F.No.X.11012/2/2021- DRS
Government of India
Ministry of Health and Family Welfare
(Department of Health & Family Welfare)
(Drugs Regulation Section)
****

Nirman Bhawan, New Delhi
Dated the 08th July, 2022

NOTICE

Subject: Draft of New Drugs, Medical Devices and Cosmetics Bill, 2022 - regarding.

The Drugs and Cosmetics Act, 1940 is a pre-independence legislation enacted by the Central Legislative Assembly. Review of obsolete laws and updating of the existing laws is a continuing process to accommodate changed requirements and adaptation of new technology. The Government has time and again emphasized the need to review obsolete laws and to periodically repeal and amend laws, for which Bill are being brought before the Parliament. The work of review and updating of Drugs and Cosmetics Rules, 1945 was vigorously taken up from the year 2016.

2. In light of recommendations of the Central Government and the felt need to have comprehensive legislation, a committee was constituted for framing the New Drugs, Cosmetics and Medical Devices Bill. As per recommendations of the Committee, Ministry of Health and Family Welfare, Government of India proposes a draft New Drugs, Medical Devices and Cosmetics Bill, 2022 in order to keep pace with changing needs, times, technology. In this regard, a draft bill has been prepared, a copy of which is enclosed.

4. It has been decided to solicit suggestions/comments/objections from the public/ stakeholders with regard to the said draft Bill. The suggestions/comments/objections may be forwarded within 45 days from the date of issue of this Notice by email to drugsdiv-mohfw@gov.in or by post to Under Secretary (Drugs Regulation), Ministry of Health and Family Welfare, Room No. 434, C Wing, Nirman Bhawan, New Delhi - 110011. The suggestions/comments/objections received on the above email/address within the period of 45 days from the date of issue of the Notice, shall be taken into consideration for finalization of the notification.

Encl: Draft Bill

(Bikash R Mahato)
Under Secretary to the Govt. of India
Tele: 2306 1141

Copy to:

1. All concerned Central Government Department
2. All additional Chief Secretaries/principal Secretaries/Secretaries Health and family Welfare/Medical Education of all States/UTs
3. All NIPER

CONFIDENTIAL
Draft Bill for circulation & comment

22-06-2022

	THE DRUGS, MEDICAL DEVICES AND COSMETICS BILL, 2022	
	A	
	BILL	
	to amend and consolidate the law relating to the import, manufacture, distribution and sale of drugs, medical devices and cosmetics to ensure their quality, safety, efficacy, performance and clinical trial of new drugs and clinical investigation of investigational medical devices and for matters connected therewith or incidental thereto.	
	BE it enacted by Parliament in the Seventy-Second Year of the Republic of India as follows:-	
	1. *(1)* This Act may be called the Drugs, Medical Devices and Cosmetics Act, 2022. *(2)* It extends to the whole of India. *(3)* It shall come into force on such date as the Central Government may, by notification, appoint and different dates may be appointed for different provisions of this Act and any reference in any such provision to the commencement of this Act shall be construed as a reference to the coming into force of that provision.	Short title, extent, commencement and application.
	2. The provisions of this Act shall be in addition to, and not in derogation of any other law for the time being in force.	Act not in derogation of any other law.
	3. In this Act, unless the context otherwise requires,— *(a)* "bioavailability study" means a study to assess the rate and extent to which the active drug is absorbed from a pharmaceutical formulation and becomes available in the systemic circulation or availability of the drug at the site of action;	Definitions.

	(b) "bioequivalence study" means a study to establish the absence of a statistically significant difference in the rate and extent of absorption of an active drug from a pharmaceutical formulation in comparison to the formulation as may be recognised by the Central Licensing Authority for use as reference having the same active drug when administered in the same molar dose under similar conditions; *(c)* "Board" means- (a)in relation to drugs and cosmetics, the Drugs Technical Advisory Board constituted under section 5; (b) in relation to Medical Devices, the Medical Devices Technical Advisory Board constituted under section 6; *(d)* "Central drugs laboratory" means a Central Drugs Laboratory established or designated under sub-section (1) of section 10; *(e)* "Central License Approving Authority" means the Central License Approving Authority referred to in sub-section (2) of section 161; *(f)* "Central Licensing Authority" for the purposes of this Act means the Drugs Controller General, India appointed under sub-section (1) of section 161; *(g)* "Central medical devices testing centre" means a Central Medical Devices Testing Centre established or designated under sub-section (1) of section 10; *(h)* "clinical investigation" means the systematic study of an investigational medical device in or on human participants to assess its safety, performance or effectiveness; *(i)* "clinical investigation plan" means a document containing background, objective, rationale, design, methodology including performance, management, adverse event, withdrawal and statistical consideration pertaining to clinical investigation; *(j)* "clinical research organisation" means a person or an organisation to whom a sponsor may transfer or delegate one or more of its functions and duties regarding conduct of clinical trial or clinical investigation; *(k)* "clinical trial" means any systematic study of new drug or investigational new drug or bioavailability or bioequivalence study of any new drug in human participants to generate data for discovering or verifying its clinical, pharmacological, including pharmacodynamic and pharmacokinetic, or adverse effects with the objective of determining safety, efficacy or tolerance of the drug; *(l)* "clinical trial protocol" means a document containing background, objective, rationale, design, methodology including performance, management, adverse event, withdrawal and statistical consideration pertaining to clinical trial; *(m)* "controlling authority" means licensing authority as defined in clause (za), shall be responsible for overall control of activities as provided in this Act or rules made thereunder; *(n)* "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 new cosmetic or any article intended for use as a component of cosmetic; *(o)* "drug" includes- (a) 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; (b) substances, other than food, intended to affect structure or any function of the human body or intended to be used for the destruction of vermin, insects or microbes which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification;	

	(c) substances intended for use as components of a drug including empty gelatin capsules; and (d) any active pharmaceutical ingredient; *(p)* "Drugs Controller General" means an officer appointed by the Central Government under section 161; *(q)* "Drugs Control Officer" means (a) in relation to drugs or cosmetics, a Drugs Control Officer appointed by the Central Government or a State Government under section 46; *(r)* "Ethics Committee" means the Ethics Committee constituted under section 74; *(s)* "Government Analyst" means in relation to drugs and cosmetics, an Analyst appointed or designated by the Central Government or a State Government under section 45; *(t)* "import" with its grammatical variations and cognate expressions means to bring into India; *(u)* "Indian Pharmacopoeia" means the official book of standards of drugs published by the Indian Pharmacopoeia Commission; *(v)* "investigational medical device" means a device which does not have a predicate device or a substantially equivalent device approved earlier by the Central Licensing Authority; *(w)* "investigational new drug" means new chemical or biological entity or substance which is under investigation in a clinical trial regarding its safety, tolerance and efficacy; *(x)* "investigator" means a person who is responsible for conducting clinical trial or clinical investigation at site; *(za)*"Licensing Authority" means the Central Licensing Authority appointed under section 161 and the State Licensing Authority appointed under section 162; *(zb)*"manufacture"- (a) in relation to any drug or any cosmetic, except human blood and its components, includes any process or part of a process for making, altering, ornamenting, finishing, labelling, packing, breaking up or otherwise treating or adopting any drug or cosmetic with a view to sell or distribute or stock 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; (b)in relation to human blood and its components includes any process of collection, processing, separation, storage, labeling, packing and testing for its use or distribution for transfusion in human beings; (c) in relation to medical device, includes any process for designing, making, assembling, configuring, finishing, packing, sterilizing, labelling, or adapting with a view to sell or distribute or stock but does not include assembling or adapting a device already approved for use for an individual patient by registered medical practitioner; and expressions 'marketed by' or 'promoted by' or any other similar expression claimed on the label of drug shall be construed as manufacture. *(zc)*"manufacturer" means a person who himself manufactures drug, cosmetic or medical device and includes any other person who undertakes such manufacturing activity on his behalf; *(zd)*"medical device" includes- (a) all devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but	

	which may assist in its intended function by such means for one or more of the specific purposes of,- (i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder; (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability; (iii) investigation, replacement or modification or support of the anatomy or of a physiological process; (iv) supporting or sustaining life; (v) disinfection of medical devices; (vi) control of conception; (b) in-vitro diagnostic device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination thereof intended to be used for examination and providing information for medical or diagnostic purposes by means of examination of specimens derived from the human bodies or animals; *(ze)*"Medical Devices Officer" means an officer appointed or designated by the Central Government or a State Government under sub-section (1) of section 133; *(zf)*"Medical Devices Testing Officer" means an officer appointed or designated by the Central Government or a State Government under section 132; *(zg)*"new cosmetic" means any cosmetic containing ingredients which have not been established as safe for human use; *(zh)*"new drug" means- (i) a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in the country to any significant extent, except in accordance with the provisions of the Act and the rules made thereunder, as per conditions specified in the labelling thereof and has not been approved as safe and efficacious by the Central Licencing Authority with respect to its claims; or (ii) a drug approved by the Central Licencing Authority for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or (iii) a fixed dose combination of two or more drugs, approved separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form; or (iv) a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the Central Licencing Authority; or (v) a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, cell and stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug; *(zi)*"notification" means a notification published in the Official Gazette and the word "notified" shall be construed accordingly; *(zj)*"notified body" means a body corporate or other legal entity, notified by the Central Government, as competent body to carry out the assessment, verification and certification of specified category of medical devices for establishing conformity with standards and other requirements under this Act; *(zk)*"over the counter drugs" means drugs that can be sold by way of retail to a consumer without prescription from a registered medical practitioner as per the conditions andin such manner as may be prescribed;	

	(zl)"predicate device" means a device approved by the Central Licensing Authority; *(zm)*"prescribed" means prescribed by rules made under this Act; *(zn)*"proprietary medicine" means a drug which is a remedy or prescription presented in a form ready for internal or external administration on human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being in force or any other Pharmacopoeia authorized in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board; *(zo)*"Schedule" means Schedule appended to this Act; *(zp)*"sponsor" includes a person, a company or an institution or an organisation responsible for the initiation and management of a clinical trial; *(zq)*"State Drugs Laboratory" means a laboratory established or designated by the State Government under sub-section (2) of section 10; *(zr)*"State Licensing Authority" for the purposes of this Act means the State Drugs Controller, by whatever name called, under section 161; *(zs)*"State Medical Devices Testing Centre" means a State Medical Devices Testing Centre established or designated under sub-section (2) of section 10.	
Presumption as to poisonous substances.	**4.** Any substance specified as poisonous by rule made under Chapter III or Chapter IV or Chapter V shall be deemed to be a poisonous substance for the purpose of Chapter III or Chapter IV or Chapter V, as the case may be.	
	CHAPTER II **TECHNICAL ADVISORY BOARDS, DRUGS LABORATORIES, MEDICAL DEVICES TESTING CENTRES AND CONSULTATIVE COMMITTEE**	
Constitution of Drugs Technical Advisory Board.	**5.** *(1)* The Central Government shall, by notification, constitute a Board to be called the Drugs Technical Advisory Board to advise the Central Government and the State Governments on technical matters pertaining to drugs and cosmetics arising out of administration of this Act and to carry out such other functions as may be assigned to it by or under this Act and rules made thereunder.	
	(2) The Board shall consist of following members, namely:-	
	(i) Director General of Health Services, Chairperson, *ex officio*;	
	(ii) Drugs Controller General, Member Secretary, *ex officio*;	
	(iii) One Director of the Central drugs laboratory to be nominated by the Central Government;	
	(iv) One person, to be nominated by the Department of Animal Husbandry, Dairying and Fisheries;	
	(v) Three persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States;	
	(vi) One person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmaceutical sciences on the staff of an Indian university or a college affiliated thereto;	
	(vii) One person, to be nominated by the National Medical Commission established under the Medical Commission Act, 2019, from amongst teachers in medicine or therapeutics;	30 of 2019

	(viii) Three persons, to be nominated by the Central Government, one each from amongst pharmaceutical industry, bio-pharmaceutical industry and cosmetic industry;	
	(ix) One persons, to be nominated by the Department of Health Research, from amongst pharmacologists;	
	(x) One person to be nominated by the Central Council of the Indian Medical Association;	
	(xi) One person to be nominated by the Central Council of the Indian Pharmaceutical Association;	
	(xii) Two persons appointed as Government Analyst to be nominated by rotation, by the Central Government;	
	(xiii) One person to be nominated by the Department of Bio-technology, Government of India;	
	(xiv) One person, to be nominated by the Central Government, from the medical institutions involved in the conduct of clinical trials;	
	(xv) One person, to be nominated by the Indian Pharmacopoeia Commission;	
	(xvi) One person, to be nominated by National Institute of Biologicals;	
Constitution of Medical Devices Technical Advisory Board.	**6.** (1) The Central Government shall, by notification, constitute a Board to be called the Medical Devices Technical Advisory Board to advise the Central Government and the State Governments on technical matters pertaining to medical devices arising out of administration of this Act and to carry out such other functions as may be assigned to it by or under the Act and the rules made thereunder.	
	(*2*) The Board shall consist of following members, namely:-	
	(i) Director General of Health Services, Chairperson, *ex officio*,;	
	(ii) Drugs Controller General, Member Secretary, ex officio;	
	(iii) One person to represent the Department of Atomic Energy, Government of India, not below the rank of a Deputy Secretary to the Government of India dealing with technical matters of medical devices;	
	(iv) One person to represent the Department of Science and Technology, Ministry of Science and Technology, Government of India, not below the rank of a Deputy Secretary to the Government of India dealing with technical matters of medical devices;	
	(v) One person to represent the Ministry of Electronics and Information Technology, Government of India, not below the rank of a Deputy Secretary to the Government of India dealing with technical matters of medical devices;	
	*(vi)*One person to represent the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 2016, not below the rank of a Deputy Secretary to the Government of India;	11 of 2016
	*(vii)*One person to represent the Defence Research and Development Organisation, Ministry of Defence, Government of India, not below the rank of a Deputy	

	Secretary to the Government of India dealing with technical matters of medical devices;	
	(viii) One person, to be nominated by rotation by the Central Government, from amongst persons who are in charge of Central medical devices testing centres;	
	(ix) Two experts, to be nominated by rotation by the Central Government, from amongst persons who are in charge of medical devices control in the State Governments;	
	(x) One expert, to be nominated by rotation by the Central Government, from amongst persons who are in charge of State medical devices testing centres;	
	(xi) One expert, to be nominated by the standards setting body, as may be constituted, by or with the approval of, the Central Government;	
	(xii) One expert, to be nominated by the Central Government, from amongst recognised technical educational institutions, in the field of biomedical technology;	
	(xiii) One expert, to be nominated by the Central Government, from amongst recognised technical educational institutions, in the field of biomaterial or polymer technology;	
	(xiv) One pharmacologist, to be nominated by the Central Government, from amongst recognised medical or research institutions, in the field of medical devices;	
	(xv) One expert, to be nominated by the Central Government, from amongst persons involved in conduct of the clinical investigation in recognised medical or research institutions; and	
	(xvi) Two experts, to be nominated by the Central Government, from the medical device industry including in-vitro diagnostics industry; and	
	(xvii) Three experts from the field of medical, surgical or dentistry practises, to be nominated by the Central Government, from Central Government or State Government Institutions.	
Tenure of nominated members.	**7.** The nominated members of Boards constituted under sub-section (1) of section 5 and sub-section (1) of section 6 shall hold office for a period of three years from the date on which they enter upon their office and shall be eligible for re-nomination:	
	Provided that no member shall be eligible for nomination for more than two consecutive terms:	
	Provided further that a member nominated by virtue of his holding an office in the Government shall hold office on a Board so long as he holds the appointment of the office by virtue of which he was nominated to such Board.	
Procedure of Boards.	**8.** *(1)* The procedure for conduct of business of Boards constituted under sections 5 and 6 shall be such as may be prescribed.	
	(2) The Boards may constitute sub-committees of its members to assist in the functions assigned to them.	

	(3) The Boards may, for consideration of particular matters, associate in their sub-committees such experts who are not members of the Boards, for such period not exceeding three years, as may be decided.	
	(4) The functions of the Boards may be exercised notwithstanding any vacancy therein.	
Removal of nominated member of Board.	**9.** *(1)* The Central Government may remove from office any member nominated under sections 5 and 6, who- (a) has been adjudged an insolvent; or	
	(b) has become physically or mentally incapable of acting as a member; or	
	(c) is, or has been, convicted of an offence which, in the opinion of the Central Government, involves moral turpitude; or	
	(d) has acquired such financial or other interest as is likely to affect prejudicially his functions as a member; or	
	(e) has so abused his position as to render his continuance in office prejudicial to the public interest:	
	Provided that no member shall be removed from his office under clause (d) or clause (e) unless he has been given a reasonable opportunity of being heard in the matter.	
	(2) Notwithstanding anything contained in section 7, a member who has been removed under this section shall not be eligible for re-nomination as a member of the Board.	
Central Drugs Laboratory, Central Medical Devices Testing Centre and State drugs laboratories and State medical devices testing centres.	**10.** *(1)* The Central Government may, by notification, establish or designate,- *(i)*Central Drugs Laboratories for,- (a) testing and analysis of drugs and cosmetics; (b) functioning as an appellate laboratory or centre; (c) carrying out other functions assigned, *(ii)* Central Medical Devices Testing Centres for,- (a) testing and evaluation of medical devices; (b) functioning as an appellate centre; (c) carrying out other functions assigned, in such manner as may be prescribed.	
	(2) The State Government may, by notification, establish or designate,- *(i)* State drugs laboratories for- (a) testing and analysis of drugs and cosmetics; (b) carrying out other functions assigned, *(ii)* State medical devices testing centres for- (a) testing and evaluation of medical devices; (b) carrying out other functions assigned in such manner as may be prescribed.	
	(3) The reports and forms for submission of samples and reports of Laboratories and Centres under sub-sections (1) and (2) shall be such as may be prescribed.	

	(4) The fee for samples and reports of laboratories and centers referred to in sub-section (3) shall be such as may be prescribed.	
Drugs, Medical Devices and Cosmetics Consultative Committee.	**11.** (1) The Central Government shall constitute a consultative committee to be called the Drugs, Medical Devices and Cosmetics Consultative Committee to advise the Central Government, the State Governments, the Drugs Technical Advisory Board and the Medical Devices Technical Advisory Board on any matter tending to secure uniformity in the country in the administration of this Act and the rules made thereunder.	
	(2) The Drugs Controller General, India shall be the Chairperson of the Drugs, Medical Devices and Cosmetics Consultative Committee.	
	(3) The Drugs, Medical Devices and Cosmetics 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, who shall be in-charge of, or dealing with the matters relating to regulation of drugs, medical devices and cosmetics in his State.	
	(4) The Drugs, Medical Devices and Cosmetics Consultative Committee shall meet as and when required to do so by the Central Government but at least once in six months.	
	(5) The Drugs, Medical Devices and Cosmetics Consultative Committee shall have power to regulate its own procedure.	
Sections 5 and 11 not to apply to Ayurvedic, Sowa Rigpa, Siddha, Unani or Homoeopathic, drugs.	**12.** Nothing contained in sections 5 and 11 shall apply to Ayurvedic, Sowa Rigpa, Siddha, Unani or Homoeopathic drugs.	
Power of Central Government to make rules for Chapter II.	**13.** (1) The Central Government may, after consultation with or on the recommendations of the Drugs Technical Advisory Board or the Medical Devices Technical Advisory Board, as the case may be, and after previous publication by notification, make rules for giving effect to the provisions of this Chapter:	
	Provided that consultation with the Boards 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 making the rules and the Central Government shall take into consideration the suggestions which the Board may make in relation to the said rules.	
	(2) In particular and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely,-	
	(a) the procedure for conduct of business of Boards under sub-section (1) of section 8;	
	(b) the manner of functions of laboratories and centres under sub-section (1) of section 10;	
	(c) the procedure and forms for submission to the laboratories and centres of samples and reports of drugs, medical devices and cosmetics for analysis, test and evaluation under Chapter III, Chapter IV, Chapter V and Chapter VII.	

	CHAPTER III **IMPORT OF DRUGS AND COSMETICS**	
Standards of quality of imported drugs or cosmetics.	**14.** (1) For the purposes of this Chapter, the expression "standard quality" means—	
	(a) in relation to an imported drug, that the drug complies with the standard set out in the First Schedule, and	
	(b) in relation to an imported 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 fifteen days' 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 First Schedule shall be deemed to be amended accordingly.	
Not of standard quality of imported drugs or cosmetics.	**15.** An imported drug or cosmetic shall be deemed to be not of standard quality, if it does not conform to the standards referred in section 14.	
Imported Misbranded drugs.	**16.** For the purposes of this Chapter, an imported 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.	
Imported adulterated drugs.	**17.** For the purposes of this Chapter, an imported 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.	
Imported spurious drugs.	**18.** For the purposes of this Chapter, an imported 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, not being a drug specified under section 15; or	
	(e) if it purports to be the product of a manufacturer of whom it is not truly a product; or	
	(f) if it does not contain the active pharmaceutical ingredient.	
Imported misbranded cosmetics.	**19.** For the purposes of this Chapter, an importedcosmetic shall be deemed to be misbranded—	
	(a) if it is not labelled in the prescribed manner; or	
	(b) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.	
Imported spurious cosmetics.	**20.** For the purposes of this Chapter, an imported 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.	
Imported adulterated cosmetics	**21.** For the purposes of this Chapter, a imported 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.	
Prohibition of import of certain drugs or cosmetics.	**22.** No person shall import-	
	(a) any drug which is not of standard quality, or is misbranded, adulterated or spurious;	
	(b) any cosmetic which is not of standard quality, or is misbranded, adulterated or spurious;	
	(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 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;	
	(f) any cosmetic containing any ingredient which may render it unsafe or harmful or use under the directions indicated or recommended;	
	(g) any drug or cosmetic the import of which is prohibited by rule made under this Chapter;	
	(h) any new drug or new cosmetic except in accordance with the permission or approval issued by Central Licensing Authority in such manner as may be prescribed:	
	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.	
Power of Central Government to prohibit import of drugs and cosmetics in public interest.	**23.** 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 drugs or cosmetics.	
Power of Central Government to regulate or restrict, import, etc., of drugs in public interest.	**24.** Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that a drug is essential to meet the requirements of an emergency arising due to epidemic or natural calamities and that in the public interest, it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate or restrict the import of such drugs.	

Application of law relating to sea customs and powers of Customs Officersin respect of drugs and cosmetics.	**25.** (1) The law for the time being in force relating to sea customs and to goods, the import of which is prohibited by section 11 of the Customs Act, 1962 shall, subject to the provisions of section 27 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 General, India and if necessary, forward the package or sample of any suspected drug or cosmetic found therein to the Central Drugs Laboratory.	
Power of Central Government to make rulesfor Chapter III.	**26.** (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) In particular and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely,—	
	(a) specify the drugs or classes of drugs or cosmetics or classes of cosmetics for the import of which a licence is required, 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;	
	(d) prescribe under clause (d) of section 17 the colour or colours which a drug may bear or contain for purposes of colouring;	
	(e) the colour which a cosmetic may bear or contain for the purposes of colouring under clause (d) of section 21;	

	(f) 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;	
	(g) 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;	
	(h) prescribe the places at which drugs or cosmetics may be imported, and prohibit their import at any other place;	
	(i) 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 drugs or classes of such drugs, and prohibit the import of the said drugs or class of drugs after the expiry of a specified period from the date of manufacture;	
	(j) 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;	
	(k) 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;	
	(l) 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;	
	(m) 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;	
	(n) 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;	
	(o) 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;	
	(p) 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;	
	(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 cosmetics or class of cosmetics;	
	(r) prescribe the manner for grant of permission or approval for import of new drug or new cosmetic under clause (h) of section 22.	
Penalty for import of drugs or cosmetics in	**27.** Whoever, himself or by any other person on his behalf, imports,-	

contravention of this Chapter.		
	(a) any drug deemed to be not of standard quality under section 15, adulterated under section 17 or spurious under section 18 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 bodily harm which amounts to grievous hurt within the meaning of section 320 of the Indian Penal Code, solely on account of such drug being not of standard quality, adulterated or spurious, 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 the value of the drugs confiscated, whichever is more:	45 of 1860
	Provided that the fine imposed under this clause shall be paid to the person who had used it:	
	Provided further that where the use of such drug has caused the death of a person who used, the fine imposed shall be paid to his legal heir;	
	(b) any drug-	
	(*i*) deemed to be adulterated under section 17, but not being a drug referred to in clause (a); or	
	(*ii*) without a licence as required under clause (c) of section 22,	
	shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and shall also be liable to fine which shall not be less than five lakh rupees:	
	Provided that the court may, for adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less than three years and fine of less than five lakh rupees;	
	(c) any drug deemed to be spurious under section 18, but not being a drug referred to in clause (a), shall be punishable with imprisonment for a term which shall not be less than seven years but which may extend to ten years and shall also be liable to fine which shall not be less than seven lakh rupees or three times the value of the drugs confiscated, whichever is more:	
	Provided that the court may, for 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 fine of less than seven lakh rupees;	
	(d) any drug deemed to be not of standard quality under section 15 or misbranded under section 16 or in contravention of any other provision of this Chapter or any rule made under this Act, 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 five lakh rupees;	
	(e) any cosmetic deemed to be spurious under section 20 or adulterated under section 21, shall be punishable with imprisonment for a term which may extend to three years and with fine which shall not be less than two lakh rupees;	

	(f) any cosmetic, other than a cosmetic referred to in clause (e), in contravention of any other provision of this Chapter or any rule made under this Act, shall be punishable with imprisonment for a term which may extend to one year or with fine which shall not be less than two lakh rupees;	
	(g) any drug or cosmetic in contravention of the provisions of any notification issued under section 23, shall be punishable with imprisonment for a term which shall not be less than one year but may extend to three years and shall also be liable to fine which shall not be less than one lakh rupees but may extend to three lakh rupees.	
Penalty for subsequent offence.	**28.** Whoever having been convicted of an offence, -	
	(i) 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 shall also be liable to fine which shall not be less than ten lakh rupees:	
	Provided that the Court may, for adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than seven years and fine of less than ten lakh rupees;	
	(ii) 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 shall also be liable to fine which shall not be less than fifteen lakh rupees;	
	(iii) 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 and shall also be liable to fine which shall not be less than seven lakh rupees:	
	Provided that the court may, for adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than two years and of fine of less than seven lakh rupees;	
	(iv) under clause (e) 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 three years and with fine which shall not be less than five lakh rupees;	
	(v) under clause (f) 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 one year and with fine which shall not be less than three lakh rupees;	
Penalty in addition to provisions of section 25.	**29.** The punishments provided under sections 27 and 28 shall be in addition to any penalty to which the offender may be liable under the provisions of section 25.	
Fee for import of drugs and cosmetics.	**30.** (1) The fee for grant of registration certificate and license for import of drugs and cosmetics shall be as specified in the Second Schedule.	
	(2) The Central Government may, by notification, amend the Second Schedule so as to enhance or reduce the rate of fees or add therein or omit therefrom any subject matter.	

Confiscation of imported drugs or cosmetics.	**31.** Where any offence punishable under section 27 has been committed, the consignment of the drugs or cosmetics in respect of which the offence has been committed shall be liable to confiscation.	
Jurisdiction.	**32.** 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 27.	
	CHAPTER IV **MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS AND COSMETICSAND CLINICAL TRIAL OF DRUGS**	
Standards of quality of drugs and cosmetics.	**33.** (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 First 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 First Schedule for the purposes of this Chapter, and thereupon the First Schedule shall be deemed to be amended accordingly.	
Not of standard quality of drugs and cosmetics.	**34.** A drug or cosmetic, as the case may be, shall be deemed to be not of standard quality, if it does not conform to the standards specified in section 33.	
Misbranded drugs.	**35.** 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.	
Adulterated drugs.	**36.** 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.	
Spurious drugs.	**37.** 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, not being a drug specified under section 34; or	
	(e) if it purports to be the product of a manufacturer of whom it is not truly a product; or	
	(f) if it does not contain active pharmaceutical ingredient.	
Misbranded cosmetics.	**38.** For the purposes of this Chapter, a cosmetic shall be deemed to be misbranded,—	
	(a) if it is not labelled in the prescribed manner; or	
	(b) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.	
Spurious cosmetics.	**39.** 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.	
Adulterated cosmetics.	**40.** 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.	

Prohibition of manufacture and sale of drugs and cosmetics.	**41.** (1) Save as otherwise provided in sub-section (5), no person shall himself or by any other person on his behalf,-	
	(a) manufacture for sale or distribution, or sell, stock, exhibit, offer for sale or distribute, any,-	
	(i) drug which is not of standard quality, or is misbranded, adulterated or spurious;	
	(ii) cosmetic which is not of standard quality, or is misbranded, adulterated or spurious;	
	(iii) proprietary medicine, unless there is displayed, on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof, in such manner as may be prescribed;	
	(iv) 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) cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;	
	(vi) drug or cosmetic, in contravention of any of the provisions of this Chapter or any rule made thereunder;	
	(vii) drug which purports or claims to prevent, mitigate, cure or convey that the same may prevent, mitigate or cure such diseases or ailments as may be prescribed or procure or assist to procure miscarriage in woman;	
	(b) sell, stock, 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 there under;	
	(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 a license issued by the State Licensing Authority in such form and manner as may be prescribed:	
	Provided that nothing in this section shall apply to the manufacture of small quantities of any drug for the purposes of examination, test or analysis:	
	Provided further that the Central Government may, after consultation with the Board, by notification, permit, subject to any condition 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.	
	(2) No person shall himself or by any other person on his behalf sell, or stock or exhibit or offer for sale, or distribute, any drug by online mode except under and in accordance with a license or permission issued in such manner as may be prescribed.	
	(3) No person shall manufacture for sale of any new drug except in accordance with the permission or approval issued by Central Licensing Authority in such manner as may be prescribed.	
	(4) The Central Licensing Authority may, in public interest, abbreviate, defer or waive off such pre-clinical and clinical data requirements for approval of such new drug,	

	relating to life threatening or serious diseases or rare diseases or diseases of special relevance to the country, in such manner as may be prescribed.	
	(5) Notwithstanding anything contained in sub-section (1), on and from the commencement of this Act, no licence in respect of manufacture for sale or for distribution of drugs specified in the Third Schedule shall be issued by the State Licensing Authority without the approval of Central License Approving Authority in the manner as may be prescribed:	
	Provided that the Central License Approving Authority may issue directions to the State Licensing Authority in respect of any of the drugs included in the Third Schedule and such direction shall be binding.	
	(6) The Central Government may, by notification, amend the Third Schedule so as to insert therein or omit there from categories of drugs.	
Disclosure of the name of the manufacturer, etc.	**42.** 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 Drugs Control Officer the name, address and other particulars of the person from whom he acquired the drugs or cosmetics.	
Maintenance of records and furnishing of information.	**43.** Every person holding a licence under section 41shall 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.	
Pleas relating to drugs and cosmetics.	**44.** (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 41 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 drugs or cosmetics 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 drugs or cosmetics occurring after the vendor or distributor became aware of such intermixture.	
	(3) A person, not being the manufacturer of a drugs or cosmetics or his agent for the distribution thereof, shall not be liable for a contravention of section 41 if he proves—	

	(a) that he acquired the drugs or cosmetics 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;	
	(c) that the drug or cosmetic, while in his possession was properly stored and remained in the same state as when he acquired it; and	
	(4) An importer or manufacturer of a drugs or cosmetics or his agent shall not be liable for contravention of the provisions of this Chapter if he proves that the drug or cosmetic did not suffer from any of the prohibitions and had been manufactured or imported or distributed in accordance with the provisions of this Act and rules made there under.	
Government Analysts under Chapter IV.	**45.** (1) The State Government may, by notification in the Official Gazette, appoint or designate 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 or designate 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 cosmeticsas may be specified in the notification.	
	(3) Notwithstanding anything contained in sub-sections (1) and (2), neither the Central Government nor a State Government, shall appoint any Officer as the Government Analyst, not serving under it, without the consent of the other 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.	
	(5) Every Government Analyst appointed under sub-sections (1) and (2) shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860).	
Drugs Control Officers under Chapter IV.	**46.** (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 and experiences, to be Drugs Control Officers for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.	
	(2) The duties which may be performed by the Drugs Control Officer, 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 aDrugs Control Officer under this section.	

	(4) Every Drugs Control Officer shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860). (5) Every Drugs Control Officer shall function under a controlling authority designated by the Central Government or the State Government respectively.The ControllingAuthority shall have such qualification and experience as may be prescribed.	
	(6) Any person appointed as an Inspector under Drugs and Cosmetics Act, 1940 and rules made thereunder, before the commencement of this Act, shall be deemed to have been appointed as the Drugs Control Officer for the purposes of this Act and shall continue to discharge his functions as the Drugs Control Officer.	
Powers of Drugs Control Officers.	**47.** (1) Subject to the provisions of section 48 and of any rules made by the Central Government in this behalf, an Drugs Control Officer 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;	
	(d) 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;	
	(e) 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;	
	(f) exercise such other powers except, power to arrest as may be necessary for carrying out the purposes of this Chapter, or any rules made thereunderforensuring the compliance of Act and rules made thereunder:	
	Provided that in case the stocks of the drugs or cosmetics, and the record, registers, documents or any other material objects connected or related thereto are seized, shall, as soon as may be, inform the Judicial Magistrate or Metropolitan Magistrate and take his orders as to the custody thereof.	
	(2) The provisions of the Code of Criminal Procedure, 1973 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 of 1974
	(3) Every record, register or other document seized under clause (d) or produced under clause (e) shall be returned to the person, from whom they were seized or who produce the same, within a period of twenty days of the date of such seizure or production, as the case may be, after copies thereof or extracts therefrom certified by that person, in such manner as may be prescribed, have been taken.	
	(4) Where Drugs Control Officer takes any action under clause (c) of sub-section (1),—	
	(a) he shall use all despatch in ascertaining whether or not the drug or cosmetic contravenes any of the provisions of the section 41 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) 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.	
	(5) If any person wilfully obstructs a Drugs Control Officer 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 (e) of sub-section (1), he shall be punishable with imprisonment which may extend to three years, or with fine which shall not be less than one lakh rupees, or with both.	
Procedure of Drugs Control Officers for sampling for testing.	**48.** (1) Where a Drugs Control Officer takes any sample ofa drugsor cosmeticsunder this Chapter, he shall tender the fair price thereof and may require a written acknowledgment therefor.	

	(2) Where the price tendered under sub-section (1) is refused, or where the Drugs Control Officer seizes the stock ofany drugor cosmetic under clause (c) of section 47, he shall tender a receipt therefor in the prescribed form.	
	(3) Where a Drugs Control Officer takes a sample of a drugs or cosmetics for the purpose of test or analysis, he shallintimate 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 drugs or cosmetics is being manufactured, it shall be necessary to divide the sample into three portions only:	
	Provided further that where the drugsor cosmeticsis made up in containers of small volume, instead ofdividing a sample as aforesaid, the Drugs Control Officer may, and if the drugs or cosmetics be such that it is likelyto 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 Drugs Control Officer 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;	
	(iii) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been mentioned on the label of the sample.	
	(5) For the specific category of drugs, the procedure for sampling and further course of action for sending it for testing in such manner as may be prescribed.	
Powers of superior officers of drugs.	**49.** The drugs officers superior in rank to a Drugs Control Officer having prescribed qualification, may exercise the same powers, throughout the local area to which they are appointed, as may be exercised by such officer within the limits of their jurisdiction.	
Police when to assist Drugs Control Officer.	**50.** Every police officer shall be bound to assist a Drugs Control Officer demanding his assistance,—	
	(a) in the investigation and preventing the escape of any person who is suspected to commit an offence under this Act; or	
	(b) in the prevention or suppression of a breach of the peace; or	
	(c) in the prevention of any injury attempted by the person to be committed against the drugs control officer.	
Persons bound to disclose place where drugs or	**51.** Every person for the time being in charge of any premises whereon any drugs or cosmetics is being manufactured or is kept for sale or distribution shall, on being	

cosmetics are manufactured or kept.	required by any Drugs Control Officer so to do, be legally bound to disclose to the Drugs Control Officer the place where the drug or cosmetic is being manufactured or is kept, as the case may be.	
Report of Government Analyst.	**52.** (1) The Government Analyst to whom a sample of any drug or cosmetic has been submitted for test or analysis under clause (i) of sub-section (4) of section 48, shall deliver to the Drugs Control Officer submitting it a signed report in triplicate in the prescribed form.	
	(2) The Drugs Control Officer 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 mentioned on the label of the sample, 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 to 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 mentioned on the label of the sample has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.	
	(4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst‘s report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug or cosmetic produced before the Magistrate under clause (ii) of sub-section (4) of section 48 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.	
Purchaser of drugs or cosmetics enabled to obtain test or analysis.	**53.** 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 fee specified in the Second Schedule, 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 69, “recognised consumer association” means a voluntary consumer association registered under any other law for the time being in force.	
Powers of Central Government to prohibit manufacture, etc., of drugs	**54.** 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	

and cosmetics in public interest.	claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate, restrict or prohibit the manufacture, sale or distribution of such drug or cosmetic.	
Power of Central Government to regulate or restrict, manufacture, etc., of drugs in public interest.	**55.** Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that a drug is essential to meet the requirements of an emergency arising due to epidemic or natural calamities and that in the public interest, it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate or restrict the manufacture, sale or distribution of such drug.	
Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter.	**56.** Whoever, himself or by any other person on his behalf, manufacture 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 36 or spurious under section 37 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, 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 a term 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:	45 of 1860
	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 realized from, the person convicted under this clause, shall be paid to the legal heir of the person who had died due to the use of the adulterated or spurious drugs referred to in this clause.	
	(b) any drug —	
	(i) deemed to be adulterated under section 36, but not being a drug referred to in clause(a), or	
	(ii) without a valid licence as required under clause (c) of section 41, shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and with fine which shall not be less than five 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 five lakh rupees;	

	(c) any drug deemed to be spurious under section 37, but not being a drug referred to in clause (a) shall be punishable with imprisonment for a term which shall not be less than seven years but which may extend to imprisonment for life and with fine which shall not be less than seven 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 fine of less than seven lakh rupees;	
	(d) any drug deemed to be not of standard quality under section 34 or misbranded under section 35, except the categories specified in the Fourth Schedule, 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 five lakh rupees;	
	(e) any drug deemed to be not of standard quality under section 34 or misbranded under section 35 and included in the Fourth Schedule or in contravention of any other provision of this Chapter or any rule made under this Act, shall be punishable with imprisonment for a term which may extend to one year or with fine which shall not be less than two lakh rupees.	
Penalty for manufacture, sale, etc., of cosmetics in contravention of this Chapter.	**57.** 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—	
	(a) any cosmetic, deemed to be spurious under section 39 or adulterated under section 40, shall be punishable with imprisonment for a term which may extend to three years and with fine which shall not be less than two lakh rupees;	
	(b) any cosmetic, other than a cosmetic referred to in clause (a), in contravention of the any other provision of this Chapter or any rule made under this Act, shall be punishable with imprisonment for a term which may extend to one year or with fine which shall not be less than two lakh rupees or with both.	
Power to amend Fourth Schedule.	**58.** The Central Government may, by notification, amend the Fourth Schedule so as to insert therein or omit there from the categories of drugs.	
Penalty for non-disclosure of the name of the manufacturer, etc.	**59.** Whoever contravenes the provisions of section 42 or section 51 shall be punishable with imprisonment for a term which may extend to one year, or with fine which shall not be less than three lakh rupees or with both.	
Penalty for not keeping documents, etc., and for non-disclosure of information.	**60.** Whoever without reasonable cause or excuse, contravenes the provisions of section 43 shall be punishable with imprisonment for a term which may extend to one year or with fine which shall not be less than three lakh rupees or with both.	
Penalty for manufacture, etc., of drugs or cosmetics in contravention of section 54 and 55.	**61.** 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 54 and 55, shall be punishable with imprisonment for a term which may shall not be less than one year but which may extend to three year and shall	

	also be liable to fine which shall not be less than one lakh but may extend to three lakh rupees.	
Penalty for use of Government Analyst's report for advertising.	**62.** 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 shall not be less than two lakh rupees.	
Penalty for subsequent offences.	**63.** (1) Whoever having been convicted of an offence,—	
	(a) under clause (b) of section 56 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 ten 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 ten lakh rupees;	
	(b) under clause (c) of section 56, 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 fifteen lakh rupees;	
	(c) under clause (d) of section 56 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 and shall also be liable to fine which shall not be less than seven lakh rupees:	
	Provided that the court may, for any adequate and special reason to be recorded in the judgment, impose a sentence of imprisonment for a term of less than three years and fine of less than seven lakh rupees;	
	(d) under clause (e) of section 56, is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and shall also be liable to fine which shall not be less than seven lakh rupees:	
	Provided that the court may, for any adequate and special reason to be recorded in the judgment, impose a sentence of imprisonment for a term of less than one years and fine of less than seven lakh rupees;	
	(2) Whoever, having been convicted of an offence under clause (a) of section 57 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term not less than three years and fine which shall not be less than five lakh rupees.	
	(3) Whoever, having been convicted of an offence under clause (b) of section 57 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term not less than one year and fine which shall not be less than three lakh rupees.	

	(4) Whoever having been convicted of an offence under section 60 or section 61 is again convicted of an offence under those sections shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and shall also be liable to fine which shall not be less than five lakh rupees.	
	(5) Whoever, having been convicted of an offence under section 62 is again convicted of an offence under the same section, shall be punishable with fine which shall not be less than five lakh rupees.	
Power of Central Government and State Government to recover certain amount as arrear of land revenue.	**64.** (1) Where any person liable to pay any amount by way of fine or penalty in pursuance of any decree or order made under the provisions of this Act or the rules made thereunder defaults in paying or depositing the whole or any part of such amount, the arrear of such amount shall be recoverable by the Central Government or the State Government, as the case may be, with simple interest due thereon computed at the rate of fifteen per cent. per annum from the date of such default to the date of recovery of such amount, as arrear of land revenue.	
	(2) Notwithstanding anything contained in any other law for the time being in force, no court, tribunal or other authority shall grant any injunction or make any order prohibiting or restraining the Government from recovering any amount as an arrears of land revenue in pursuance of the provisions of sub-section (1).	
Confiscation relating to drugs and cosmetics.	**65.** (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 35, adulterated under section 36 or spurious under section 37; 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 licence as required under section 41, 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 a Drugs Control Officer 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.	
Application of provisions to Government departments.	**66.** The provisions of this Chapter except those contained in section 65 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.	

Improvement Notices.	**67.** Where the licensing authority has reasonable ground for believing that any licensee has failed to comply with any provision of this Act or rules made thereunder, may, issue a notice to the said licensee (in this Act herein after referred as "improvement notice")-	
	(a) state the grounds for believing that the said licensee has failed to comply with the any provision of this Act or rules made thereunder;	
	(b) specify the matters which constitute the licensee's failure so to comply;	
	(c) specify the measures which, in the opinion of the said Authority, the licensee must take, in order to secure compliance; and	
	(d) require the licensee to take those measures, or measures which are at least equivalent to them, within a reasonable period (not being less than fourteen days) as may be specified in the notice.	
Suspension and Cancellation of license.	**68.** (1)The Licensing Authority may, for such licences granted or renewed by him, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Chapter or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, or direct the licensee to stop manufacture, sale or distribution of the said drugs and thereupon order the destruction of drugs and the stock thereof in the presence of a Drugs Control Officer if, in his opinion, the licensee has failed to comply with improvement notice or any of the conditions of the licence or with any provisions of the Act or rules made thereunder.	
	(2)The Central Licence Approving Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons there for, cancel a licence issued under this Chapter, or suspend it for such period as he thinks fit either wholly or in respect of any of the drugs to which it relates or direct the licensee to stop manufacture, sale or distribution of the said drugs and thereupon order the destruction of drugs and the stock thereof in the presence of a Drugs Control Officer, if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or rules made thereunder.	
	(3) A licensee whose licence has been suspended or cancelled by the Licensing Authority or Central Licence Approving Authority under sub-rule (1) or sub-rule (2), as the case may be, may within ninety days of the receipt of a copy of the order by him prefer an appeal to the State Government or the Central Government, as the case may be, and the State Government or the Central Government may after giving the licensee an opportunity of being heard, confirm, reverse or modify such order.	
Cognizance of offences relating to drugs and cosmetics.	**69.** (1) No prosecution under this Chapter shall be instituted except by—	
	(a) a Drugs Control Officer with the previous sanction of the controlling authority; 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 or 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.	
Power of Court to implead the manufacturer, etc.	**70.** 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 drugs or cosmetics 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, proceed against him as though a prosecution had been instituted against him under section 72.	2 of 1974
Compoundingof certain offences relating to drugs and cosmetics.	**71.** (1) Notwithstanding anything contained in the Code of Criminal Procedure, 1973, any offence punishable under clause (f) of section 27, clause (e) of section 56, clause (b) of section 57, section 59, section 60 and clause (b) of section 79 and section 81 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 be compounded, by Drugs Controller General, India appointed by the Central Government or the State Drugs Controllers by whatever name called appointed by the State Government under this Act, as the case may be, on payment for credit to that Government of such sum and in such manner as may be prescribed:	2 of 1974
	Provided that such sum shall not, in any case, less or exceed the maximum amount of the fine which may be imposed under this Act for the offences so compounded:	
	Provided further that in cases of subsequent offences, except the offences under clause (e) of section 56, clause (b) of section 57, clause (b) of section 79 and section 81, the same shall not be compoundable.	
	(2) 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 offences so compounded and the offender, if in custody, shall be released forthwith.	
	(3) The Drugs Controller General, India or State Drugs Controllers, as the case may be, may, with the approval of the Central Government or the State Government, as the case may be, by an Order in writing, delegate his powers of compounding as referred under sub-section (1), to any other officer under his control, having such qualifications and experience as may be prescribed.	

No clinical trial without permission.	**72.** (1) No person shall by himself or by any other person on his behalf shall conduct any clinical trial in respect of a new drug, investigational new drug, bioavailability or bioequivalence study of any new drug, in human participants except under, and in accordance with, the permission granted by the Central Licensing Authority subject to such conditions and in such form and manner as may be prescribed. *Explanation:* For the removal of doubt, it is hereby declared that the person includes sponsor, clinical research organization, any other organisation or investigator.	
	(2) A new drug shall continue to be a new drug for the purposes of this Act for such period as may be prescribed.	
Medical management and compensation for injury or death related to clinical trial.	**73.** (1) Where any participant is injured on account of his participation in the clinical trial the person permitted under sub-section (1) of section 72 shall provide medical management to that participant.	
	(2) Where an injury is caused to a participant in a clinical trial and is attributable to the study drug or on account of his participation in such trial, the person permitted under sub-section (1) of section 72 shall provide to that participant such compensation in such manner as may be prescribed.	
	(3) Where death of a participant is related to clinical trial and is attributable to the study drug or on account of his participation in such trial, the person permitted under sub-section (1) of section 72 shall provide to legal heir of the participant, such compensation in such manner as may be prescribed.	
Constitution, functions and responsibilities of Ethics Committee.	**74.** (1) The Ethics Committee, for overseeing the conduct of clinical trial and to safeguard the rights, safety and well-being of trial participants enrolled in such clinical trial, shall be constituted and accredited in such manner as may be prescribed.	
	(2) The Ethics Committee shall consist of not less than seven members from medical, scientific, non-medical, non-scientific, legal and social fields including an individual from general public.	
	(3) The Ethics Committee shall perform such functions and grant or revoke approval to the clinical trial protocol and other related documents in such manner as may be prescribed.	
Action against Ethics Committee.	**75.** (1) Where the Central Licensing Authority is satisfied that the Ethics Committee is not discharging its functions in accordance with the provisions of this Act and the rules made thereunder, it may, for reasons to be recorded in writing, debar the Committee and any of its members from overseeing the clinical trials for such period as may be considered appropriate.	
	(2) Where an Ethics Committee is debarred, its permission or registration shall be deemed to have been revoked.	
Power of Drugs Control Officer relating to clinical trial.	**76.** (1) The Drugs Control Officer with the prior approval of the controlling authority or any other officer authorized by the Central Licensing Authority may, with or without prior notice, enter into any premises related to clinical trial to inspect the	

	facilities, record, data, documents, books, and drugs including investigational new drugs.	
	(2) The officer empowered under sub-section (1) shall have the power to seek clarification, information and record pertaining to clinical trial or matters relating thereto.	
Maintenance of record and furnishing of information relating to clinical trial.	**77.** Every person conducting a clinical trial or his agent holding a permission under this Chapter shall keep and maintain such data, record, registers and other documents as may be prescribed and shall furnish such information as may be required by the Central Licensing Authority or any officer authorised by it in this behalf under section 76.	
Disclosure of name, address and particulars of persons involved in clinical trial.	**78.** Every person conducting a clinical trial or his agent, as the case may be, shall, if so required, disclose to the Drugs Control Officer or any other officer authorised by the Central Licensing Authority under section 76, the names, addresses and other particulars of the persons involved in conducting clinical trial and participants in such trial.	
Penalty for conducting clinical trial without permission.	**79.** Whoever himself, or by any other person on his behalf, conducts clinical trial of any new drug or investigational new drug,without obtaining permission under sub-sections (1) of section 72, shall be liable to a penalty with fine which shall not be less than three lakh rupees which may extend to five lakh rupees to be imposed by the adjudicating officer authorised by Central Government having experience of regulation under this Act along with medical management and such compensation as specified under section 73 of this Act to participant of clinical trial in such manner as may be prescribed.	
Penalty for violation of conditions of permission.	**80.** (1) Whoever himself, or by any other person on his behalf, conducts clinical trial of any new drug or investigational new drug, in contravention of any condition of permission granted under sub-section (1) of section 72 or any other provision of this Act or the rules made thereunder, the Central Licensing Authority, may, after giving an opportunity to show cause as why such an order should not be passed, by an order in writing stating the reasons thereof,	
	(a) issue warning letter giving details of deficiency found during the inspection, which might affect the right or well-being of the clinical trial subject or the validity of the study conducted at that site;	
	(b) direct that study may be rejected or discontinued;	
	(c) suspend or cancel the clinical trial permission;	
	(d) debar the investigator(s), sponsor including their employee(s), subsidiaries and branch(es), their agent(s), contractor(s), and sub-contractor(s) to conduct any clinical trial in future.	
	(2) The person including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial Investigators, against whom action as referred in sub-section (1) has been taken by the Central Licensing Authority, may, within ninety days of the receipt of the copy of the order of the Central Licensing	

	Authority prefer an appeal to the Central Government, and the Central Government may, after giving such appellant an opportunity of being heard, confirm, reverse or modify such order.	
Penalty for failure to provide compensation.	**81.** Where any person permitted under sub-section (1) of section 72 fails to provide the required medical management or compensation under section 73, shall be punishable with imprisonment which may extend to one year or with fine which shall not be less than twice the amount of compensation:	
	Provided that where the participant voluntarily withdraws or abstains from receiving medical management and the person responsible for providing such medical management has taken all such steps as could have been taken in the ordinary course, then such person shall be liable only for payment of compensation under sub-section (2) of section 73.	
Fee for grant of license, permission, approval, etc.	**82.** (1) The fee for grant of license, permission, approval, etc. shall be such as specified in the Second Schedule.	
	(2) The Central Government may, by notification, amend the Second Schedule so as to enhance or reduce the amount of fee or add therein or omit therefrom any subject matter.	
Powerof Central Government to make rulesfor Chapter IV.	**83.** (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 purposes of giving effect to the provisions of this Chapter:	
	Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.	
	(2) In particular and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely,—	
	(a) standards of cosmetics under clause (b) of sub-section (1) of section 33;	
	(b) the manner of labelling a drug under clause (b) of section 35;	
	(c) the colour which a drug may bear or contain for purposes of colouring under clause (d) of section 36;	
	(d) the manner of labelling a cosmetic under clause (b) of section 38;	
	(e) the colour which a cosmetic may bear or contain for purposes of colouring under clause (d) of section 40;	
	(f) manner of displaying on the label of proprietary medicine, the true formula or list of active ingredients contained therein together with the quantities thereof under sub-clause (iii) of clause (a) of sub-section (1) of section 41;	

	(g) other effect which a drug may have under sub-clause (iv) of clause (a) of sub-section (1) of section 41;	
	(h) the form and manner of issue of license or permission under section 41;	
	(i) manner and conditions of packing, labelling, displaying and proportion of substances, in drugs and cosmetics, under sub-clause (vi) of clause (a) of sub-section (1) of section 41;	
	(j) the diseases or ailments, which a drug shall not purport or claim to prevent, mitigate, cure or convey under sub-clause (vii) of clause (a) of sub-section (1) of section 41;	
	(k) the conditions subject to which and the extent to which small quantity of drug may be manufactured for the purposes of test, analysis or examination under the proviso to sub-section (1) of section 41;	
	(l) the manner for regulation and restriction for online mode of sale, or stock or exhibit or offer for sale, or sell,or distribution, of any drug under sub-section (2) of section 41;	
	(m) the manner for grant of permission or approval by the Central Licensing Authority under Sub-section (3) of section 41;	
	(n) pre-clinical and clinical data requirements of new drugs to be abbreviated, deferred or waived off under sub-section (4) of section 41;	
	(o) the records, registers and other documents to be kept and maintained under section 43;	
	(p) qualifications of Government Analyst under section 45;	
	(q) qualifications, experience and duties of Drugs Control Officer under section 46;	
	(r) the manner of certifying copies or extracts of record, register or other documents under sub-section (3) of section 47;	
	(s) the form and manner of taking sample of drug or cosmetic under section 48;	
	(t) the manner in which the report of the Government Analyst may be challenged under sub-section (1) of section 52;	
	(u) the procedure for further actions on the report of the Government Analyst under sub-section (2) of section 52;	
	(v) the manner of submission of application under section 53;	
	(w) extent and manner to determine the sum under sub-section (1) of section 71;	
	(x) the conditions subject to which and the form and the manner in which the permission may be granted under section 72;	
	(y) the period for which a new drug shall continue to be a new drug under sub-section (2) of section 72;	
	(z) the manner of providing compensation under section 73;	
	(za) the manner of constitution of the Ethics Committee under sub-section (1) of section 74;	

	(zb) the functions of the Ethics Committee and manner of granting or revoking approval by the said Committee under sub-section (3) of section 74;	
	(zc) the data, record, register and other documents to be maintained under section 77;	
	(zd) the manner of imposing penalty by the adjudicating officer under section 79.	
Chapternot to apply to Ayurveda, Siddha, Sowa-Rigpa, Unani and Homeopathy drugs.	**84.** Save as otherwise provided in this Act, nothing contained in this Chapter shall apply to Ayurveda, Siddha, Sowa-Rigpa, Unani or Homeopathy drugs.	
	CHAPTER V **PROVISIONS RELATING TO AYURVEDA, SIDDHA, SOWA RIGPA, UNANI AND HOMOEOPATHIC DRUGS**	
	A. Board and Committee	
Application of Chapter V.	**85.** The Chapter V shall apply to Ayurveda, Siddha, Sowa-Rigpa, Unani and Homeopathy drugs.	
Definitions in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic.	**86.** In this Chapter unless the context otherwise requires,— *(a)* "Ayurveda, Siddha, Sowa Rigpa or Unani or 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 Ayurvedic, Siddha, Sowa Rigpa and Unani Tibb systems of medicine, specified in the Fifth Schedule; *(b)* "Board" means- *(i)* in relation to Ayurveda, Siddha, Sowa Rigpa, Unani or Homoeopathic drug, the Ayurveda, Siddha, Sowa Rigpa, Unani and Homoeopathic Drugs Technical Advisory Board constituted under section 87; *(ii)* in relation to Ayurveda, Siddha, Sowa Rigpa, or Unani research and innovative drugs, the Scientific Research Board constituted under section 89; *(iii)* in relation to the matters related to medicinal plants, the National Medicinal Plant Board constituted under section 92; *(c)* "Central Drug Laboratory for Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs" means,- any laboratory notified by the Central Government for the purpose of quality testing of Ayurveda, or Siddha, or Sowa-Rigpa or Unani or Homoeopathy Drugs as under section 91; *(d)* "Central Drug Regulatory Authority" for Ayurveda, Siddha, Sowa-Rigpa, Unani, and Homeopathy drugs means the authority designated by Central Government under section 101; *(e)* "Central Government" in relation to this Chapter shall be the Ministry of Ayush in the Government of India; *(f)* "Central License Approving Authority for Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs, medical devices and cosmetics" means an entity established and authorized by the Central Government under section 161; *(g)* "Central Licensing Authority for the purpose of Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs, medical devices and cosmetics" means the authority appointed by Central Government under section 161; *(h)* "Central medical device testing Centre for Ayurveda, Siddha, Sowa-Rigpa, Unani means a Centre established or designated by the Central Government under clause (b) of sub-section (1) of section 91;	.

	(i) "Controlling Authority" for Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy means the officer designated under sub-section (5) of Section 106; *(j)* "drug" in relation to Ayurveda, Siddha, Sowa-Rigpa or Unani drugs includes- (a) is a substance or combination of substances other than food, recognized by an official pharmacopoeia or formulary of India or authoritative books specified in the Fifth schedule of the Act; intended to affect the structure or any function of the body of human beings or animals, for internal or external use and is used in the diagnosis, cure, mitigation, treatment, or prevention of disease or disorder, for which indications, usage and dosage are established, (b) Substances intended to be used for destruction of vermin, insects or microbes which cause disease in human beings or animals, as may be specified from time to time by the Central Government in the Official Gazette. *(k)* "Drugs Control Officer" means in relation to Ayurvedic, Homoeopathic, Sowa Rigpa, Siddha or Unani drugs, a Drugs Control Officer appointed by the Central Government or a State Government under section 106; *(l)* "Government Analyst" means in relation to Ayurvedic, Homoeopathic, Sowa Rigpa, Siddha or Unani drugs, an Analyst appointed by the Central Government or a State Government under section 105; *(m)* "Homoeopathy drug" includes any Homeopathic Medicine or a drug which is recorded in Homoeopathy provings or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative literature of Homoeopathy, as may be specified from time to time by the Central Government by notification in the Fifth Schedule; and which is prepared according to the techniques of the Homoeopathy Pharmacopoeia of India; *(n)* "Innovative drug of Ayurveda or Unani or Siddha or Sowa-Rigpa" means- (i)a drug manufactured by using natural substances not specified in the respective authoritative texts of Ayurveda, Siddha, Sowa-Rigpa, and Unani, excluding the single isolated molecule and prepared by using such modern advances as notified by the Central Government from time to time; with certain therapeutic claims including critical care management in human beings or animals with specified route of administration, dosage and dosage form and is manufactured in accordance with research guidelines and relevant rules notified by the Central Government in consultation with the Research Board constituted under Section 89. (ii) A drug of Ayurveda, Siddha, Sowa Rigpa or Unani approved by Central or State LicencingAuthority for certain claims and proposed to marketed for new claims or route of administration. (iii) A drug of Ayurveda, Siddha, Sowa Rigpa or Unani prepared using the combination of substances mentioned in authoritative texts and those out of authoritative texts. *(o)* "Marketer" means a person who as an agent or in any other capacity adopts any drug manufactured by another manufacturer under an agreement for marketing of such drug by labeling or affixing his name on the label of the drug with a view for its sale and distribution; *(p)* "over the counter Ayurveda, Siddha, Sowa-Rigpa, Unani and Homeopathy drugs" means the drugs can be sold by way of retail to a consumer without prescription of a registered medical practitioner as may be prescribed by the Central Government; *(q)* "Pharmacopoeia" in relation to Ayurveda, Siddha, Sowa-Rigpa, Unani and Homeopathy drugs means the Ayurveda or Unani or Sowa-Rigpa, Siddha or Homoeopathy Pharmacopoeia of India published by the Pharmacopoeia Commission of Indian Medicine and Homeopathy; *(r)* "proprietary medicine" means in relation to Ayurveda, Siddha, Sowa-Rigpa, Unani or Homeopathy systems of medicine, all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of	

	Ayurveda, Siddha, Sowa-Rigpa, Unani or Homeopathy systems of medicine specified in the Fifth 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); *(s)* "Registered Medical Practitioner" means- (i) for the purpose of Ayurveda, Unani, Siddha, Sowa-Rigpa systems, a person holding a qualifications granted by Universities, Boards or medical institutions recognized under the National Commission for Indian System of Medicine Act, 2020 and enrolled the name in the register maintained by State Council and/or National Commission for registration of an Ayurveda, Siddha, Sowa-Rigpa and Unani practitioner medical practitioners under relevant State or Central Act; (ii) for the purpose of Homoeopathy drugs, a person holding qualifications granted by Universities, Boards or medical institutions recognized under the National Commission for Homoeopathy Act, 2020 and enrolled the name in the register maintained by State Council and/or National Commission for registration of Homoeopathy practitioner. *(t)* "State drug laboratory" means laboratory established or designated by the concerned State Government under sub-section of (2) of section 91; *(u)* "State Government" referred to in this Chapter for the matters pertaining to Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy shall be the State Department dealing with matters pertaining to Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy; *(v)* "State Licensing Authority for Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs" means an entity established and authorized by the State Government for effective regulation of manufacture, sale, post marketing surveillance, of these drugs and cosmetics under section 162; *(w)* "State Medical Device testing Centre" relating to Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy medical devices means a testing Centre established or designated by the State Government under section 91; *(x)* Traditional Medicine includes the indigenous systems of medicines legally recognized in the countries of their origin other than Allopathy or western medicine.	
Constitution, tenure, function and procedure of Ayurveda, Siddha, SowaRigpa, Unani Homeopathy Drug Technical Advisory Board.	**87.** (1) The Central Government shall, as soon as may be constitute a Ayurveda, Siddha, Sowa-Rigpa, Unani, Homoeopathy Drugs Technical Advisory Board by notification in the Official Gazette and with effect from such date as may be specified therein to advise the Central Government and the State Governments on technical matters pertaining to drugs, medical devices and cosmetics arising out of this Chapter and to carry out the other functions assigned to it by or under this Act and rules made thereunder.-	
	(2) the Board shall consist of the following members, namely:-	
	(i) the principal officer dealing with Ayurveda, Siddha, Sowa Rigpa, Unani or Homoeopathy medicines in the Ministry of Ayush, ex-officio	
	(ii) the CEO, National Medicinal Plant Board, Ex officio	
	(iii) the Drugs Controller General of India, ex officio	
	(iv) the Deputy Drug Controller Ayush, ex officio	
	(v) An officer in Directorate General of Health Services dealing with Ayurveda, Siddha, Sowa-Rigpa, Unani, Homoeopathy Drugs, ex officio	
	(vi) the Director of the Pharmacopoeia Commission of Indian system of Medicine and Homoeopathy, ex officio;	

	(vii)The Director or representative of Indian Pharmacopoeia Commission, Ex officio;	
	(viii) The head of Scientific Research Board constituted under section 89.	
	(ix) one person each to be nominated from Central Council for Research in Ayurveda Sciences, Central Council for Research in Siddha, Central Council for Research in Unani, Central Council for Research in Homeopathy and Dept. of Health Research from among Pharmacologists.	
	(x) one expert from Department of Animal Husbandry	
	(xi) one representative from Department of Pharmaceutical	
	(xii) one person to be nominated by Central Government from the medical institution involved in conduct of Clinical trial	
	(xiii) one person from Department of Science and Technology.	
	(xiv) one person holding the appointment of Government Analyst under section 105, to be nominated by the Central Government;	
	(xv) one Pharmacognocist to be nominated by the Central Government;	
	(xvi) one Phyto-chemist to be nominated by the Central Government;	
	(xvii) two persons to be nominated by the Central Government from amongst the persons who are in charge of Ayurveda, or Siddha, or Sowa Rigpa or Unani or Homoeopathy Drug control department in the States	
	(xviii) five persons to be nominated by the Central Government, two from amongst the members of the Ayurveda Sub Committee, one from amongst the members of the Siddha sub-committee, one from amongst the members of the Sowa-Rigpasub-committee, one from amongst the members of the Unani sub-committee and one from amongst the members of the Homoeopathy sub-committee;	
	(xix) one expert each in Dravyaguna, ILM-UL-ADVIA, Gunapadam, and Homoeopathy Materia Medica to be nominated by the Central Government;	
	(xx) five persons, one each to represent. the Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drug industry, to be nominated by the Central Government;	
	(xxi) two persons to be nominated by Central Government from among Cosmetic and Bio-technology industry.	
	(xxii) five persons, one each from among the Registered Medical practitioners of Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs system 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 re-nomination;	
	(5) The functions of the Board may be exercised notwithstanding any vacancy therein;	
	(6) 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;	

	(7) The Board may, subject to the previous approval of the Central Government, appoint system wise Sub-Committees, as and when deemed necessary;	
	(8) The procedure for conduct of business of Board shall be such as may be prescribed.	
The Ayurveda, Siddha, Sowa Rigpa, Unani, Homeopathy Drugs, Medical Devices and Cosmetics Consultative Committee	**88.** (1) The Central Government shall constitute an advisory Committee to be called the Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy Drugs, Medical Devices and Cosmetics Consultative Committee to advise the Central Government, the State Governments and the Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy Drugs Technical Advisory Board on any matter for the purpose of securing uniformity throughout India in the administration of this Chapter in so far as it relates to these Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs, cosmetics and medical devices.	
	(2) The Central Government shall nominate the Chairperson to the committee.	
	(3) The Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy Drugs Consultative Committee shall consist of four 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.	
	(4) The Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy Drugs Consultative Committee shall meet as and when required to do so by the Central Government.	
	(5) The Ayurveda, Siddha, Sowa Rigpa, Unani, Homeopathy Drugs, Medical Devices and Cosmetics Consultative Committee shall have power to regulate its own procedure.	
The Scientific Research Board	**89.** (1) The Central Government shall, by notification in the Official Gazette and with effect from such date as may be specified therein establish a Scientific Research Board to support the regulatory authority on the scientific advances used for developing, innovative Drug of Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy, their safety and efficacy, devices and other such related matters.	
	(2) The Board shall consist of such experts and scientists of interdisciplinary nature as may be prescribed including the experts of Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy and the ex-officio members.	
	(3) The Chairperson of the Board shall be nominated by the Central Government.	
	(4) The Board may, subject to the previous approval of the Central Government, make bye- laws, regulating its own procedure and conduct of all business to be transacted by it.	
	(5) The Board shall have its infrastructure including laboratories or may adopt or authorise such other laboratories to undertake its functions.	
Modern science and technology in Ayurveda, Siddha, Sowa-Rigpa or Unani innovative drug and devices.	**90.** The Central Government as well as the State Governments shall encourage use of modern science and technology for development of innovative drug and devices in Ayurveda, Siddha, Sowa-Rigpa or Unani through such means as may be prescribed.	

The Central Drugs Laboratory and State drug laboratory for Ayurveda, Siddha, Sowa Rigpa, Unani, Homeopathy.	**91.** (1) For the purpose of Ayurveda, or Siddha, or Sowa-Rigpa, or Unani or Homoeopathy Drugs, devices and cosmetics, the Central Government may, by notification, establish or designate:- (a) Central Drug Laboratories for - (i) testing and analysis of Ayurveda, or Siddha, or Sowa-Rigpa, or Unani or Homoeopathy Drugs and cosmetics; (ii) functioning as an appellate authority or centre; (iii) carrying out other functions assigned. (b) Central Medical Devices testing centres relating to Ayurveda, or Siddha, or Sowa-Rigpa, or Unani or Homoeopathy systems of Medicine for:- (i) testing and evaluation of medical devices; (ii) functioning as an appellate centre; (iii) carrying out other functions assigned. in such manner as prescribed.	
	(2) The State Government may, by notification, establish or designate; (a) State drugs laboratory for —- (i) testing and analysis of Drugs and cosmetics of Ayurveda, or Siddha, or Sowa-Rigpa, or Unani or Homoeopathy (ii) carrying out other functions assigned. (b) State Medical devices testing centres relating to Ayurveda, or Siddha, or Sowa-Rigpa, or Unani or Homoeopathy systems of Medicine for:- (i) testing and evaluation of medical devices; (ii) carrying out other functions assigned. in such manner as may be prescribed.	
	(3) The reports and forms for submission of samples and reports of Laboratories and Centres under sub-sections (1) and (2) shall be such as may be prescribed.	
	(4) The fee for samples and reports of laboratories and centres referred to in sub-section (3) shall be such as may be prescribed.	
Constitution of National Medicinal Plant Board, State Medicinal Plant Board and Regional cultivation and facilitation Centre for medicinal plant.	**92.** (1) The Central Government shall, by notification in the Official Gazette and with effect from such date as may be specified therein empower the National Medical Plant Board to advise the Central Government and the State Governments on matters pertaining to medicinal plants and to carry out the other functions assigned to it by or under this Act and rules made thereunder—	
	(2) The Board shall be headed by a Chief Executive Officer and shall be supported by such scientific and administrative and other staff necessary to carry out its function.	
	(3) The Board shall undertake such activities as prescribed in bye laws to ensure quality of raw material, promote cultivation of medicinal plants, availability of herbal and other raw material used in manufacture of Ayurveda, Siddha, Sowa-Rigpa, Unani drugs and such other activities related to medicinal plants.	

	(4) The Board shall also advise the Central Government on policies related to medicinal plants and shall generate such data as may be necessary by such means as prescribed.	
	(5) The State Governments shall by notification empower Medicinal Plant Boards in each state to support the National Medicinal Plant Board to carry out its activities in respective State.	
	(6) The National Medicinal Plant Board shall be supported with Regional cultivation and facilitation Centres for Medicinal Plants to undertake such activities as defined in bye laws under sub-section (3) above.	
	(7) The State Governments and Central Government shall encourage cultivation of medicinal plants and shall take such measures as prescribed to ensure sustainable availability of raw material used in formulations of Ayurveda, Siddha, Sowa-Rigpa, Unani and Homeopathy drugs.	
	B. Manufacture, Sale, Distribution and Clinical Trial of Drugs	
Standards of quality of drugs and cosmetics in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic.	**93.** (1) For the purposes of this Chapter, the expression "standard quality" means—	
	(a) in relation to Ayurveda, Unani, Siddha, Sowa-Rigpa and Homoeopathy drugs shall be the standards specified in the Sixth Schedule.	
	(b) the cosmetic of Ayurveda, Siddha, Sowa-Rigpa, Unani, and Homeopathy 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 sixth Schedule for the purposes of this Chapter, and thereupon the Sixth Schedule shall be deemed to be amended accordingly.	
Not of standard quality of drugs and cosmetics in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic.	**94.** A drug shall be deemed to be not of standard quality, if it does not conform to the standards specified in section 93.	
Misbranded drugs in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic.	**95.** (1) For the purposes of this Chapter, an Ayurvedic, Homoeopathic, Sowa Rigpa, 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.	
Misbranded cosmeticin relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic.	**96.** For the purposes of this Chapter, an Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy cosmetic shall be deemed to be misbranded:-	
	(a) if it is not labelled in the prescribed manner; or	
	(b) if its label or container or anything accompanying the cosmetic bears any statement, which is false or misleading in any particular.	
Adulterated drugs in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic.	**97.** (1) For the purposes of this Chapter, an Ayurvedic, Sowa Rigpa, Siddha Unani or Homoeopathic 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.	
Adulterated cosmetic in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic.	**98.** For the purposes of this Chapter, an Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy 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.	
Spurious drugs in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic.	**99.** For the purposes of this Chapter, an Ayurvedic, Homoeopathic, Sowa Rigpa, 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; except the classical formulation of Ayurveda, Siddha, Sowa Rigpa or Unani bearing the same name but different formulation 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 except those permitted according Ayurveda, Siddha, Unani Pharmacopoeia; or	
	(e) if it purports to be the product of a manufacturer of whom it is not truly a product.	
	(f) if it does not contain an ingredient claimed on the label except those substances prohibited under some other Act.	
	Explanation: - For the purpose of clause (a), the classical formulations bearing same name but different formula should mention the classical reference in clear terms including the 'Rogadhikar' on the label. *(a)* For the purpose of clause (f), certain substances like musk, elephant tusk, certain medicinal plants are prohibited for protection of those species.	
Spurious Cosmetic in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic	**100.** For the purposes of this Chapter, an Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy cosmetic shall be deemed to be spurious	

drugs and Cosmetic.		
	(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 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.	
Regulation of manufacture for sale of Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic.	**101.** (a) The Central Drug Regulatory authority for Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs, devices and cosmetic appointed by the Central Government shall regulate the manufacture and sale of Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs. The Central regulatory authority shall develop such infrastructure, at State level as prescribed by the Central Government to effectively enforce the provisions in this Act for the quality assurance of Ayurveda, Siddha, Sowa-Rigpa, Unani, and Homeopathy drugs.	
	(b) No person shall manufacture for sale or for distribution any Ayurvedic, Sowa Rigpa, Siddha Unani or Homoeopathic drug except in accordance with such standards, if any, as may be prescribed in relation to that drug.	
	(2) Safety Monitoring of Ayurveda, Siddha, Sowa-Rigpa, Unani, Homoeopathy drugs- The drug manufacturer and drug marketer, as the case, may be shall be legally responsible for the safety, efficacy, and quality management as well as other regulatory compliance for the drug including the research drug.	
	(3) No marketer shall adopt any drug manufactured by another manufacturer for marketing of such drug by labelling or affixing his name on the label of the drug with a view for its sale and distribution without an agreement as prescribed in rules.	
Prohibition of manufacture and sale of certain Ayurvedic, Homoeopathic, Sowa Rigpa, Siddha and Unani drugs and cosmetic.	**102.** 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-	
	(1) manufacture for sale or for distribution—	
	(i) any misbranded, adulterated or spurious Ayurvedic, Homoeopathic, Sowa Rigpa, Siddha or Unani drug;	
	(ii) any drug; 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, Homoeopathic, Sowa Rigpa, Siddha or Unani drug in contravention of any of the provisions of this Chapter or any rule made thereunder;	

	(iv) sell, stock or exhibit or offer for sale or distribute any Ayurvedic, Homoeopathic, Sowa Rigpa, Siddha or Unani drug which has been manufactured or imported in contravention of any of the provisions of this Act, or any rule made thereunder;	
	(v) manufacture for sale or for distribution, any Ayurvedic, Homoeopathic, Sowa Rigpa, Siddha or Unani drug, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter by the prescribed authority: Provided that nothing in this section shall apply to Registered Medical Practitioners who manufacture Ayurvedic, Sowa Rigpa, Siddha Unani and Homeopathy 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, Sowa Rigpa, Unani or Homoeopathic drug for the purpose of examination, test or analysis.	
	(2) No person shall manufacture for sale of any innovative drug except in accordance with the permission or approval issued by Central Licensing Authority in such manner as may be prescribed.	
	(3) No person shall himself or by any other person or his behalf sell, or stock or exhibit or offer for sale, or distribute, any drug by online mode except in such manner as may be prescribed.	
	(4) Notwithstanding anything contained in sub-section (1), on and from the commencement of this Act, no license in respect of manufacture for sale or for distribution of Ayurveda, Siddha, Sowa Rigpa or Unani drugs specified in the Seventh Schedule shall be issued by the State Licensing Authority without the approval of Central License Approving Authority in the manner as may be prescribed:	
	(5) Provided that the Central License Approving Authority may issue directions to the State Licensing Authority in respect of any of the Ayurveda, Siddha, Sowa Rigpa or Unani drugs included in the Seventh Schedule and such direction shall be binding.	
	(6) The Central Government may, by notification, amend Seventh Schedule so as to insert therein or omit there from categories of Ayurveda, Siddha, Sowa Rigpa or Unani drugs.	
Application of manner and procedure prescribed under Section 44	**103.** As regards to pleas related to drugs, the manner and procedure as prescribed under section 44 shall be in so far applicable to Ayurveda, Siddha, Sowa Rigpa or Unani drugs.	
Power of Central Government to prohibit manufacture, etc., of Ayurvedic, Homoeopathic, Sowa Rigpa, Siddha or Unani drugs in public interest.	**104.** 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, Homoeopathic, Sowa Rigpa, 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.	

Government Analysts under Chapter V.	**105.** (1) The Central Government or the State Government, as the case may be, 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.	
Drugs Control Officers under Chapter V.	**106.** (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 Drugs Control Officers 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 a Drugs Control Officer 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 a Drugs Control Officer under this section.	
	(4) Every Drugs Control Officer 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.	
	(5) Every Drugs Control Officer shall function under a controlling authority designated by the Central Government or the State Government respectively. The Controlling Authority shall have such qualification and experience as may be prescribed.	
Application of provisions of sections 47, 48, 50, 51, 52 and 53.	**107.** The provisions of sections 47, 48, 50, 51, 52 and 53 and the rules, if any, made thereunder shall, so far as may be, apply in relation to a Drugs Control Officer and a Government Analyst appointed under this Chapter as they apply in relation to a Drugs Control Officer 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, Sowa Rigpa, Unani or Homoeopathic drug.	
Penalty for manufacture, sale, etc., of Ayurvedic, Homoeopathic, Sowa Rigpa, Siddha or Unani drug in contravention of this Chapter	**108.** (1) Whoever himself or by any other person on his behalf— manufactures for sale or for distribution, or sells, or stocks or exhibits or offer for sale or distributes —	

	(a) any Ayurvedic, Siddha, Sowa Rigpa, Unani or Homoeopathic drug deemed to be not of standard quality under section 94, or misbranded under section 95 and included in Eighth Schedule, shall be punishable with fine which shall not be less than fifty thousand rupees.	
	(b) any Ayurveda, Unani, Siddha, Sowa-Rigpa, Homoeopathy drugs deemed to be not of standard quality under section 94 or misbranded under section 95, except the categories specified in the Eighth Schedule, shall be punishable with fine not exceeding one lakh rupees**.**	
	(c) any Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs— (i) deemed to be adulterated under Section 97, (ii) without a valid licence or in violation of any of the conditions thereof, as required under section-102, shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than one lakh rupees or three times the value of the drugs confiscated, whichever is more;	
	(d) any Ayurveda, Unani, Siddha, Sowa-Rigpa, Homoeopathy drug- deemed to be spurious under section 99, shall be punishable with imprisonment for a term not less than one year but which may extend to three years and with fine which shall not be less than two lakh rupees or three times the value of the drugs confiscated, whichever is more:	
	(e) any Ayurveda, Unani, Siddha, Sowa-Rigpa, Homoeopathy drug in contravention of the provisions of any notification issued under Section 104 shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to 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 judgement, impose a sentence of imprisonment for a term of less than one year and of fine of less than three lakh rupees or three times the value of the drugs confiscated, whichever is more: or	
	(2) contravenes any other provisions of this Chapter or of Section 107 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 thirty thousand rupees.	
Penalty for manufacture, sale, etc., of Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy cosmetics in contravention of this Chapter	**109.** Whoever himself or by any other person on his behalf—	
	(1) manufactures for sale or for distribution, or sells, or stocks or exhibits or offer for sale or distributes- (a) any Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy cosmetic—	

	(i) deemed to be adulterated under Section 98, or spurious under section 100 shall be punishable with imprisonment for a term which may extend to one year or with fine which shall not be less than fifty thousand rupees or with both;	
	(ii) any cosmetic other than a cosmetic referred to in clause (i), in contravention of any other provision of this chapter or any rule made under this Act shall be punishable with imprisonment for a term which may extend to one year or with fine which shall not be less than fifty thousand rupees or with both;	
Compounding of certain offences relating to Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathydrugs and Cosmetic.	**110.** (1) Notwithstanding anything contained in the Code of Criminal Procedure, 1973, any offence punishable under this Chapter (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 be compounded, by officer having prescribed qualification and experience appointed by the Central Government or the officer having prescribed qualification and experience appointed by the State Government under this Act, as the case may be, on payment for credit to that Government of such sum and in such manner as may be prescribed.	2 of 1974
	Provided that such sum shall not, in any case, less or exceed the maximum amount of the fine which may be imposed under this Act for the offences so compounded: Provided further that in cases of subsequent offences, except the offences under clause(1) of section 102. The same shall not be compoundable.	
	(2) Where an offence is compounded under sub-section (1), no proceeding or further proceeding, as the case may be, shall be taken against the offence in respect of the offences so compounded and the offender, if in custody, shall be released forthwith.	
	(3) The officer appointed by the Central Government or the officer appointed by the State Government under this Act, as the case may be, by an Order in writing, delegate his powers of compounding as mentioned under sub-section (1), to any other officer under his control, having such qualifications and experience as may be prescribed.	
Penalty for subsequent offences in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic.	**111.** Whoever having been convicted of an offence,—	
	(1) under clause (a) of sub-section (1) of section 108 is again convicted for three subsequent offences under that clause, shall be punishable with fine of one lakh rupees and compounding each time in the multiples of one lakh rupees and suspension of licence by one year. If convicted for five subsequent offences under that clause, shall be punishable with cancellation of licence.	
	(2) under clause (b) of sub-section (1) of section 108 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 three lakh rupees or three times the value of the drugs confiscated, whichever is more.	

	(3) under clause (c) of sub-section (1) of section 108 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to six years and with fine which shall not be less than five 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 judgement, impose a sentence of imprisonment for a term of less than two years and of fine of less than five lakh rupees or three times the value of the drugs confiscated, whichever is more.	
	(4) under sub-section (2) of section 108 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 one lakh rupees or three times the value of the drugs confiscated, whichever is more.	
Confiscation in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic.	**112.** (1) Where any person has been convicted under this Chapter, the stock of the Ayurveda, Unani, Siddha, Sowa-Rigpa, Homoeopathy drugs or cosmetics as the case may be, with respect of which the contravention has been made, shall be liable to confiscation.	
	(2) Recall of Ayurveda, Unani, Siddha, Sowa-Rigpa , Homoeopathy drug: Where a manufacturer, marketer, importer, as the case may be, has sold or distributed any Ayurveda, Unani, Siddha, Sowa-Rigpa, Homoeopathy drug for which the licence has been granted for import or manufacture for, sale or stock or distribution by the Central Controlling authority or the State Licensing Authority, as the case may be, and the said authority has the reason to believe after granting such licence that such Ayurveda, Unani, Siddha, Sowa-Rigpa, Homoeopathy drug is unsafe for use, the said authority may in addition to other actions, also order recall of such drug from the market in such manner as maybe prescribed.	
Disclosure of name of manufacturer, etc in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic.	**113.** Every person, not being the manufacturer of any Ayurveda, Unani, Siddha, Sowa-Rigpa, Homoeopathy drug or cosmetic as the case may be or his agent for the distribution thereof, shall, if so required, disclose to the Drugs Control Officer the name, address and other particulars of the person from whom he acquired the Ayurveda, Unani, Siddha, Sowa-Rigpa , Homoeopathy drug or cosmetic.	
Maintenance of records and furnishing of information in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic.	**114.** (1) Every person holding a licence under section 102 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.	
	(2) Every person holding a licence under section 102 shall keep and maintain such records, registers and other documents related to raw material used in manufacturing	

	of drugs, as may be prescribed and shall furnish the data to the National Medicinal Plant Board from time to time as prescribed by the Central Government.	
Application of provisions to Government departments in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic.	**115.** The provisions of this Chapter except those contained in section112 shall apply in relation to the manufacture for sale, sale or distribution of any Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drug or cosmetic as the case may be, by any department of Government as they apply in relation to the manufacture for sale, sale or distribution of such drug or cosmetic by any other person.	
Safety and efficacy evaluation of Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs or cosemtics.	**116.** (1) The safety and efficacy evaluation of innovation drug or cosmetic of Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy, shall be carried out in such manner as may be prescribed by the Scientific Research Board referred in section 89.	
	(2) In the event of any adverse drug reaction occurring due to use of any Ayurveda, Siddha, Sowa-Rigpa, Unani, Homoeopathy drug by any person, the manufacturer or importer or marketer of the said drug shall inform about the said reaction to the Central Controlling Authority or the State Licensing Authority who had granted the licence for import or manufacture or market authorization for sale or stock or distribution for the said drug in such time, form and manner as may be prescribed.	
Cognizance of offences related to Ayurvedic, Homoeopathic, Sowa Rigpa, Siddha, and Unani drugs.	**117.** (1) No prosecution under this Chapter shall be instituted except by a Drugs Control Officer with the previous sanction of the authority specified under sub-section (4) and (5) of section 106.	
	(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.	
Power of Central Government to make rules for Chapter V.	**118.** (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) In particular and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely,—	
	(a) the manner of functions of laboratories and centres under sub-section (1) of section 91;	
	(b) provide for the establishment of laboratories for testing and analysing Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs;	

	(c) the manner of carrying out the safety and efficacy evaluation of Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs under section 116;	
	(d) prescribe the qualifications and duties of Government Analysts and the qualifications of Drugs Control Officers;	
	(e) prescribe the methods of test or analysis to be employed in determining whether any Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drug or cosmetic is labelled with the true list of the ingredients which it is purported to contain;	
	(f) specify any substance as a poisonous substance;	
	(g) prescribe the forms of licences for the manufacture for sale of Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs or cosmetics, and for sale of processed Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs or cosmetics, the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same and the fees payable therefor; and provide for the cancellation or suspension of such licences in any case where any provision of this Chapter or rules made there under is contravened or any of the conditions subject to which they are issued is not complied with;	
	(h) prescribe the conditions to be observed in the packing of Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs or cosmetics including the use of packing material which comes into direct contact with the drugs or cosmetics, regulate the mode of labelling packed drugs or cosmetics and prescribe the matters which shall or shall not be included in such labels;	
	(i) prescribe the conditions subject to which small quantities of Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs may be manufactured for the purpose of examination, test or analysis; and	
	(j) prescribe under clause (d) of section 97 the colour or colours which an Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs may bear or contain for purposes of colouring;	
	(k) prescribe the standards for Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs under section 93;	
	(l) prescribe the records, registers or other documents to be kept and maintained;	
	(m) Prescribe the records and data of raw material used to be submitted to National Medicinal Plant Board and the manner in which the data to be submitted;	
	(n) prescribe the manner in which research to be conducted for development of Research drugs and devices and the data to be submitted to the authority for seeking approval;	
	(o) prescribe the composition of the Board, consultative committee or any other supportive structure that may be felt necessary for execution of the provisions under this Act.;	
	(p) prescribe the manner in which the raw material to be used in Ayurveda, Siddha, Sowa-Rigpa, Unani and Homeopathy drugs is to be collected, stored, handled and supplied;	

	(q) prescribe the manner in which the drugs of Ayurveda, Siddha, Sowa-Rigpa, Unani and Homeopathy with poisonous ingredients are to be retailed;	
	(r) the manner of regulation and restriction for online mode of sale, or stock or exhibit or offer for sale, or sell, or distribute, of any drug under this chapter;	
	(s) prescribe the requirements relating to export as under section 124; and	
	(t) any other matter which is to be or may be prescribed under this Chapter.	
Power to amend Fifth, Sixth, Seventh and Eighth Schedule.	**119.** 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 Fifth, Sixth, Seventh and Eighth Schedule for the purposes of this Chapter and thereupon the said Schedules shall be deemed to be amended accordingly.	
	C. Import of Drugs and Cosmetics	
Standard quality in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic.	**120.** (1) For the purpose of this Chapter, the expression 'standard quality" means—	
	a. in relation to an imported Ayurveda or Siddha or Sowa-Rigpa or Unani or Homoeopathy drug, that the drug complies with the standard set out in the Sixth Schedule, and	
	b. in relation to an imported Ayurveda or Siddha or Sowa-Rigpa or Unani or Homoeopathy 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 fifteen days' notice of its intention so to do, may by alike notification add to or otherwise amend the Sixth Schedule, for the purposes of this Chapter, and thereupon Schedule shall be deemed to be amended accordingly.	
	(3) In relation to import of a product of any traditional system of medicine other than Ayurveda, Siddha, Sowa-Rigpa Unani or Homeopathy, that the product complies with standards and specifications as may be prescribed by the Central Government.	
Not of standard quality of imported Ayurveda, Siddha, Sowa-Rigpa, Unani, Homoeopathy drug or cosmetics or herbal or traditional medicinal product	**121.** An imported drug or cosmetic shall be deemed to be not of standard quality, if it does not conform to the standards referred in section 120.	
Modified application of Chapter III in relation to import of Ayurveda,	**122.** The provisions of Chapter III except section 14 and 15, shall so far as applicable may apply, in relation to import of Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs or cosmetics or Herbal/ Traditional Medicinal Product under this	

Unani, Siddha, Sowa-Rigpa , Homoeopathy drugs or cosmetics, etc.	chapter as they apply in relation to Drugs and Cosmetics under Chapter III, subject to the modification that the references to "drugs" or “cosmetics” in the said section, shall be constructed as references to "Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs or cosmetics" and the references to "Central licensing Authority" in the said section, shall be constructed as reference to " Central Licensing Authority for Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs" under this Chapter, and the references to "Central Government", “Board”, and “Central Drugs Laboratory” under Chapter III, shall be constructed as reference to "Central Government”, “Board” , “Central Drugs Laboratory” dealing with the matters related to Ayurveda, Siddha, Sowa-Rigpa , Unani and Homoeopathy drugs and cosmetics under this Chapter”.	
Modified application of provisions of Chapter VI in relation to import of Ayurveda, Unani, Siddha, Sowa-Rigpa , medical devices.	**123.** The provisions of Chapter VI shall, so far as applicable may apply, in relation to import of Ayurveda, Siddha, Sowa-Rigpa,Unani, medical devices under this chapter as they apply in relation to Medical Devices under Chapter VI, subject to the modification that the references to "medical devices" in the said Chapter, shall be constructed as references to "Ayurveda, Unani, Siddha, Sowa-Rigpa , Medical Devices" and the references to "Central licensing Authority" in the said section, shall be constructed as reference to "Central Licensing Authority for Ayurveda, Siddha, Sowa-Rigpa , Unani and Homoeopathy drugs" under Chapter V, and the references to "Central Government", “Board”, and “Central Drugs Laboratory” in the Chapter VI, shall be constructed as reference to "Central Government, Board, Central Drugs Laboratory dealing with the matters related to Ayurveda, Siddha, Sowa-Rigpa , Unani medical devices" under this Chapter”.	
Export of Drugs and Cosmetics relating to Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy.	**124.** The exporter shall comply with rules, regulations or guidelines as may be prescribed by the Central Government for export of Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs.	
	CHAPTER VI **IMPORT, MANUFACTURE, SALE, DISTRIBUTION AND CLINICAL INVESTIGATION OF MEDICAL DEVICES.**	
Regulation of medical devices.	**125.** (1) The medical devices as defined in clause *(zd)* of section 3 shall have risk-based classification for conformity assessment and regulation in such manner as may be prescribed.	
	(2) An importer or manufacturer who has received license in respect of medical device shall, after the device has been made available on the market, submit the adverse event reports and periodic safety update reports in respect of the device in such form, at such frequency, and for such duration, as may be prescribed:	

	Provided that for different medical devices, different requirements related to post market surveillance may be imposed depending on the risk to health or safety presented by the device.	
Standards of Medical Devices.	**126.** For the purposes of this Chapter, the expression "standard quality" means the medical device complies with such standard as may be prescribed keeping in view the contemporary scientific and technological knowledge and development.	
Misbranded medical devices.	**127.** A medical device shall be deemed to be misbranded if it,-	
	(a) is configured so as to conceal any damage or made to appear of better or greater functional value or made to appear of lesser risk than it really is; or	
	(b) is not labeled or packed in such manner as may be prescribed; or	
	(c) bears label, container, statement, design or device which makes any false claim; or	
	(d) containing colours not expressly permitted in the license or permission issued under this Chapter.	
Adulterated medical devices.	**128.** A medical device shall be deemed to be adulterated if it,-	
	(a) consists, in whole or in part, of rusted or corroded or filthy or putrid or decomposed substance; or	
	(b) is prepared, packed or stored under insanitary conditions where by it may have been rendered injurious to health; or	
	(c) contains any harmful or toxic substance or component or software or parts thereof which may render it dangerous to use or injurious to health; or	
	(d) is having any substance or component or software or part thereof mixed or added thereto or substituted or removed there from so as to reduce its quality or performance or safety which may render it dangerous to use or injurious to health; or	
	(e) is having a pack or container composed, in whole or in part, of any deleterious substance which may render it dangerous to use or injurious to health.	
Spurious medical devices.	**129.** A medical device shall be deemed to be spurious if it,-	
	(a) is having the label or pack or the container bearing the name of an individual or firm or company purporting to be the manufacturer of the device, which individual or a firm or a company is fictitious or does not exist; or	
	(b) purports to be the product of a manufacturer who is actually not the manufacturer of the product.	
Prohibition of import or manufacture and sale of medical devices.	**130.** (1) No person shall himself or by any other person on his behalf import or manufacture for sale or distribution, or sells, stocks, exhibits or offers for sale or distribute any medical device which,-	
	(a) does not conform to such standards of quality, safety and performance as may be prescribed;	
	(b) is misbranded, adulterated or spurious;	

	(c) does not display such details as may be prescribed in respect of accompanying software, part, component or instrument;	
	(d) by means of any false statement, design or accessory accompanying it or by any other means, purports or claims to cure any disease or ailment, or to have any such other effect as may be prescribed;	
	(e) is in contravention of any of the provisions of this Act or rules made there under:	
	Provided that nothing contained in clause (a) to (e) shall apply to import or manufacture of any medical devices in such small quantity for the purposes of demonstration, test, analysis or examination not on human beings, or for personal use and subject to such conditions as may be prescribed:	
	Provided further that the Central Government may, in consultation with the Medical Devices Technical Advisory Board, by notification, subject to conditions specified therein, permit the import or manufacture of any medical device, not approved by the Central Government or not being of standard quality, for sale or for distribution.	
	(2) No person shall himself or by any other person on his behalf, import or manufacture for sale, stock, distribution of medical devices, as may be prescribed, for which a license or permission is required to be obtained from the Licensing Authority, except under and in accordance with such licence or permission subject to such exemptions and conditions and in such form and manner as may be prescribed.	
	(3) No person shall himself or by any other person on his behalf sell, stock, distribute, exhibit or offer for sale or distribution medical devices, as may be prescribed, for which a license or permission is required to be obtained from the State Licensing Authority, except under and in accordance with such licence or permission subject to such exemptions and conditions and in such form and manner as may be prescribed.	
	(4) No person shall himself or by any other person on his behalf sale, distribute or offer for sale the medical devices by online method, as may be prescribed, for which a license or permission is required to be obtained from the licensing authority, except under and in accordance with such licence or permission subject to such exemptions and conditions and in such form and manner as may be prescribed.	
	(5) The notified bodies shall carry out the assessment, verification and certification of medical devices referred to in sub-section (3) in such manner as may be prescribed.	
Application of law relating to sea customs and powers of Customs Officers in respect of medical devices.	**131.** (1) The law for the time being in force relating to customs and goods, the import of which is prohibited under section 11 of the Customs Act, 1962 (52 of 1962) or rules made or notifications issued thereunder or any other law for the time being in force, shall subject to the provisions of section 155and section 158 of this Act, apply in respect of medical devices, 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 medical devices as they have for the time being in respect of the said goods.	

	(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 medical device, the import of which is prohibited under this Chapter or any other law for the time being in force and shall forthwith report such detention to the Drugs Controller General, India and forward the package or sample of any such suspected medical device found therein to the medical devices testing centre.	
Appointment or designation of Medical Devices Testing Officer.	**132.** (1) The Central Government or the State Government may, by notification, appoint such person as it thinks fit, having such qualifications as may be prescribed, to be Medical Devices Testing Officer for such area and in respect of such medical devices or classes of medical devices, as may be specified in the notification.	
	(2) The Central Government or the State Government may, by notification, designate such person as it thinks fit, having such qualifications as may be prescribed, to be Medical Devices Testing Officer for such area and in respect of such medical devices or classes of medical devices, as may be specified in the notification.	
	(3) Notwithstanding anything contained in sub-sections (1) and (2), neither the Central Government nor a State Government, shall appoint any Officer as the Medical Devices Testing Officer, not serving under it, without the consent of the other Government under which he is serving.	
	(4) No person who has any financial interest in the import, manufacture or sale of medical devices shall be appointed or designated as the Medical Devices Testing Officer under sub-sections (1) and (2).	
	(5) Every Medical Devices Testing Officer appointed under sub-sections (1) and (2) shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code.	45 of 1860
	(6) Any person designated as a Medical Devices Testing Officer under Drugs and Cosmetics Act, 1940 and rules made thereunder, before the commencement of this Act, shall be deemed to have been appointed as the Medical Devices Testing Officer for the purposes of this Act and shall continue to discharge his functions as the Medical Devices Testing Officer.	
Appointment or designation of Medical Devices Officer.	**133.** (1) The Central Government or the State Government may, by notification, appoint or designate such person, as it thinks fit, having such qualifications and experience as may be prescribed, to be the Medical Devices Officer for such area as may be specified in the notification.	
	Explanation.- Subject to the other provisions of this section, for the purposes of this Act, any other officer of the Central Government or State Government lower in rank to the controlling authority and higher in rank to the Medical Devices Officer and also possessing the qualifications referred to in sub-section (1) shall be deemed to be the Medical Devices Officer.	
	(2) The duties to be performed by a Medical Devices Officer, in relation to medical devices or classes of medical devices 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 or manufacture or sale or distribution of medical devices shall be appointed to be a Medical Devices Officer under this section.	
	(4) Every Medical Devices Officer shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code.	
	(5) Every Medical Device Officer shall function under a controlling authority designated by the Central Government or the State Government respectively. The Controlling Authority shall have such qualification and experience as may be prescribed.	
	(6) Any person appointed or designated as a Medical Devices Officer under Drugs and Cosmetics Act, 1940 and rules made thereunder, before the commencement of this Act, shall be deemed to have been appointed or designated as the Medical Devices Officer for the purposes of this Act and shall continue to discharge his functions as the Medical Devices Officer.	
Powers of Medical Devices Officer.	**134.** (1) The Medical Devices Officer may, within the local limits of the area for which he is appointed,-	
	(a) inspect any premises wherein any medical device is being manufactured, sold, stocked, exhibited, offered for sale or distributed;	
	(b) take samples of any medical device, which is being manufactured, sold, stocked, exhibited, offered for sale or distributed;	
	(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 medical device 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 medical device in respect of which an offence under this Act has been, or is being, committed, and order in writing the person in possession of the medical device in respect of which the offence has been, or is being, committed, not to dispose of any stock of such medical device for a specified period not exceeding twenty days, or, unless the alleged offence is such that the defect may be removed by the possessor or of the medical device, seize the stock of such medical device 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;	
	(d) 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;	

	(e) require any person to produce any record, register, or other document relating to the manufacture for sale or distribution, selling, stocking, exhibition for sale, offer for sale or distribution of any medical device in respect of which he has reason to believe that an offence under this Act has been, or is being, committed; and	
	(f) exercise such other powers, except power of arrest, as may be necessary for carrying out the provisions of this Act and rules made thereunder forensuring the compliance of Act and rules made thereunder:	
	Provided that in case the stock of medical devices, or the record, registers, documents or any other material objects connected or related thereto are seized, he shall, as soon as may be, inform the Judicial Magistrate of the First Class in the area and take his orders as to the custody thereof.	
	(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 91 of the said Code.	
	(3) Every record, register or other document seized under clause (d) or produced under clause (e) 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 there from certified by that person, in such manner as may be prescribed, have been taken.	
	(4) Where an medical devices officer takes any action under clause (c) of sub-section (1),-	
	(a) he shall use all dispatch in ascertaining whether or not the medical device contravenes any of the provisions of the section 129 and, if it is ascertained that the medical device 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) 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 medical device, he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.	
	(5) If any person wilfully obstructs a Medical Devices Officer 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 (e) of sub-section (1), he shall be punishable with imprisonment which may extend to one year or with fine which may extend to two lakh rupees or with both.	
Police when to assist medical device officer.	**135.** Every police officer shall be bound to assist a medical device officer demanding his assistance,-	
	(a) in the investigation and preventing the escape of any person who is suspected to commit an offence under this Act; or	
	(b) in the prevention or suppression of a breach of the peace; or	

	(c) in the prevention of any injury attempted by the person to be committed against the medical device officer.	
Procedure of Medical Devices Officer for getting the samples of medical device tested, evaluated and verified.	**136.** The Medical Devices Officer shall, get the sample of medical device tested, evaluated or verified from Medical Devices Testing Officer or any other person authorised by the Central Government or the State Government, as the case may be, for obtaining the report thereof in such form and manner as may be prescribed.	
Report of Medical Devices Testing Officer.	**137.** (1) TheMedical Devices Testing Officer shall, after testing, verifying or evaluating the sample under section 136, submit the report in that regard to the Medical Devices Officer in such form and manner as may be prescribed.	
	(2) The report of testing, evaluation or verification obtained by medical devices officer, in respect of sample of medical device under section 136, shall be the conclusive evidence of the fact stated therein unless challenged in such manner as may be prescribed.	
	(3) The procedure for further action on the report of the Medical Devices Testing Officer shall be such as may be prescribed.	
Power of Central Government to regulate or restrict or prohibit import or manufacture, sale or distribution of medical device in public interest.	**138.** (1) Without prejudice to any other provision contained in this Act or the rules made thereunder, if the Central Government is satisfied that the use of any medical device is likely to involve risk to human beings or animals or that any medical device does not have the functional value claimed or purported to be claimed for it or which is not safe or effective for use or for which there is no functional justification and that in the public interest, it is necessary or expedient so to do, then, that Government may, by notification, regulate, restrict or prohibit the import, manufacture, sale, stock or distribution of such medical device.	
	(2) The notification issued under sub-section (1) shall be laid, as soon as may be after it is made, before each House of Parliament.	
Conduct of clinical investigation.	**139.** (1) No person, sponsor, clinical research organization, any other organisation or investigator, shall conduct any clinical investigation in respect of any investigational medical device, in human participants except under, and in accordance with, the permission granted by the Central Licensing Authority subject to such conditions in such form and manner as may be prescribed.	
	(2) Clinical investigation shall be carried out in respect of such investigational medical devices in such manner as may be prescribed.	
	(3) The Central Licensing Authority may, in public interest, abbreviate, defer, or waive the requirement of conducting clinical investigation for reasons to be recorded in writing.	
	(4) Medical device requiring clinical investigation but claiming substantial equivalence to a predicate device shall not be marketed unless the Central Licensing Authority approves equivalence in such manner as may be prescribed.	
	Explanation.- For the purposes of this sub-section, a device shall be deemed to be substantially equivalent if, in comparison to a predicate device, it has the same intended	

	use and same technological characteristics or has the same intended use and different technological characteristics and also demonstrates that the device is at least as safe and effective as the predicate device.	
	(5) The Ethics Committee specified in sub-section (1) of section 74 shall also be the Ethics Committee for the purposes of clinical investigation under this Chapter.	
Medical treatment and compensation for injury or death related to clinical investigation.	**140.** (1) Where any participant is injured on account of his participation in the clinical investigation, the person, sponsor, clinical research organisation, any other organisation or investigator permitted under sub-section (1) of section 139 shall provide medical management to that participant.	
	(2) Where an injury is caused to the participant in the clinical investigation of any investigational medical device and such injury is attributable to the use of investigational medical device, the person, sponsor, clinical research organisation, any other organisation or investigator permitted under sub-section (1) of section 139 shall provide to that participant such compensation in such manner as may be prescribed.	
	(3) Where death of a participant is related to clinical investigation and is attributable to the use of an investigational medical device, the person, sponsor, clinical research organisation, any other organisation or investigator permitted under sub-section (1) of section 139 shall provide to the legal heir of that participant, such compensation in such manner as may be prescribed.	
Power of Medical Devices Officer relating to clinical investigation.	**141.** (1) The Medical Devices Officer, with the prior approval of Controlling Authority or any other officer authorised by the Central Licensing Authority may, with or without prior notice, enter into any premises related to clinical investigation to inspect the facilities, record, data, documents, books, and medical devices including investigational medical devices.	
	(2) The officer empowered under sub-section (1) shall have the power to seek clarifications, information and record regarding clinical investigation or matters relating thereto.	
Maintenance of record and furnishing information.	**142.** Every person, sponsor, clinical research organization, any other organisation or investigator conducting a clinical investigation or his agent holding a permission under this Chapter shall keep and maintain such data, record, registers and other documents as may be prescribed and shall furnish such information as may be required by the Central Licensing Authority or any other officer authorised by it in this behalf under section 141.	
Disclosure of name, address, etc. of persons involved in clinical investigation.	**143.** Every person, sponsor, clinical research organization, any other organisation or investigator conducting a clinical investigation or his agent, as the case may be, shall, if so required, disclose to the Medical Devices Officer or any other officer authorised by the Central Licensing Authority under section 161, the names, addresses and other particulars of the persons involved in conducting clinical investigation and participants in such clinical investigation.	
Penalty for conducting clinical investigation of	**144.** Whoever himself, or by any other person on his behalf, conducts clinical investigation of any investigational medical device,without obtaining permission under	

investigational medical device without permission.	sub-section (1) of section 139, shall be liable to a penalty with fine which shall not be less than three lakh rupees which may extend to six lakh rupees to be imposed by the adjudicating officer authorised by Central Government having experience of regulation under this Act along with medical management and such compensation as specified under section 135 to participant of clinical trial in such manner as may be prescribed;	
Penalty for violation of conditions of permission.	**145.** (1) Whoever himself, or by any other person on his behalf, conducts clinical investigation of investigational medical device, in contravention of any condition of permission granted under sub-section (1) of section 139 or any other provision of this Act or the rules made thereunder, the central licensing authority, may, after giving an opportunity to show cause as why such an order should not be passed, by an order in writing stating the reasons thereof,	
	(a) issue warning letter giving details of deficiency found during the inspection, which might affect the right or well-being of the clinical investigation subject or the validity of the study conducted at that site;	
	(b) direct that study may be rejected or discontinued;	
	(c) suspend or cancel the clinical investigation permission;	
	(d) debar the investigator(s), sponsor including their employee(s), subsidiaries and branch(es), their agent(s), contractor(s), and sub-contractor(s) to conduct any clinical investigation in future.	
	(2) The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial Investigators, against whom action as mentioned in sub- rule (1) has been taken by the central licensing authority, may, within ninety days of the receipt of the copy of the order of the central licensing authority prefer an appeal to the Central Government, and the Central Government may, after giving such appellant an opportunity of being heard, confirm, reverse or modify such order.	
Penalty for failure to provide medical management and compensation.	**146.** Whoever responsible to provide compensation for medical management or clinical investigation related to injury or death under section 139, fails to do so, shall be punishable with imprisonment for a term which may extend to one year or with fine which shall not be less than twice the amount of the compensation.	
Penalty for contravention of any provision of this chapter.	**147.** Whoever initiates or conducts clinical investigation of any investigational medical device in contravention of any provision under this Chapter, except the provisions of sections 139, 140, 141, 142, 143, 144, 145 and section 146 and the rules made under this Act shall be liable for penalty which shall not be less than fifty thousand rupees but which may extend to two lakh rupees to be imposed by the adjudicating officer authorised by Central Government or State Government, as the case may be, having experience of enforcement under this Act in such manner as may be prescribed.	
Application of provisions to Government Departments.	**148.** The provisions of this Chapter except those contained in section 154 shall apply in relation to the manufacture, sale or distribution of medical device by any department	

	of Government as they apply in relation to the manufacture, sale or distribution of medical device by any other person.	
Improvement notices.	**149.** (1) The licensing authority has reasonable ground for believing that any licensee has failed to comply with any provision of this Act or rules made thereunder, he may, be issued a notice to the said licensee (in this Act herein after referred as "improvement notice")-	
	(a) state the grounds for believing that the said licensee has failed to comply with the any provision of this Act or rules made thereunder;	
	(b) specify the matters which constitute the licensee's failure so to comply;	
	(c) specify the measures which, in the opinion of the said Authority, the licensee must take, in order to secure compliance; and	
	(d) require the licensee to take those measures, or measures which are at least equivalent to them, within a reasonable period (not being less than fourteen days) as may be specified in the notice.	
Suspension and Cancellation of license.	**150.** (1) The licensing authority may, after giving the licensee an opportunity to show cause, why such an order should not be passed by an order in writing stating the reasons therefor, cancel a license issued by them, or suspend it for such period as he thinks fit either wholly or in respect of any of the medical device to which it relates or direct the licensee to stop manufacture, sale or distribution of said medical device and thereupon order the destruction of medical device and the stock thereof in the presence of an medical devices officer, if in opinion, the licensee has failed to comply with improvement notice or any of the conditions of the licence or with any provisions of the Act or rules made thereunder.	
	(2) Any licensee who is aggrieved by cancellation or suspension of licence by licensing authority under sub-rule (1), may within ninety days of the receipt of a copy of the order by him prefer an appeal to the Central Government or the State Government, as the case may be, and the Central Government or the State Government may after giving the licensee an opportunity of being heard, confirm, reverse or modify such order.	
Cognizance of offence relating to medical devices.	**151.** (1) No prosecution under this Chapter shall be instituted, except on a complaint made by,-	
	(a) a Medical Devices Officer or any other officer duly authorised in this behalf by the Drugs Controller General; or	
	(b) a Medical Devices Officer duly authorised in this behalf by the State Drugs Controller by whatever name called; or	
	(c) a Gazetted officer of the Central or the State Government authorised by that Government by an order made in this behalf; or	
	(d) the person aggrieved; or	
	(e) any recognised consumer association.	

	(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.	
	(3) Nothing contained in this Chapter shall be deemed to prevent any person from being prosecuted under any other law for the time being in force for any act or omission which constitute an offence against this Chapter.	
Offences for import or manufacture, sale or distribution of medical device in contravention of this Chapter.	**152.** Whoever, himself or by any other person on his behalf, import, or manufacture, for sale or for distribution, or sell, or stock or exhibit or offer for sale any medical device,-	
	(a) deemed to be adulterated under section 129 or spurious under section 130 and which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder, causes such bodily harm which amounts to grievous hurt within the meaning of section 320 of the Indian Penal Code (45 of 1860), or is likely to cause such bodily harm or death, solely on account of such medical device, shall be punishable with imprisonment for a term which shall not be less than five years but which may extend to seven years and shall also be liable to fine which shall not be less than seven lakh rupees:	
	Provided that the fine imposed under this clause shall be paid to the person who had been administered such medical device:	
	Provided further that where the use of such medical device caused death of a person who was administered such medical device, the fine imposed shall be paid to his legal heir;	
	(b) deemed to be spurious under section 129, but not being a device referred to in clause (a), shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and shall also be liable to fine which shall not be less than three lakh rupees;	
	(c) deemed to be adulterated under section 128 but not being a device referred to in clause (*a*) or without a valid licence or permission as required under clauses (2) and (3) of section 133, shall be punishable with imprisonment for a term which shall not be less than six months but may extend to one year or with fine which shall not be less than three lakh rupees;	
	(d) other than a device referred to in clause (a) or clause (b) or clause (c), deemed to be misbranded under section 127, or in contravention of any other provision of this Chapter or any rule made under this Act, shall be liable to pay penalty which shall not be less than one lakh rupees but which may extend to two lakh rupees to be imposed by the adjudicating officer authorized by Central Government or State Government, as the case may be having experience of enforcement under this Act, in such manner as may be prescribed.	
Penalty for import or manufacture, etc. of medical device in	**153.** Whoever himself, or by any other person on his behalf, imports, manufactures, sells or distributes any medical device in contravention of the provisions of any	

contravention of section 121.	notification issued under section 133, shall be punishable with imprisonment for a term which shall not be less than three years and with fine which may extend to five lakh rupees.	
Confiscation relating to medical devices.	**154.** (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 medical device 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 medical device deemed to be misbranded under section 127, adulterated under section 128 or spurious under section 129; or	
	(ii) manufacture for sale, or for distribution, sale, or stocking or exhibiting or offering for sale, or distribution of any medical device without a valid licence as required under section 133, any implements or machinery used in such manufacture, sale or distribution and any receptacles, packages or coverings in which such medical device is contained and the animals, vehicles, vessels or other conveyances used in carrying such medical device 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 a Medical Devices Officer or otherwise and after such inquiry as may be necessary that the medical device is not of standard quality or is a misbranded or spurious or adulterated medical device, as the case may be, shall be liable for confiscation.	
Pleas relating to medical devices.	**155.** (1) A person not being a manufacturer or distributor shall not be liable for a contravention of the provisions of this Chapter if he proves–	
	(a) that he acquired the medical device from a duly licensed or registered manufacturer or importer or distributor or dealer thereof;	
	(b) that he did not know and could not, with reasonable diligence, have ascertained that the medical device in any way contravened the provisions of this chapter; and	
	(c) that the medical device, while in his possession was properly stored and remained in the same state as when he acquired it.	
	(2) An importer, manufacturer or his agent, of a medical device shall not be liable for a contravention of the provisions of this Chapter if he proves that the medical device did not suffer from any of the prohibitions and had been manufactured, imported or distributed in accordance with the provisions of this Act and the rules made thereunder.	
Punishment for failure to pay financial penalty imposed by adjudicating officer.	**156.** Whoever responsible to pay financial penalty imposed by the adjudicating officer authorised by Central Government or State Government, as the case may be, under this Chapter fails to pay that penalty shall be liable for imprisonment for a term which shall not be less than one year.	
Compounding of certain offences relating of medical devices.	**157.** (1) Notwithstanding anything contained in the Code of Criminal Procedure, 1973 (2 of 1974), any offence punishable under section 147 and sub-clause (c) of section 152 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 be compounded, by Drugs Controller General, India appointed by the Central Government or the State Drugs Controllers appointed by the State Government under this Act, as the case may be, under this Act, on payment for credit to that Government of such sum and in such manner as may be prescribed:	
	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 offences so compounded.	
	(2) 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 offences so compounded and the offender, if in custody, shall be released forthwith.	
	(3) The Drugs Controller General, India or State Drugs Controllers, as the case may be, may, with the approval of the Central Government or the State Government, as the case may be, by an Order in writing, delegate his powers of compounding as mentioned under sub-section (1), to any other officer under his control, having such qualifications and experience as may be prescribed.	
Powers of the Central Government to make rules for Chapter VI.	**158.** (1) The Central Government may, after consultation with or on the recommendation of, the Medical Devices Technical Advisory Board and subject to previous publication, by notification, make rules for carrying out the provisions of this Act:	
	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.	
	(2) Without prejudice to the generality of the foregoing power, such rules may provide for-	
	(a) the manner for risk-based classification of medical devices and conformity assessment of different classes of medical devices under sub-section (1) of section 125;	
	(b) the form, manner, frequency and duration of submission for the adverse event reports and periodic safety update reports in respect of the medical device under sub-section (2) of section 125;	
	(c) the standards of medical devices keeping in view the contemporary scientific and technological knowledge and development under section 126;	
	(d) the manner of labelling and packing medical devices under clause (b) of section 127;	
	(e) standards of quality, safety and performance of medical devices under clause (a) of sub-section (1) of section 130;	
	(f) manner of displaying details in respect of accompanying software, part, component or instrument under clause (c) of sub-section (1) of section 130;	
	(g) other effect which a medical device may purport or claim to cure any disease or ailment under clause (d) of sub-section (1) of section 130;	

	(h) the conditions subject to which and the extent to which small quantity of medical devices may be imported or manufactured for the purposes of test, analysis or examination under the proviso to sub-section (1) of section 130;	
	(i) the categories of medical devices for which license or permission may be required under section 130;	
	(j) the form and the manner of issue and revocation license and permission along with exemptions and conditions under sub-sections (2), (3) and (4) of section 130;	
	(k) the manner for assessment, verification and certification of medical devices under sub-section (5) of section 130;	
	(l) the manner of providing compensation under sub-section (6) of section 130;	
	(m) the qualifications of the Medical Devices Testing Officer under section 132;	
	(n) the qualifications, experience and duties of the Medical Devices Officer under 133;	
	(o) the manner of certifying copies or extracts of record, register or other documents under sub-section (3) of section 134;	
	(p) the form and manner of taking the sample of medical device for test, verification or evaluation under section 136;	
	(q) the form and manner of submission of the report under sub-section (1) of section 137;	
	(r) the manner in which report of the medical devices testing officer may be challenged under sub-section (2) of section 137;	
	(s) the procedure for further action on the report of the Medical Devices Testing Officer under sub-section (3) of section 137;	
	(t) the form and the manner of permission under section 139;	
	(u) the manner of equivalence under sub-section (4) of section 139;	
	(v) the manner of providing compensation under section 140;	
	(w) the data, record, register and other documents to be maintained by persons, sponsors, clinical research organisation, any other organisations or investigators under section 142;	
	(x) the manner of imposing penalty under section 145, section 147 and clause (d) of section 152;	
	(y) the extent and manner to determine the sum under section 157.	
	(z) to prescribe the manner of regulating online sale or distribution or offer for sale of the medical device.	
Fee for grant of license. registration certificate, permission, etc. of medical devices.	**159.** (1) The fee for grant of license. registration certificate, permission, etc. of medical devices shall be such as specified in the Second Schedule.	
	(2) The Central Government may, by notification, amend the Second Schedule so as to enhance or reduce the rate of fee or add therein or omit there from any subject matter.	
	CHAPTER VII **MISCELLANEOUS**	

Power to give directions.	**160.** 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.	
Drugs Controller General, India and Central License Approving Authority.	**161.** (1) The Central Government, shall by notification, appoint an officer, having such qualifications and experience as may be prescribed, as the Drugs Controller General, India.	
	(2) The Drugs Controller General, India shall be the Central License Approving Authority for the purposes of sub-section (5) of section 41.	
	(3) The Central Government shall by notification appoint an Officer having such qualification and experience as may be prescribed as the Central Licensing Approving Authority for the purposes of Chapter V.	
State Drugs Controller and State Licensing Authority.	**162.** (1) The State Government may, by notification, appoint an officer, having such qualifications and experience as may be prescribed, as the State Drugs Controller by whatever name called. (2) The State Drugs Controller shall be the State Licensing Authority for the purposes of sub-section (1) of section 41. (3) The State Government shall by notification, appoint an Officer having such qualification and experience as may be prescribed, as the State Drugs Controller by whatever name called for the purposes of Chapter V.	
Delegation of power of Central Licensing Authority and State Licensing Authority.	**163.** (1) The Drugs Controller General, India may, with the approval of the Central Government, delegate, any of his power subject to such conditions and restrictions, as the Central Licensing Approving Authority or Central Licensing Authority, as the case may be, by specifying an Order in writing, to any other officer under his control, having such qualifications and experience as may be prescribed.	
	(2) The State Drugs Controller, by whatever name called, may, with the approval of the State Government, delegate, any of his power subject to such conditions and restrictions, as the State Licensing Authority, by specifying an Order in writing, to any other officer under his control, having such qualifications and experience as may be prescribed.	
	(3) The State Drugs Controller, by whatever name called, may, with the approval of the State Government, by an order in writing, delegate his powers as State Licensing Authority, to any other officer under his control, having such qualifications and experience as may be prescribed as the State Licensing Approving Authority for the purposes of Chapter V.	
Appeal to Central Government against decision or action of Central Licensing Authority or any officer.	**164.** Where any person against whom an action or decision has been taken by the Central Licensing Authority or of an officer to whom the powers under the provisions of the Act and rules made there under have been delegated, is aggrieved by any action or decision, may prefer an appeal to the Central Government in such manner as may be prescribed.	

Appeal to State Government against the decision or action of State Licensing Authority or any officer.	**165.** Where any person against whom an action or decision has been taken by the State Licensing Authority or of an officer to whom the powers under the provisions of the Act and rules made there under have been delegated, is aggrieved by any action or decision, may prefer an appeal to the State Government in such manner as may be prescribed.	
Offences by company, limited liability partnership firm or any such arrangement.	**166.** (1) Where an offence under this Act has been committed by a company or a limited liability partnership firm or any such arrangement, every person who, at the time the offence was committed was in-charge of, and was responsible to the company or the limited liability partnership firm or any such arrangement, for the conduct of the business, and the company or the limited liability partnership firm or any such arrangement, 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, 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 or a limited liability partnership firm or any such arrangement 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 partner or other officer of the company or the limited liability partnership firm or any such arrangement, as the case may be, such director, manager, secretary or partner or other officer, as the case may be; shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.	
Offences by Government Departments.	**167.** Where an offence under Chapter III, Chapter IV or Chapter V or Chapter VI has been committed by any department of Government, such authority as is specified by the Central Government to be in charge of import, manufacture, sale or distribution of drugs, medical devices or cosmetics 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 III, Chapter IV or Chapter V or Chapter VI, 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.	
Penalty for vexatious search or seizure.	**168.** Any Drugs Control Officer or Medical Devices Officer 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, medical device or cosmetic, or any substance or article, or any record, register, document or other material object; or	
	(d) commits, as such Drugs Control Officer or Medical Devices Officer, 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 thirty thousand rupees.	
	Provided that in case any false complaint is made against any Drugs Control Officer or any Medical Devices Officer, as the case may be, and it is proved so, the complainant shall be guilty of an offence under this Act and he shall be punishable with fine which shall not be less than fifty thousand rupees.	
Penalty for submission of misleading or wrong information or refusal to furnish information.	**169.** Whoever himself or by any other person on his behalf imports, manufactures, stocks, sells, or distributes, or intends to do so, any drug or cosmetic or notified category of medical device and submits misleading or wrong information or refuses to provide correct information in that regard as required by the Licensing Authority under this Act shall be punishable with imprisonment for a term which shall not be less than two years and shall also be liable to fine which shall not be less than one lakh rupees.	
Publication of sentences passed under this Act.	**170.** (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 Drugs Control Officer or the Medical Devices Officer, cause the offender's name, place of residence, the offence of which he has been convicted and the penalty which has been inflicted upon him, to be published at the expense of such person in such newspapers or in such other manner as the Court may direct.	
	(2) The expenses of such publication shall be deemed to form part of the costs relating to the conviction and shall be recoverable in the same manner as those costs are recoverable.	
Convicted person liable for cost of storage.	**171.** Any person convicted for an offence under this Act shall be liable to bear the cost of storage of any article related to such offence, seized under this Act and the rules made thereunder.	
Drugs, medical devices and cosmetics proved spurious, misbranded, adulterated or not of standard quality to be destroyed.	**172.** The seized spurious or misbranded or adulterated or not of standard quality drugs, cosmetics and notified category of medical devices, having been proved so and after their use as evidence in the case before the court is over, shall be destroyed by the official authority in custody of these products in the manner as may be prescribed and the convicted person shall be liable to bear the cost of destruction of seized articles.	
Obligation of officers to assist each other.	**173.** All officers appointed by Central Government or State Government, as the case may be, under this Act upon notice given or request made, be legally bound to assist each other in the interstate or any matter requiring the assistance for carrying out the provisions of this Act.	
Magistrate's power to impose enhanced penalties.	**174.** 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 authorized by this Act in excess of his powers under the said Code.	
Certain offences to be tried summarily.	**175.** 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 159 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 98, 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.	
Special Courts.	**176.** (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 27, sub-section (3) of section 47, clauses (a) and (c) of section 56, section 59, section 60, section 61 and clause (b) of sub-section (1) of section 63, clauses (a) and (c) of section 152 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, be charged at the same trial.	2 of 1974.
Offences to be cognizable and non-bailable in certain cases.	**177.** (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 27, clause (a) of sub-section (2) of section 27, sub-section (3) of section 47, clauses (a) and (c) of section 56,	

	section 59, section 60, section 61 and sub-sections (1) and (2) of section 63, clauses (a) and (c) of section 152 and other offences relating to adulterated drugs or spurious drugs, shall be cognizable.	
	(b) no person accused, of an offence punishable under clauses (a) and (c) of sub-section (1) of section 27, clause (a) of sub-section (2) of section 27, sub-section (3) of section 47, clauses (a) and (c) of section 56, section 59, section 60, section 61 and sub-sections (1) and (2) of section 63 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 176.	
Application of Code of Criminal Procedure, 1973 to proceedings before Special Court.	**178.** (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.	

Appeal and revision.	**179.** 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.	
Protection of action taken in good faith.	**180.** No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done under this Act.	
General powers of the Central Government to make rules.	**181.** (1) The Central Government may, after consultation with or on the recommendation of, the Medical Devices Technical Advisory Board and subject to previous publication, by notification, make rules for carrying out the provisions of this Act:	
	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.	
	(2) In particular and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely-	
	(a) qualifications and experience of the Drugs Controller General, India under clause (a) of section 161;	
	(b) qualifications and experience of the State Drugs Controller under section 162;	
	(c) qualifications and experience of officers under section 163;	
	(d) the manner of making an appeal under section 164 and section 165; and	
	(e) the manner of destruction of the confiscated stocks of drugs, cosmetics and medical devices under section 172.	
Laying of Rules and notification, etc. before Parliament.	**182.** Every rule made and notification 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.	
Power to remove of difficulties.	**183.** (1) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of this Act as appear to it to be necessary or expedient for removing the difficulty:	
	Provided that no order shall be made under this section after the expiry of a period of three years from the commencement of this Act	
	(2) Every order made under this section shall be laid, as soon as may be after it is made, before each house of Parliament.	

Transitory provisions.	**184.** Notwithstanding the repeal of the enactment and orders specified in the Nineth Schedule, the standards and other provisions of the Act and the rules made thereunder and orders listed in that Schedule shall continue to be in force and operate till new standards are specified under this Act or rules made thereunder.	
Repeal and savings.	**185.** (1) With effect from such date as the Central Government may appoint in this behalf, the enactment and orders specified in the Nineth Schedule shall stand repealed:	
	Provided that such repeal shall not affect:—	
	(i) the previous operations of the enactment and orders under repeal or anything duly done or suffered there under; or	
	(ii) any right, privilege, obligation or liability acquired, accrued or incurred under any of the enactment or orders under repeal; or	
	(iii) any penalty, forfeiture or punishment incurred in respect of any offences committed against the enactment and orders under repeal; or	
	(iv) any investigation or remedy in respect of any such penalty, forfeiture or punishment, and any such investigation, legal proceedings or remedy may be instituted, continued or enforced and any such penalty, forfeiture or punishment may be imposed, as if this Act had not been passed:	
	(2) If there is any other law for the time being in force in any State, corresponding to this Act, the same shall upon the commencement of this Act, stand repealed and in such case, the provisions of section 6 of the General Clauses Act, 1897(10 of 1897) shall apply as if such provisions of the State law had been repealed.	
	(3) Notwithstanding the repeal of the aforesaid enactment and Orders, the licences issued under any such enactment or order, which are in force on the date of commencement of this Act, shall continue to be in force till the date of their expiry for all purposes, as if they had been issued under the provisions of this Act or the rules made thereunder.	
	(4) Notwithstanding anything contained in any other law for the time being in force, no court shall take cognizance of an offence under the repealed Act or orders after the expiry of a period of three years from the date of the commencement of this Act.	

First Schedule
(See sections 14 and 33)

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

S No.	Class of drug	Standard to be complied with
1	Proprietary medicines	The formula or list of ingredients displayed in the prescribed manner on the label or container and such other standards as may be prescribed.
2	Substances commonly known as vaccines, sera, toxins, toxoids, antitoxins, and antigens and biological products of such nature for human or 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 W.H.O from time to time, and such further standards of strength, quality and purity as may be prescribed
3	Substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals.	Such standards as may be prescribed.
4	Other drugs:	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.
	(a) Drugs included in the Indian Pharmacopoeia	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 which are 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 such 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 of such official Pharmacopoeia and such other standards as may be prescribed.

Second Schedule
[See section 30, section 82 and section 159]

Fee payable for license, permission, registration certificate and approval

Sr. No.	Section.	Subject.	Amount of fee in rupees/$.
(1)	(2)	(3)	(4)
1		import registration certificate for drug,- (a) one site: (b) per product:	 (a) $10000 (b) $5000
2		import license for drug,- (a) one site: (b) per product:	 (a) 10000 (b) 5000
3		import registration certificate for cosmetic,- (a) per category: (b) per variant:	 (a) $2000 (b) $50
4		import test license for drug,- (a) one site: (b) per product:	 (a) 5000 (b) 2000
5		overseas Inspection	$25000
6		approval of drugs by Central license approving authority	10000
7	41	grant or renewal of license for manufacture of drug,- (i) license: (ii) inspection: (iii) approval per product:	 (i) 100000 (ii) 15000 (iii) 2000

8	41	grant or renewal of license for manufacture of cosmetic,- (i) license: (ii) inspection: (iii) approval per product:	 (i) 50000 (ii) 15000 (iii) 1000
9	41	grant or renewal of license for distribution, sale, stock, exhibit and offer for sale of drug,- (i) license: (ii) inspection:	 (i) 10000 (ii) 2000
10	41	permission or approval of new drug	500000
11	41	permission or approval of new veterinary drug	250000
12	41	permission or approval of new cosmetic	50000
13	41	approval of drug by the Central license approving authority	per product: 10000
14	72	permission for conducting clinical trial of new drug	300000
15	72	permission for conducting clinical trial of investigational new drug	300000
16	72	permission for conducting bioequivalence or bioavailability study	200000
19		grant or renewal of license for manufacture of medical device,- (i) license: (ii) approval per product:	 (i) 50000 (ii) 1000
20	130	import license for medical device,- (a) license: (b) per product:	 (a) $3000 (b) $1500
21	130	grant or renewal of license for distribution, sale, sell, stock, exhibit, offer for sale of medical device,- (i) license: (ii) inspection:	 (i) 10000 (ii) 2000
22	130	registration of notified body	25000
23		permission for conducting clinical investigation of investigational medical device	100000
24		permission or approval of investigational medical device	50000

Third Schedule

[See sub-sections (5) and (6) of section 41]

Categories of drugs for which the central license approving authority approval is required for the issue of licence.

1. antigens and anti-toxins;
2. blood, blood components and blood products;
3. drug products containing modified living organisms;
4. gene therapeutic products;
5. large volume parenterals;
6. monoclonal anti-bodies;
7. recombinant-deoxyribo nucleic acid derived drugs;
8. ribo nucleic acid derived drugs;
9. sera;
10. solution of serum proteins intended for injection;
11. cells and stem cells derived products;
12. toxins;
13. vaccines;
14. xenografts.

Fourth Schedule

[See clauses (d) and (e) of section 56]

CATEGORIES OF DRUGS FOR THE PURPOSE OF SECTION 56(e).

(A) Categories of misbranded drugs,-

(1) spelling errors in the label
(2) omission to indicate mandatory symbols including Rx, NRx, XRx, Red line in label.

(B) Categories of not of standard quality drugs not conforming to any of the following parameters,-

1. absorbency
2. acid value, iodine value, peroxide value, saponification value, acetyl value
3. ash
4. assay (more than seventy per cent. and less than the prescribed limit of label claim)
5. boiling point
6. clarity of solution
7. description
8. disintegration
9. dissolution (twenty per cent. less than minimum limit of specification)
10. extractable volume
11. extractive value
12. fluorescence
13. heavy metal
14. leak test (meter dose preparation)
15. limit test
16. loss on drying
17. loss on ignition
18. melting point
19. number of deliveries per container (meter dose preparation)
20. optical rotation
21. osmolality
22. particle size
23. particulate contamination/ foreign matter
24. pouvoir hydrogen (pH) test
25. polymorph
26. refractive index
27. related substance
28. solubility test
29. specific gravity
30. sulphated ash

31. thread count
32. total organic carbon
33. uniformity of content/volume
34. uniformity of delivered dose (meter dose preparation)
35. uniformity of dispersion
36. uniformity of weight
37. viscosity
38. water content/moisture content
39. weight per mL
40. wt/unit area (surgical)
41. acidity
42. appearance of solution
43. chiral purity

Fifth Schedule

[See sections 86(a), 86(k) and 86(J)]

A.- AYURVEDIC, SIDDHA AND SOWA RIGPA SYSTEMS

Serial No.	**Name of Book**
	Ayurveda
1.	ArogyaKalpadruma
2.	ArkaPrakasha
3.	AryaBhishak
4.	AshtangaHridaya
5.	AshtangaSamgraha
6.	AyurvedaKalpadruma
7.	AyurvedaPrakasha
8.	AyurvedaSamgraha
9.	BhaishajyaRatnavali
10.	BrihatBhaishajyaRatnakara
11.	BhavaPrakasha
12.	BrihatNighantuRatnakara
13.	CharakaSamihita
14.	ChakraDatta
15.	GadaNigraha
16.	KupiPakvaRasayana
17.	NighantuRatnakara
18.	RasaChandanshu
19.	RasaRajaSundara
20.	RasaratnaSamuchaya
21.	RasatantraSaraVaSiddhaPrayogaSangraha—Part1
22.	RasatantraSaraVaSiddhaPrayogaSangraha—PartII
23.	RasaTarangini
24.	RasaYogaSagara
25.	RasaYogaRatnakara
26.	RasaYogaSamgraha
27.	RasendraSaraSamgraha
28.	RasaPradipika
29.	Sahasrayoga
30.	SarvarogaChikitsaRatnam
31.	SarvayogaChikitsaRatnam
32.	SharangadharaSamhita
33.	SiddhaBhaishajyaManimala
34.	SiddhaYogaSamgraha
35.	SushrutaSamhita
36.	VaidyaChintamani
37.	VaidyakaShabdaSindu
38.	VaidyakaChikitsaSara
39.	VidyaJiwan
40.	VasavaRajeeyam
41.	YogaRatnakara
42.	YogaTarangini

	43.	YogaChintamani
	44.	Kashyapasamhita
	45.	Bhelasamhita
	46.	Vishwanathachikitsa
	47.	Vrindachikitsa
	48.	Ayurvedachintama
	49.	Abhinavachintamani
	50.	Ayurveda-Ratnakara
	51.	Yogaratnasangraha
	52.	Rasamrita
	53.	Dravyagunanighantu
	54.	Rasamanjari
	55.	Bangasena
	56.	Ayurvedic FormularyofIndiaanditsParts
	57.	AyurvedaSaraSamgraha
	58.	AyurvedicPharmacopoeiaofIndia.
		AyurvedicPharmacopoeiaofIndiaanditsParts.
		Siddha
	59.	Siddha Vaidya Thirattu
	60.	TherayarMahaKarisal
	61.	Brahma Muni Karukkadai (300)
	62.	Bhogar (700)
	63.	Pulippani (500)
	64.	AgasthiyarParipuranam (400)
	65.	TherayarYamagam
	66.	AgasthiyarChenduram (300)
	67.	Agasthiyar (1500)
	68.	Athmarakshamrutham
	69.	Agasthiyar Pin (80)
	70.	AgasthiyarRathnaChurukkam
	71.	TherayarKarisal (300)
	72.	Veeramamuni Nasa Kandam
	73.	Agasthiyar (600)
	74.	AgasthiyarKanmaSoothiram
	75.	18 Siddar'sChillaraiKovai
	76.	YogVathaKaviyam
	77.	TherayarTharu
	78.	Agasthiyar Vaidya Kaviyam (1500)
	79.	BalaVagadam
	80.	ChimittuRathna (Rathna) Churukkam
	81.	Nagamuni (200)
	82.	AgasthiyarChillaraiKovai
	83.	ChikichaRathnaDeepam
	84.	Agasthiyar Nayana Vidhi
	85.	YugiKarisal (151)
	86.	AgasthiyarVallathi (600)
	87.	Therayar Thaila Varkam
	88.	Siddha Formulary of India (Part I)
		Siddha Formulary of India and its Parts
		Sowa Rigpa
	89.	Dud-tsinying-poyan-lag gyad-pa sang-wa man-ngaggi-gyudzes-ja-wa(Four Tantras)
	90.	Yan LakrGyad pa
	91.	Je-wa Ring srel
	92.	Situ sMan-dus(A)
	93.	Situ sMan-dus (Wam)
	94.	Padarthachandrikaprabhasa-nama-astangahrdayavivrtti
	95.	TsangTodzintig
	96.	Zing TigmzesrGyan
	97.	JorwarGyad pa
	98.	MiphamChestus
	99.	sManpyadDaweGyalpo
	100.	Cha lag Chogyed
	101.	Bum Khutsur
	102.	sManNgagLanthabs
	103.	SorigZintik
	104.	sMensbjorDudtseBumzang
	105.	Lag lenChesdus

	106. RintersMenyigChesTus 107. Be sngon 108. sMenbsjorNuspachogdus 109. Shel gong Sheltreng 110. Mespo'IZallung 111. NgulchuDrupisTanchos 112. MenngagRinchenJungnas 113. Dri gung chestus BjispaNyerjorDrophensNying Nor
	B.– UNANI TIBB SYSTEM 1 KarabadinQadri 2 KarabadinKabir 3 KarabadinAzam 4 Ilaj-ul-Amraz 5 AlKarabadin 6 BiazKabirVol.II 7 KarabadinJadid 8 Kitab-ul-Taklis 9 Sanat-ul-Taklis 10 Mifta-ul-Khazain 11 Madan-ul-Aksir 12 Makhzan-ul-murabhat 13 National Formulary of Unani Medicine Unani Pharmacopoeia of India
	C.- HOMOEOPATHIC SYSTEM 1. Allen, Timothy Field.: Encyclopedia of Pure Materia Medica (12 volumes.) 2. Hering, Constantine.: The Guiding Symptoms (10 volumes.) 3. Clarke, John Henry.: A Dictionary of Practical Materia Medica (3 Volumes) 4. William Boericke: Pocket Manual of Homoeopathic Materia Medica 5. Hughes, Richard: A Manual of Pharmacodynamics and Encyclopaedia of Drug Pathogenesy 6. Julian O.A.: Materia Medica of New Remedies and Nosodes 7. Knerr, Calvin.B.: Drug Relationships 8. Lippe Adolph Text Book of Materia Medica 9. Paterson John : Bowel Nosodes 10. Phatak Shankar Raghunath: concise Materia Medica of Homoeopathic Medicines 11. Pulford: Homoeopathic Materia Medica of Graphical Drug Pictures. 12. Schroyens Fredrick: 1001 Small Remedies 13. Stephenson James. : Hahnemannian Provings 14. Tyler, Margret Lucy: Pointer to Common Remedies 15. Vithoulkas, George : The Essence of Homoeopathic Materia Medica Viva (8 volumes) 16. Mahesh Bhattacharya: Homoeopathic Pharmacopoeia 17. Homoeopathic Pharmacopoeia of India – All volumes 18. Sharat Chandra Ghose: Drugs of Hindoosthan 19. Blackwood- Materia Medica, Therapeutics and Pharmacology 20. Homoeopathic Pharmaceuticals codex- Govt. of India 21. Verma P.N., InduVaid: Encyclopedia of Homoeopathic Pharmacopoeia- 4 volumes.
	"*Explanation*: (i) Ingredients and formulations listed in the above original editions of authoritative books and those authoritative texts (only mool shloka/ version)written and published prior to 1964 shall only be considered valid for the purposes of this Act and, those Ingredients and formulations listed in appendix or annexure to the above authoritative texts in first schedule shall be considered invalid.

(ii) The Authoritative Books and their authors / publishers published after 1964 shall be validated by the Central Government before incorporating in this schedule.

Sixth Schedule

(See section 88)

Standards to be complied with by Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy imported drugs and by drugs manufactured for sale, sold, stocked or exhibited for sale or distributed.

Sr.No	Class of Drugs	Standard to be complied with
(1)	(2)	(3)
1.	**Ayurveda, or Siddha, or Sowa-Rigpa or Unani Medicine**	
a.	Drugs included in Ayurveda or Siddha, or Sowa-rigpa or Unani Pharmacopoeia	Standards of identity, purity and strength specified in Ayurveda or Siddha, or Sowa-Rigpa or Unani Pharmacopoeia of India for the time being and such other standards as may be prescribed.
b.	Drugs not included in Ayurveda or Siddha, or Sowa-Rigpa or Unani Pharmacopoeia	The formula or list of ingredients displayed in the prescribed manner on the label of the container and such other standards as may be prescribed by the Central Government
2.	**Homoeopathic Medicines**	
a.	Drugs included in the Homoeopathic Pharmacopoeia of India.	Standards of identity, purity and strength specified in Homoeopathic Pharmacopoeia of India.
b.	Drugs not included in the Homoeopathic Pharmacopoeia of India.	The formula or list of ingredients displayed in the prescribed manner on the label of the container and such other standards as may be prescribed by the Central Government.

Seventh Schedule

[See clauses (4), (5) and (6) of section 102]

CATEGORIES OF AYURVEDA, SIDDHA, SOWA RIGPA OR UNANI DRUGS FOR WHICH THE CENTRAL LICENSE APPROVING AUTHORITY APPROVAL IS REQUIRED FOR THE ISSUE OF LICENCE.

Eighth Schedule

[See clauses (a) and (b) of section 108]

CATEGORIES OF DRUGS FOR THE PURPOSE OF SECTION 108.

(A) Categories of misbranded drugs,-

(1) spelling errors in the label

(B) Categories of not of standard quality drugs not conforming to any of the following parameters,-

1. absorbency
2. acid value, iodine value, peroxide value, saponification value, acetyl value
3. ash
4. assay (more than seventy per cent. and less than the prescribed limit of label claim)
5. boiling point
6. clarity of solution
7. description
8. disintegration
9. dissolution (twenty per cent. less than minimum limit of specification)
10. extractable volume
11. extractive value
12. fluorescence
13. heavy metal
14. leak test (meter dose preparation)
15. limit test
16. loss on drying
17. loss on ignition
18. melting point
19. number of deliveries per container (meter dose preparation)
20. optical rotation
21. osmolality
22. particle size
23. particulate contamination/ foreign matter
24. pouvoir hydrogen (pH) test
25. polymorph
26. refractive index
27. related substance
28. solubility test
29. specific gravity
30. sulphated ash
31. thread count
32. total organic carbon
33. uniformity of content/volume
34. uniformity of delivered dose (meter dose preparation)
35. uniformity of dispersion
36. uniformity of weight
37. viscosity
38. water content/moisture content
39. weight per mL
40. wt/unit area (surgical)
41. acidity
42. appearance of solution
43. chiral purity

Nineth Schedule

(See section 184 and 185)

1. The Drugs Rules, 1945
2. The Medical Devices Rules, 2017
3. The New Drugs and Clinical Trials Rules, 2019
4. The Cosmetics Rules, 2020