][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 licence issued for such purpose under this Chapter:

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

PROVIDED FURTHER that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the [3][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.

[4][x x x]

COMMENTS

Scope of

Sec. 18 of the Act prohibits sale or distribution of any drug which is not of standard quality which is misbranded or which is adulterated (see section 17B). Sec. 18 imposes certain other restrictions for sale, but there is no provision which prescribes additional experience to a licensed manufacturer or Loan Licence manufacturer to market his products. A person having obtained licence for manufacture, can be prohibited to sell the drug only in accordance with s. 18 and on no other account. To prescribe 'experience' for the supplies is to impose further conditions which the

1 Substituted by Act 68 of 1982, w.e.f. 1-2-1983.
2 Substituted by Act No. 26 of 2008, dt. 5-12-2008, w.e.f. 10-8-2009 vide SO 2076(E), dt. 10-8-2009.
3 Substituted for "manufacture for sale, sale" by Act 68 of 1982, w.e.f. 1-2-1983.
4 Explanation omitted, ibid.

Act and Rules do not authorise; hence the imposition is clearly *ultra vires* and is beyond the powers of the Authority.

Stocking large quantity cannot be for personal use

Large quantity of misbranded drug found in the possession of the accused held left no room for doubt that he had stocked or kept the drug for sale. It could not have been meant for the personal use.—*S.K. Anis v. State of Maharashtra AIR 1974 SC 469*

When licence to manufacture not required

As the standard quality of Gudakhu has not been prescribed the petitioner cannot be called upon to take a licence for manufacture of Gudakhu without a licence.—*Gopilal Agarwal v. State of Orissa AIR 1973 Orissa 15*

Storage of sale : Scope of

Temporary storage on *ad hoc* basis without intent to sell at that place comes within scope of 'storage for sale' in section 18(c).—*Swantraj & Ors. v. State of Maharashtra AIR 1974 SC 517*

Benefit of vacuum in law

Where there is a vacuum, as spelled out before, its benefit must go to the appellant. The appellant has been able to successfully pleas and prove that in the absence of the requisites laid down in sections 18(c) and 33, the hospital could not be required to obtain a licence for manufacture and distribution of the drug on the date when the offence was allegedly committed. The benefit of the vacuum in the law must go to the citizen, as he cannot be held to have violated the law.—*Dr. Aletta Grace Beli v. Dr. S. Tirkey (1996) 1 SCC 285 : AIR 1996 SC 538*

Drug must be of standard quality

In respect to any drug, it includes any process or part of process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise etc. The drug must be of standard quality, is the crux of the offence. Standard quality has already been defined under section 16 of the Act.—*Drugs Inspector v. Chaman Lal & Co. AIR 1968 MP 238*

Liability of accused must be proved

Before a person can be liable for prosecution or conviction under section 2(a)(1)(ii) r/w section 18(c), it must be proved by the prosecution affirmatively that he was manufacturing the drugs for sale or was selling the same or had stocked them or exhibited the article for sale. The possession simpliciter of the articles does not appear to be punishable under any provisions of the Act. If therefore the essential ingredients of section 27 are not satisfied the plea of guilty cannot lead the court to convict the appellant.—*Mohd. Sabbir v. State of Maharashtra AIR 1979 SC 564*

When charges can be quashed

Prosecution unable to prove that drugs were exhibited for sale, though drugs were stored, therefore charges quashed.—*Purna Nand v. State 29 (1986) DLT 282*

Mere stocking does not prove sale

Whether the medicines in question were kept for sale could not be proved where they were founded to have been stocked in the rear room.—*Pushpinder Kumar v. State of Punjab 1984 FAJ 33 (P&H)*

When the articles are displayed in a shop so as to make a customer know that they were available for purchase, is an offence under the Act. Section 18(a) prohibits offer of sale of certain drug.—*State of Karnataka v. Karnataka Stores 1994 Cr. LJ 743 (Kar)*

Appellant found possessing large quantity of medicines without licence could not be convicted without proof of having stocked medicines for sale.—*Sanat Kumar Basu v. State of West Bengal 1984 Cr. LR 931 (Cal)*

Sale of drug without licence is offence

Sale of drugs without licence is an offence under section 18(c) and liable to be convicted under section 27A of the Act.—*State of Punjab v. Lashkar Singh 1992 Cr. LJ 1745 (P&H)*

Eligibility to become medical practitioner

Everyone holding degree or diploma of an Ayurvedic or Unani College recognised by the faculty are eligible for being registered as medical practitioner.—*Phul Singh v. State of Haryana 1986 FAJ 91*

Circular to obtain licence not arbitrary

Where the Drugs Controller issued a circular directing private hospitals to obtain licence under section 18, the action of Drugs Controller could not be said to be arbitrary or discriminatory. Pharmacies which are attached to private hospitals cannot by any stretch of imagination be said to be similar to pharmacies attached to hospitals run by Government or local bodies which are manned by qualified personnels and subject to strict government control. Similarly, a private hospital which caters to the prescriptions of several doctors storing huge quantity of drugs cannot be equated with a registered medical practitioner which administers and supplies drugs of emergency purposes to his own patients only by storing limited quantity and therefore they are not entitled for any exemptions which is granted to government hospitals and private practitioners. However, drugs stored in emergency/casualty/duty rooms attached to private hospitals were exempted from requirement of obtaining licence.—*Dr. A.N. Thomas and etc. v. Union of India AIR 2000 Ker. 325*

Scope

Section 18 of the Act interdicts the manufacture for sale or distribution, sale, stock or exhibit for sale or distribution of any drug except under and in accordance with the conditions of, a licence issued for such purpose under Chapter IV of the Act.—*Cadila Pharmaceuticals Ltd. v. State of Kerala AIR 2002 Ker. 357*

Section 18(a)(i) of the Drugs and Cosmetics Act prohibits sale of any drug which is not of a standard quality or is mis-branded, adulterated or spurious.—*Rajesh Kumar Sharma v. Director, Animal Husbandry & Veterinary Services, Cuttack, Orissa AIR 2006 Orissa 42*

18A. Disclosure of the name of the manufacturer, etc.

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

COMMENTS

Applicability

For the application of s. 18A, the person concerned shall not be a manufacturer of the drug or his agent. In other words, the person to whom s. 18A applies is anyone other than a manufacturer or his agent for distribution thereof. The *raison d'etre* of it is that, if he is the manufacturer or his agent he cannot disclose the name of the person from whom he acquired the drug because he himself is its manufacturer. To expect the other way is to expect the impossible. Hence there is no question of requiring him to disclose the identity of the person from whom he acquired the drug. Exclusion of manufacturer and his agent from the purview of section 18A is, therefore, on understandable premise. The section, therefore, would apply to any person other than the manufacturer of a drug or cosmetic or his agent. For failure to disclose the name of the person from whom he acquired the drugs, he need not be sent to jail as such failure could have happened perhaps because he was oblivious of the name and address of the person from whom he purchased the drug.

When violation of section remains unestablished

Non-production of Inspector or non-proving of the report by the Inspector who submitted report after verification that name and address of the firm from whom the accused claims to have the drugs was false and fictitious is fatal to the prosecution. Obviously, therefore, the defence

version remains unrebutted and violation of section 18A of the Drugs and Cosmetics Act, 1940 remained unestablished.—*State of Karnataka v. Pratap Chand AIR 1981 SC 872*

Requirement

The obligation of the Inspector is to give one portion of the sample to the person whose name, etc. have been disclosed as the person from whom the vendor acquired the drug. The requirement of the provisions would stand complied with when the Inspector gives one portion of the sample to the person from whom he took the sample and forwarded the other portion to the Govt. Analyst and third portion to the court etc.—*Amery Pharmaceuticals v. State of Rajasthan AIR 2001 SC 1303*

[1][**18B. Maintenance of records and furnishing of information**

Every person holding a licence under clause (c) of section 18 shall keep and maintain such records, registers and other documents as may a 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.]

COMMENT

Where a person denied opportunity to get sample examined by Central Laboratory, he is entitled to be discharged.—*State of Gujarat v. Alpin Industries, New Delhi & Ors., 2003 Cr. LR (Guj.) 141*

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 brought 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 [2][adulterated or spurious] or to be below standard quality nor shall be 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 a 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;

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1 Inserted by Act 68 of 1982, w.e.f. 1-2-1983.
2 Substituted for "adulterated", ibid.