| | THE DRUGS, MEDICAL DEVICES AND COSMETICS BILL, 2022 | DRUGS AND COSMETICS ACT, 1940 |
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| | A<br>BILL<br>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. | An Act to regulate the import, manufacture, distribution and sale of drugs and cosmetics.<br><br>WHEREAS it is expedient to regulate the import, manufacture, distribution and sale of drugs and cosmetics;<br><br>AND WHEREAS the Legislatures of all the Provinces have passed resolutions in terms of section 103 of the Government of India Act, 1935 (26 Geo. 5, c. 2), in relation to such of the above-mentioned matters and matters ancillary thereto as are enumerated in List II of the Seventh Schedule to the said Act: |

## CHAPTER II

| | TECHNICAL ADVISORY BOARDS, DRUGS LABORATORIES, MEDICAL DEVICES TESTING CENTRES AND CONSULTATIVE COMMITTEE | THE DRUGS TECHNICAL ADVISORY BOARD, THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE |
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| 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. | **5.** (1) The Central Government shall, as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act. |
| | *(2)* The Board shall consist of following members, namely:- | (2) The Board shall consist of the following members, namely:— |
| | (i) Director General of Health Services, Chairperson, *ex officio*; | (i) the Director General of Health Services, ex officio, who shall be Chairman; |
| | (ii) Drugs Controller General, Member Secretary, *ex officio*; | (ii) the Drugs Controller, India, ex officio; |
| | (iii) One Director of the Central drugs laboratory to be nominated by the Central Government; | (iii) the Director of the Central Drugs Laboratory, Calcutta, ex officio; |
| | (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; | (ix) two 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 | (x) one person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry |

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| | staff of an Indian university or a college affiliated thereto; | or pharmacognosy 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; | |
| | (viii) Three persons, to be nominated by the Central Government, one each from amongst pharmaceutical industry, bio-pharmaceutical industry and cosmetic industry; | (xii) one person to be nominated by the Central Government from the pharmaceutical 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; | (xiv) one person to be elected by the Central Council of the Indian Medical Association; |
| | (xi) One person to be nominated by the Central Council of the Indian Pharmaceutical Association; | (xv) one person to be elected by the Council of the Indian Pharmaceutical Association; |
| | (xii) Two persons appointed as Government Analyst to be nominated by rotation, by the Central Government; | (xvi) two persons holding the appointment of Government Analyst under this Act, to be nominated 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; | |
| | | **Note**: The 2022 Bill excludes the following:<br><br>The President of Medical Council of India, ex officio<br>Director of the Central Research Institute, Kasauli, ex officio<br>Director of Indian Veterinary Research Institute, Izatnagar, ex officio<br>President of the Pharmacy Council of India, ex officio<br>Director of Central Drug Research Institute, Lucknow, ex officio<br>One person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto<br>One pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research |
| Central Drugs Laboratory, Central Medical | **10.** *(1)* The Central Government may, by notification, establish or designate,-<br>*(i)* Central Drugs Laboratories for,- | **6.** (1) The Central Government shall, as soon as may be, establish a Central Drugs Laboratory under the control of a Director to be appointed by the Central |

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| Devices Testing Centre and State drugs laboratories and State medical devices testing centres. | (a) testing and analysis of drugs and cosmetics;<br>(b) functioning as an appellate laboratory or centre;<br>(c) carrying out other functions assigned,<br>~~*(ii)* Central Medical Devices Testing Centres for,~~<br>~~(a) testing and evaluation of medical devices;~~<br>~~(b) functioning as an appellate centre;~~<br>(c) ~~carrying out other functions assigned, in such manner as may be prescribed.~~ | Government, to carry out the functions entrusted to it by this Act or any rules made under this Chapter:<br><br>Provided that, if the Central Government so prescribes, the functions of the Central Drugs Laboratory in respect of any drug or class of drugs or cosmetic or class of cosmetics shall be carried out at the Central Research Institute, Kasauli, or at any other prescribed Laboratory and the functions of the Director of the Central Drugs Laboratory in respect of such drug or class of drugs or such cosmetic or class of cosmetics shall be exercised by the Director of that Institute or of that other Laboratory, as the case may be. |
| | *(2)* The State Government may, by notification, establish or designate,-<br>*(i)* State drugs laboratories for-<br>(a) testing and analysis of drugs and cosmetics;<br>(b) carrying out other functions assigned,<br>*(ii)* State medical devices testing centres for-<br>(a) testing and evaluation of medical devices;<br>(b) carrying out other functions assigned in such manner as may be prescribed. | **Note**:- Provisions for states to establish drug laboratories for testing not provided under the 1940 Act or 1945 Rules. |
| | *(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. | (2) the Central Government may, after consultation with the Board, make rules prescribing—<br><br>(d) the procedure for the submission to the said Laboratory under Chapter IV or Chapter IVA of samples of drugs or cosmetics for analysis or test, the forms of Laboratory‘s reports thereon ~~and the fees payable in respect of such reports~~; |
| | *(4)* The fee for samples and reports of laboratories and centers referred to in sub-section (3) shall be such as may be prescribed. | **6.** (2) (d) ~~the procedure for the submission to the said Laboratory under Chapter IV or Chapter IVA of samples of drugs or cosmetics for analysis or test, the forms of Laboratory‘s reports thereon and~~ the fees payable in respect of such reports; |
| 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. | **7.** (1) The Central Government may constitute an advisory committee to be called the Drugs Consultative Committee to advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any other matter tending to secure uniformity throughout India in the administration of this Act. |
| | (2) The Drugs Controller General, India shall be the Chairperson of the Drugs, Medical Devices and Cosmetics Consultative Committee. | **Note**: This is has been the current practice (See DCC minutes here: https://cdsco.gov.in/opencms/opencms/en/dcc-dtab-committee) |
| | (3) The Drugs, Medical Devices and Cosmetics Consultative Committee shall | (2) The Drugs Consultative Committee shall consist of two representatives of |

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| | 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. | the Central Government to be nominated by that Government and one representative of each State Government to be nominated by the State Government concerned. |
| | (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. | (3) The Drugs Consultative Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure. |
| | (5) The Drugs, Medical Devices and Cosmetics Consultative Committee shall have power to regulate its own procedure. | (3) The Drugs Consultative Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure. |
| 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. | **7A.** Nothing contained in sections 5 and 7 shall apply to Ayurvedic, Siddha or Unani 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:<br><br>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; | **5.** (4) The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it. |
| | (b) the manner of functions of laboratories and centres under sub-section (1) of section 10; | **6.** (2) the Central Government may, after consultation with the Board, make rules prescribing—<br>(a) the functions of the Central Drugs Laboratory; |

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| | (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. | **6.** (2) (d) the procedure for the submission to the said Laboratory under Chapter IV or Chapter IVA of samples of drugs or cosmetics for analysis or test, the forms of Laboratory‘s reports thereon and the fees payable in respect of such reports; |

# DRUGS & COSMETICS

## IMPORT-RELATED PROVISIONS

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| Standards of quality of imported drugs or cosmetics. | **14.** (1) For the purposes of this Chapter, the expression "standard quality" means— | **8.** (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 | (a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and |
| | (b) in relation to an imported cosmetic, that the cosmetic complies with such standard as may be prescribed. | (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 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. | (2) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend the Second Schedule, for the purposes of this Chapter, and thereupon the Second Schedule shall be deemed to be amended accordingly. |
| 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. | **Note**: No equivalent provision in the 1940 Act. This insertion seems to be in response to a demand from drug manufacturers who claim that violators are currently being prosecuted for offences relating to spurious and adulterated drugs. (See press report: http://www.pharmabiz.com/NewsDetails.aspx?aid=136524&sid=1) |
| Imported Misbranded drugs. | **16.** For the purposes of this Chapter, an imported drug shall be deemed to be misbranded,— | **9.** 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 | (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 | (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. | (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,— | **9A.** 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 | (a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or |

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| | (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 | (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 | (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 | (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 | (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. | (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,— | **9B.** For the purposes of this Chapter, a drug shall be deemed to be spurious— |
| | (a) if it is imported under a name which belongs to another drug; or | (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 | (b) if it is an imitation of, or 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 | (c) if the label or the 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 | (d) if it has been substituted wholly or in part by another drug or substance; or |
| | (e) if it purports to be the product of a manufacturer of whom it is not truly a product; 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 the active pharmaceutical ingredient. | **Note**: No equivalent provision in the 1940 Act or 1945 Rules. |
| Imported misbranded cosmetics. | **19.** For the purposes of this Chapter, an imported cosmetic shall be deemed to be misbranded— | **9C.** For the purposes of this Chapter, a cosmetic shall be deemed to be misbranded—<br>(a) if it contains a colour which is not prescribed; or |
| | (a) if it is not labelled in the prescribed manner; or | (b) 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. | (c) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular. |

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| Imported spurious cosmetics. | **20.** For the purposes of this Chapter, an imported cosmetic shall be deemed to be spurious,— | **9D.** For the purposes of this Chapter, a drug shall be deemed to be spurious,— |
| | (a) if it is imported under a name which belongs to another cosmetic; or | (a) if it is imported under the 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 | (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 or 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 | (c) if the label or the 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. | (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,- | **17E.** 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 | (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 | (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 | (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 | (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 | (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. | (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- | **10.** From such date as may be fixed by the Central Government by notification in the Official Gazette in this behalf, no person shall import- |
| | (a) any drug which is not of standard quality, or is misbranded, adulterated or spurious; | (a) any drug ~~or cosmetic~~ which is not of standard quality;<br>(b) any misbranded drug or misbranded or spurious ~~cosmetic~~;<br>(bb) any adulterated or spurious drug; |

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| | (b) any cosmetic which is not of standard quality, or is misbranded, adulterated or spurious; | (a) any ~~drug~~ or cosmetic which is not of standard quality;<br>(b) any ~~misbranded drug~~ or misbranded or spurious cosmetic;<br><br>**Note**: Section 10 of the 1940 Act does not prohibit import of *adulterated* cosmetics. |
| | (c) any drug or cosmetic for the import of which a licence is prescribed, otherwise than under, and in accordance with, such licence; | (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; | (d) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it, together with the quantities thereof; |
| | (e) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed; | (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; | (ee) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended; |
| | (g) any drug or cosmetic the import of which is prohibited by rule made under this Chapter; | (f) 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: | **Note**: No equivalent condition prescribed in the 1940 Act. |
| | 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 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. | Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the import of any drug or class of drugs not being of standard quality. |

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| 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. | **10A.** Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do then, that Government may, by notification in the Official Gazette, prohibit the import of such drug or cosmetic. |
| 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. | **Note**: No equivalent provision in the 1940 Act to regulate or restrict imported drugs on public interest grounds. Section 26B below is limited to manufacture, sale or distribution.<br>26B. 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. |
| Application of law relating to sea customs and powers of Customs Officers in 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. | **11.** (1) The law for the time being in force relating to sea customs and to goods, the import of which is prohibited by section 18 of the Sea Customs Act, 1878 (8 of 1878) shall, subject to the provisions of section 13 of this Act, apply in respect of drugs and cosmetics the import of which is prohibited under this Chapter, and officers of Customs and officers empowered under that Act to perform the duties imposed thereby on a Commissioners 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. | (2) Without prejudice to the provisions of sub-sections (1), the Commissioners of Customs any officer of the Government authorized by the Central Government in this behalf, may detain any imported package which he suspects to contain any drug or cosmetic the import of which is prohibited under this Chapter and shall forthwith report such detention to the Drugs Controller, India, and, if necessary, forward the package or sample of any suspected drug or cosmetic found therein to the Central Drugs Laboratory. |
| Power of Central Government to make rules for | **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: | **12.** (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: |

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| Chapter III. | 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. | 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,— | (2) Without prejudice to the generality of the forgoing power, such rules may |
| | *(a)* specify the drugs or classes of drugs or cosmetics or classes of cosmetics for the import of which a licence is required, 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; | (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; | (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; | (c) prescribe, in respect of biological and organometallic compounds, the units or methods of standardization; |
| | *(d)* prescribe under clause (d) of section 17 the colour or colours which a drug may bear or contain for purposes of colouring; | (cc) prescribe under clause (d) of section 9A the colour or colours which a drug may bear or contain for purposes or colouring; |
| | *(e)* the colour which a cosmetic may bear or contain for the purposes of colouring under clause (d) of section 21; | **33.** (2) Without prejudice to the generality of the foregoing power, such rules may—<br>(dda) prescribe under clause (d) of section 17E the colour or colours which a cosmetic may bear or contain for the purposes of colouring |
| | *(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; | (d) specify the diseases or ailments which an imported drug may not purport or claim to prevent, cure or mitigate and such other effects which such drug may not purport or claim to have; |
| | *(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; | (e) prescribe the conditions subject to which small quantities of drugs, the import of which is otherwise prohibited under this Chapter, may be imported for the purpose of examination, test or analysis or for personal use; |

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| | *(h)* prescribe the places at which drugs or cosmetics may be imported, and prohibit their import at any other place; | (f) 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; | (g) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label or container of any specified imported drug or class of such drug, and prohibit the import of the said drug or class of drug after the expiry of a specified period from the date of manufacture; |
| | *(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; | (h) regulate the submission by importers, and the securing, of samples of drugs or cosmetics for examination, test or analysis by the Central Drugs Laboratory, and prescribe the fees, if any, payable for such examination, test or analysis; |
| | *(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; | (i) prescribe the evidence to be supplied, whether by accompanying documents or otherwise, of the quality of drugs or cosmetics sought to be imported, the procedure of officers of Customs in dealing with such evidence, and the manner of storage at places of import of drugs or cosmetics detained pending admission; |
| | *(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; | (j) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter and the rules made thereunder of drugs or cosmetics imported for the purpose only of transport through, an 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; | (k) prescribe the conditions to be observed in the packing in bottles, packages or other containers, of imported drugs or cosmetics including the use of packing material which comes into direct contact with the drugs; |
| | *(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; | (l) regulate the mode of labeling 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; | (m) prescribe the maximum proportion of any poisonous substance which may be added to or contained in any imported drug, prohibit the import of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder; |
| | *(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; | (n) require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the label or wrapper of any imported, patent or proprietary medicine containing such drug; |

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| | *(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; | (o) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder, of any specified drug or class of drugs or cosmetic or class of cosmetics. |
| | *(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 contravention of this Chapter. | **27.** Whoever, himself or by any other person on his behalf, imports,- | **13.** (1)Whoever himself or by any other person on his behalf – |
| | (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:<br><br>Provided that the fine imposed under this clause shall be paid to the person who had used it:<br><br>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; | **Note**:- This clause is similar to Section 27 of the 1940 – but it is applicable for only for manufacture, sale or distribution. It does not cover *imported* drugs or cosmetics. |
| | (b) any drug- | |
| | (*i*) deemed to be adulterated under section 17, but not being a drug referred to in clause (a); or | (a) any drug deemed to be adulterated under section 9A ~~or deemed to be a spurious drug under section 9B or any spurious cosmetic referred to in section 9D or any cosmetic of the nature referred to in clause (ee) of section 10~~ shall be punishable with imprisonment for a term which may extend to three years and a fine which may extend to five thousand rupees; |
| | (*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: | **Note**: No equivalent provision in the 1940 Act. |

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| | 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: | (a) any drug ~~deemed to be adulterated under section 9A or~~ deemed to be a spurious drug under section 9B ~~or any spurious cosmetic referred to in section 9D or any cosmetic of the nature referred to in clause (ee) of section 10~~ shall be punishable with imprisonment for a term which may extend to three years and a fine which may extend to five thousand 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 but not less than three years and fine of less than seven lakh rupees; | **Note**: No equivalent provision in 1940 Act. |
| | (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; | (b) any drug or cosmetic other than a drug or cosmetic referred to in clause (a), the import of which is prohibited under section 10, or any rule made under this Chapter, shall be punishable with imprisonment for a term which may extend to six months, or with fine which may extend to five hundred rupees, or with both; |
| | (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; | (a) ~~any drug deemed to be adulterated under section 9A or deemed to be a spurious drug under section 9B or~~ any spurious cosmetic referred to in section 9D or any cosmetic of the nature referred to in clause (ee) of section 10 shall be punishable with imprisonment for a term which may extend to three years and a fine which may extend to five thousand 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; | (b) any drug or cosmetic other than a drug or cosmetic referred to in clause (a), the import of which is prohibited under section 10, or any rule made under this Chapter, shall be punishable with imprisonment for a term which may extend to six months, or with fine which may extend to five hundred rupees, or with both; |
| | (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. | (c) any drug or cosmetic in contravention of the provisions of any notification issued under section 10A, shall be punishable with imprisonment for a term which may extend to three years, or with fine which may extend to five thousand rupees, or with both; |
| Penalty for | **28.** Whoever having been convicted of an offence, - | (2) Whoever having been convicted of an offence— |

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| subsequent 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: | (a) under clause (a) or clause (c) of sub-section (1), is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten thousand rupees, or with both; |
| | 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; | **Note**: No equivalent provision in 1940 Act. |
| | (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; | (a) under clause (a) or clause (c) of sub-section (1), is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten thousand rupees, or with both; |
| | (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: | (b) under clause (b) of sub-section (1), is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to one thousand rupees, or with both. |
| | 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; | **Note**: No equivalent provision in 1940 Act. |
| | (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; | (a) under clause (a) or clause (c) of sub-section (1), is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten thousand rupees, or with both; |
| | (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; | (b) under clause (b) of sub-section (1), is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to one thousand rupees, or with both. |
| 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. | |

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| 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. | **14.** Where any offence punishable under section 13 has been committed, the consignment of the drugs or cosmetics in respect of which the offence has been committed shall be liable to confiscation. |
| 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. | **15.** No Court inferior to that of a Metropolitan Magistrate or of a Judicial Magistrate of the first class shall try an offence punishable under section 13. |

## CHAPTER IV
## MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS AND COSMETICSAND CLINICAL TRIAL OF DRUGS

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| Standards of quality of drugs and cosmetics. | **33.** (1) For the purposes of this Chapter, the expression "standard quality" means— | **16**. (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 | (a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and |
| | (b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed. | (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. | (2) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend the Second Schedule for the purposes of this Chapter, and thereupon the Second Schedule shall be deemed to be amended accordingly. |
| 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. | **Note**: No equivalent provision in the 1940 Act. This insertion seems to be in response to a demand from drug manufacturers who claim that violators are currently being prosecuted for offences relating to spurious and adulterated drugs. (See press report: http://www.pharmabiz.com/NewsDetails.aspx?aid=136524&sid=1) |
| Misbranded drugs. | **35.** For the purposes of this Chapter, a drug shall be deemed to be misbranded,— | **17.** 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 | (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 | (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. | (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,— | **17A.** 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 | (a) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or |

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| | (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 | (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 | (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 | (d) if it bears or contains, for the 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 | (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. | (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,— | **17B.** 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 | (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 | (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 | (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 | (d) if it has been substituted wholly or in part by another drug or substance; or |
| | (e) if it purports to be the product of a manufacturer of whom it is not truly a product; 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 active pharmaceutical ingredient. | **Note**: No equivalent provision in the 1940 Act or 1945 Rules. |
| Misbranded cosmetics. | **38.** For the purposes of this Chapter, a cosmetic shall be deemed to be misbranded,— | **17C.** For the purposes of this Chapter, a cosmetic shall be deemed to be misbranded,<br>(a) if it contains a colour which is not prescribed; or |
| | (a) if it is not labelled in the prescribed manner; or | (b) if it is not labelled in the prescribed manner; or |

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| | (b) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular. | (c) 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,— | **17D.** 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 | (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 | (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 | (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. | (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,- | **17E.** 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 | (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 | (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 | (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 | (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 | (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. | (f) if any substance has been mixed therewith so as to reduce its quality or strength. |

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| 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,- | **18.** From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf |
| | (a) manufacture for sale or distribution, or sell, stock, exhibit, offer for sale or distribute, any,- | (a) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale or distribute— |
| | (i) drug which is not of standard quality, or is misbranded, adulterated or spurious; | (i) any drug which is not of a standard quality, or is misbranded, adulterated or spurious; |
| | (ii) cosmetic which is not of standard quality, or is misbranded, adulterated or spurious; | (ii) any cosmetic which is not of a standard quality or is misbranded 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; | (iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof; |
| | (iv) 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; | (iv) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to prevent, cure or mitigate any such disease or ailment, or to have any such other effect as may be prescribed; |
| | (v) cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended; | (v) any 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; | (vi) any 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; | **Rule 106, Drugs and Cosmetics Rules, 1945 –**<br>(2) No drug may purport or claim to procure or assist to procure, or may convey to the intending user thereof any idea that it may procure or assist to procure, miscarriage in women. |
| | (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; | (b) sell, or stock or exhibit or offer for sale, or distribute any drug [or cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder; |
| | (c) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute, any drug or cosmetic, except under and in accordance with a license issued by the State Licensing Authority in such form and manner as may be prescribed: | (c) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter: |

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| | 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:<br><br>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. | Provided that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis:<br><br>Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the manufacture for sale, or for distribution, sale, stocking or exhibiting or offering for sale or distribution of any drug or class of drugs not being of standard quality. |
| | (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. | **Note**: 1940 Act does not regulate online pharmacies |
| | (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. | **Note**: No such restriction prescribed in the 1940 Act. |
| | (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. | **Note**:<br><br>(1) 2019 Rules, Clause 2 of the Second Schedule, deals with situations where data requirements for new drugs can be relaxed, abbreviated, omitted or deferred.<br>(2) 2019 Rules (R. 86) permits the import of unapproved new drug by government hospital or medical institutions if it is approved in the country of origin for treatment of life-threatening diseases. R. 91 allows for manufacture of unapproved drugs in similar circumstances – as long clinical trials are underway. |
| | (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: | **Note**: The Third Schedule of 2022 Bill contains items which are defined in the definition of 'new drug' under 2019 Rules.<br><br>(w) "new drug" means,—<br>(v) a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug; |

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| | 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. | **18A.** Every person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic. |
| Maintenance of records and furnishing of information. | **43.** Every person holding a licence under section 41 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. | **18B.** Every person holding a licence under clause (c) of section 18 shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act. |
| 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. | **19.** (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— | (2) For the purposes of section 18 a drug shall not be deemed to be misbranded or adulterated or spurious or to be below standard quality nor shall a cosmetic be deemed to be misbranded or to be below standard quality only by reason of the fact that— |
| | (a) there has been added thereto some innocuous substance or ingredient because the same is required for the manufacture or preparation of the drug or cosmetic as an article of commerce in a state fit for carriage or consumption, and not to increase the bulk, weight or measure of the drugs or cosmetics or to conceal its inferior quality or other defects; or | (a) there has been added thereto some innocuous substance or ingredient because the same is required for manufacture or preparation of the drug or cosmetic as an article of commerce in a state fit for carriage or consumption, and not to increase the bulk, weight or measure of the drug or cosmetic or to conceal its inferior quality or other defects; or |

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| | (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. | (b) in the process of manufacture, preparation or conveyance some extraneous substance has unavoidably become intermixed with it: Provided that this clause shall not apply in relation to any sale or distribution of the drug or cosmetic occurring after the vendor or distributor became aware of such intermixture |
| | (3) A person, not being the manufacturer of a drugs or cosmetics or his agent for the distribution thereof, shall not be liable for a contravention of section 41 if he proves— | (3) A person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall not be liable for a contravention of section 18 if he proves— |
| | (a) that he acquired the drugs or cosmetics from a duly licensed manufacturer, distributor or dealer thereof; | (a) that he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer thereof; |
| | (b) that he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of that section; | (b) that he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of that section; and |
| | (c) that the drug or cosmetic, while in his possession was properly stored and remained in the same state as when he acquired it; and | (c) that the drug or cosmetic, while in his possession, was properly stored and remained in the same state as when he acquired it. |
| | (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. | **Note**: No equivalent safeguard for importers and manufacturers in the 1940 Act |
| 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. | **20.** (1) The State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas in the state and in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification. |
| | (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 cosmetics as may be specified in the notification. | (2) The Central Government may also, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification. |

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| | (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. | (3) Notwithstanding anything contained in sub-section (1) or sub-section (2), neither the Central Government nor a State Government shall appoint as a Government Analyst any official not serving under it without the previous consent of the Government under which he is serving. |
| | (4) No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be a Government Analyst under sub-section (1) or sub-section (2) of this section. | (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. | 21. (1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or 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. | (2) The powers which may be exercised by an Inspector and the duties which may be performed by him, the drugs or [classes of drugs or cosmetics or classes of cosmetics] in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed shall be such as may be prescribed. |
| | (3) No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be a Drugs Control Officer under this section. | (3) No person who has any financial interest [in the import, manufacture or sale of drugs or cosmetics] shall be appointed to be an Inspector under this section. |
| | (4) Every 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). | (4) Every Inspector shall be deemed to be public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860), and shall be officially subordinate to such authority having the prescribed qualifications, as the Government appointing him may specify in this behalf. |
| | (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. | **Drugs and Cosmetics Rules, 1945**<br>**50.** (1) All Inspectors appointed by the Central Government shall be under the control of an officer appointed in this behalf by the Central Government. |

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| | (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. | **Note**:- Transitory provision. |
| 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,— | 22. (1) Subject to the provisions of section 23 and of any rules made by the Central Government in this behalf, an Inspector may, within the local limits of the area for which he is appointed,— |
| | (a) inspect,— | (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; | (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; | (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,— | (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; | (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; | (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,— | (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 | (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 | (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 |

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| | (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; | (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), | (cc) examine any record, register, document or any other material object found [with any person, or in any place, vehicle, vessel or other conveyance referred to in clause (c), |
| | and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act or the Rules made thereunder; | 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; | (cca) require any person to produce any record, register, or other document relating to the manufacture for sale or for distribution, stocking, exhibition for sale, offer for sale or distribution of any drug or cosmetic in respect of which he has reason to believe that an offence under this Chapter has been, or is being, committed; |
| | (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 thereunder for ensuring the compliance of Act and rules made thereunder: | (d) exercise such other powers as may be necessary for carrying out the purposes of this Chapter or any 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. | **23.** (6) Where an Inspector seizes any record, register, document or any other material object under clause (cc) of sub- section (1) of section 22, he shall, as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof. |
| | (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) The provisions of the Code of Criminal Procedure, 1973 (2 of 1974) shall, so far as may be, apply to any search or seizure under this Chapter as they apply to any search or seizure made under the authority of a warrant issued under section 94 of the said Code |

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| | (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. | (2A) Every record, register or other document seized under clause (cc) or produced under clause (cca) shall be returned to the person, from whom they were seized or who produce the same, within a period of twenty days of the date of such seizure or production, as the case may be, after copies thereof or extracts therefrom certified by that person, in such manner as may be prescribed, have been taken. |
| | (4) Where Drugs Control Officer takes any action under clause (c) of sub-section (1),— | **23.** (5) Where an Inspector takes any action under clause (c) of section 22,— |
| | (a) he shall use all despatch in ascertaining whether or not the drug or cosmetic contravenes any of the provisions of 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; | (a) he shall use all despatch in ascertaining whether or not the drug or cosmetic contravenes any of the provisions of the section 18 and, if it is ascertained that the drug [or cosmetic does not so contravene, forthwith revoke the order passed under the said clause or, as the case may be, take such action as may be necessary for the return of the stock seized;<br><br>(b) if he seizes the stock of the drug or cosmetic, he shall as soon as may be inform a Judicial Magistrate and take his orders as to the custody thereof; |
| | (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. | (c) without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the drug [or cosmetic], he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause. |
| | (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. | (3) If any person wilfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this Chapter, [or refuses to produce any record, register or other document when so required under clause (cca) of sub- section (1), he shall be punishable with imprisonment which may extend to three years, or with fine, or with both. |
| Procedure of Drugs Control | **48.** (1) Where a Drugs Control Officer takes any sample of a drugs or cosmetics under this Chapter, he shall tender the fair price thereof and may require a written acknowledgment therefor. | **23.** (1) Where an Inspector takes any sample of a drug [or cosmetic] under this Chapter, he shall tender the fair price thereof and may require a written acknowledgment therefor |

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| Officers for sampling for testing. | (2) Where the price tendered under sub-section (1) is refused, or where the Drugs Control Officer seizes the stock of any drug or cosmetic under clause (c) of section 47, he shall tender a receipt therefor in the prescribed form. | (2) Where the price tendered under sub-section (1) is refused, or where the Inspector seizes the stock of any drug [or cosmetic] under clause (c) of section 22, he shall tender a receipt therefor in the prescribed form |
| | (3) Where a Drugs Control Officer takes a sample of a drugs or cosmetics for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked: | (3) Where an Inspector takes a sample of a drug [or cosmetic] for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked: |
| | Provided that where the sample is taken from premises whereon the drugs or cosmetics is being manufactured, it shall be necessary to divide the sample into three portions only: | Provided that where the sample is taken from premises whereon the drug or cosmetic is being manufactured, it shall be necessary to divide the sample into three portions only: |
| | Provided further that where the drugs or cosmetics is made up in containers of small volume, instead of dividing a sample as aforesaid, the Drugs Control Officer may, and if the drugs or cosmetics be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them. | Provided further that where the drug [or cosmetic] is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug [or cosmetic] be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them. |
| | (4) The 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:— | (4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows:— |
| | (i) one portion or container he shall forthwith send to the Government Analyst for test or analysis; | (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; | (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. | (iii) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A. |
| | (5) 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 | |

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| | 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,— | **Note**:- No equivalent provision in 1940 Act or 1945 Rules |
| | (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 cosmetics are manufactured or kept. | **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 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. | **24.** Every person for the time being in charge of any premises whereon any drug or cosmetic is being manufactured or is kept for sale or distribution shall, on being required by an Inspector so to do, be legally bound to disclose to the Inspector the place where the drug or cosmetic is being manufactured or is kept, as the case may be. |
| 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. | **25.** (1) The Government Analyst to whom a sample of any drug or cosmetic has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form. |
| | (2) The 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. | (2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A, and shall retain the third copy for use in any prosecution in respect of the sample. |

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| | (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 contravention of the report. | (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 disclosed under section 18A has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in contravention 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 contravention 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. | (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 contravention 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 sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein. |
| | (5) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct. | (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. | 26. Any person or any recognised consumer association, whether such person is a member of that association or not, shall, on application in the prescribed manner and on payment of the prescribed fee, be entitled to submit for test or analysis to a Government Analyst any drug or cosmetic purchased by him or it and to receive a report of such test or analysis signed by the Government Analyst. |
| | *Explanation*.— For the purposes of this section and section 69, “recognised consumer association” means a voluntary consumer association registered under any other law for the time being in force. | Explanation.— For the purposes of this section and section 32, “recognised consumer association” means a voluntary consumer association registered under the Companies Act, 1956 (1 of 1956) or any other law for the time being in force. |

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| Powers of Central Government to prohibit manufacture, etc., of drugs and cosmetics in public interest. | **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 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. | **26A.** Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate, restrict or prohibit the manufacture, sale or distribution of such drug or cosmetic. |
| 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. | **26B.** 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,- | 27. Whoever, himself or by any other person on his behalf, manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes, — |
| | (a) any drug deemed to be adulterated under section 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: | (a) any drug deemed to be adulterated under section 17A or spurious under section 17B and which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt within the meaning of section 320 of the Indian Penal Code (45 of 1860), solely on account of such drug being adulterated or spurious or not of standard quality, as the case may be, shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to a term of life and with fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more; |
| | Provided that the fine imposed on and released from, the person convicted under this clause shall be paid, by way of compensation, to the person who had used the adulterated or spurious drugs referred to in this clause: | Provided 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. |

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| | 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. | Provided further that where the use of the adulterated or spurious drugs referred to in this clause has caused the death of a person who used such drugs, the fine imposed on and realised from, the person convicted under this clause, shall be paid to the relative of the person who had died due to the use of the adulterated or spurious drugs referred to in this clause.<br><br>Explanation.—For the purposes of the second proviso, the expression "relative" means—<br>(i) spouse of the deceased person; or<br>(ii) a minor legitimate son, and unmarried legitimate daughter and a widowed mother; or<br>(iii) parent of the minor victim; or<br>(iv) if wholly dependent on the earnings of the deceased person at the time of his death, a son or a daughter who has attained the age of eighteen years; or<br>(v) any person, if wholly or in part, dependent on the earnings of the deceased person at the time of this death,—<br>(a) the parent; or<br>(b) a minor brother or an unmarried sister; or<br>(c) a widowed daughter-in-law; or<br>(d) a widowed sister; or<br>(e) a minor child of a pre-deceased son; or<br>(f) a minor child of a pre-deceased daughter where no parent of the child is alive; or<br>(g) the paternal grandparent if no parent of the member is alive. |
| | (b) any drug — | "(b) any drug— |
| | (i) deemed to be adulterated under section 36, but not being a drug referred to in clause(a), or | (i) deemed to be adulterated under section 17A, but not being a drug referred to in clause (a), or |
| | (ii) without a valid licence as required under clause (c) of section 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: | (ii) without a valid licence as required under clause (c) of section 18, shall be punishable with imprisonment for a term which shall not be less than three year but which may extend to five years and with fine which shall not be less than one lakh rupees or three times the value of the drugs confiscated, whichever is more: |

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| | Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than three years and of fine of less than five lakh rupees; | Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than three years and of fine of less than one 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: | (c) any drug deemed to be spurious under section 17B, but not being a drug referred to in clause (a) shall be punishable with imprisonment for a term which shall not be less than seven years but which may extend to imprisonment for life and with fine which shall not be less than three lakh rupees or three times the value of the drugs confiscated, whichever is more: |
| | Provided that the Court may, for any adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less than seven years but not less than three years and fine of less than seven lakh rupees; | Provided that the Court may, for any adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less than seven years but not less than three years and of fine of less than one 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; | (d) any drug, other than a drug referred to in clause (a) or clause (b) or clause (c), in contravention of any other provision of this Chapter or any rule made thereunder, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and with fine which shall not be less than twenty thousand rupees:<br><br>Provided that the Court may, for any adequate and special reasons, to be recorded in the judgment impose a sentence of imprisonment for a term of less than one year. |
| | (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. | **Note**:- The 1940 Act or 1945 Rules do not specify qualities or deficiencies enumerated in the Fourth Schedule of 2022 Bill. |
| 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— | **27A**. 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; | (i) any cosmetic deemed to be spurious under section 17D or adulterated under section 17E shall be punishable with imprisonment for a term which may extend to three years and with fine which shall not be less than fifty thousand rupees or three times to value of the cosmetics confiscated, whichever is more; |

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| | (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. | (ii) any cosmetic other than a cosmetic referred to in clause (i) in contravention of any provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to twenty thousand rupees, or with both. |
| 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. | Note: No equivalent regime under the 1940 Act or 1945 Rules |
| 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. | **28.** Whoever contravenes the provisions of section 18A or section 24 shall be punishable with imprisonment for a term which may extend to one year, or with fine which shall not be less than twenty thousand rupees or with both. |
| 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. | **28A.** Whoever without reasonable cause or excuse, contravenes the provisions of section 18B shall be punishable with imprisonment for a term which may extend to one year or with fine which shall not be less than twenty thousand 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. | **28B.** Whoever himself or by any other person on his behalf manufactures or sells or distributes any drug or cosmetic in contravention of the provisions of any notification issued under section 26A, shall be punishable with imprisonment for a term which may extend to three years and shall also be liable to fine which may extend to five thousand rupees.<br><br>**Note**: No penalties for violating Section 26B (equivalent to Cl. 61 of 2022 Bill) of the 1940 Act. |
| 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. | **29.** Whoever uses any report of a test or analysis made by the Central Drugs Laboratory or by a Government Analyst, or any extract from such report, for the purpose of advertising any drug or cosmetic, shall be punishable with fine, which may extend to five hundred rupees |
| Penalty for | **63.** (1) Whoever having been convicted of an offence,— | **30.** (1) Whoever having been convicted of an offence.- |

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| subsequent offences. | (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:<br><br>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; | (a) Under clause (b) of section 27, is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than seven years but which may extend to ten years and with fine which shall not be less than two lakh rupees; |
| | (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; | (b) under clause (c) of section 27 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall less than ten years but which may extend to imprisonment for life and with fine which shall not be less than three lakh rupees |
| | (c) under clause (d) of section 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:<br><br>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; | (c) under clause (d) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to four years or with fine which shall not be less than fifty thousand rupees, or with both. |
| | (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:<br><br>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; | **Note**: No equivalent provision in the 1940 Act. |
| | (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. | (1A) Whoever, having been convicted of an offence under section 27A is again convicted under that section, shall be punishable with imprisonment for a term which may extend to two years, or with fine which may extend to two thousand rupees, or with both. |

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| | (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. | (1A) Whoever, having been convicted of an offence under section 27A is again convicted under that section, shall be punishable with imprisonment for a term which may extend to two years, or with fine which may extend to two thousand rupees, or with both. |
| | (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. | **Note**: No equivalent provision in the 1940 Act. |
| | (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. | (2) Whoever, having been convicted of an offence under section 29 is again convicted of an offence under the same section shall be punishable with imprisonment which may extend to two tears, or with fine which shall not be less than ten thousand rupees, or with both. |
| 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. | **Note**: No equivalent provision in the 1940 Act. |
| | (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— | **31.** (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 | (i) manufacture of any drug deemed to be misbranded under section 17, adulterated under section 17A or spurious under section 17B; or |

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| | (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. | (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 clause (c) of section 18; any implements or machinery used in such manufacture, sale or distribution and any receptacles, packages or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances used in carrying such drug shall also be liable to confiscation. |
| | (2) Without prejudice to the provisions contained in sub-section (1) where the Court is satisfied, on the application of 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. | (2) Without prejudice to the provisions contained in sub-section (1) where the Court is satisfied, on the application of an Inspector or otherwise and after such inquiry as may be necessary that the drug or cosmetic is not of standard quality or is a misbranded, adulterated or spurious drug or misbranded or spurious cosmetic, such drug or, as the case may be, such cosmetic shall be liable to confiscation. |
| 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. | **31A.** The provisions of this Chapter except those contained in section 31 shall apply in relation to the manufacture, sale or distribution of drugs of 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”)- | **Note:- Clause 67 is similar to Section 32, Food Safety and Standards Act, 2006.**<br><br>(1) If the Designated Officer has reasonable ground for believing that any food business operator has failed to comply with any regulations to which this section applies, he may, by a notice served on that food business operator (in this Act referred to as an "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; | (a) state the grounds for believing that the food business operator has failed to comply with the regulations; |
| | (b) specify the matters which constitute the licensee’s failure so to comply; | (b) specify the matters which constitute the food business operator'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 | (c) specify the measures which, in the opinion of the said Authority, the food business operator must take, in order to secure compliance; and |

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| | (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. | (d) require the food business operator 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. | **1945 Rules: Manufacture or sale of drugs**<br>85. (2) 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 Part 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 an Inspector 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. |
| | (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. | 85. (1) 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 therefor, cancel a licence issued under this Part, 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 an Inspector, 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. | (3) A licensee whose licence has been suspended or cancelled by the Central Licence Approving Authority or Licensing 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 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.<br><br>**Note**: Clause 68(3) of the 2022 Bill has been copied from the 1945 Rules and without making necessary changes. |

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| Cognizance of offences relating to drugs and cosmetics. | **69.** (1) No prosecution under this Chapter shall be instituted except by— | **32.** (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 | (a) an Inspector; or |
| | (b) any Gazetted officer of the Central Government or a State Government authorized 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 | (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 | (c) the person aggrieved; or |
| | (d) a recognised consumer association whether such person is a member of that association or not. | (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. | (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. | (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. | **32A.** Where, at any time during the trial of any offence under this Chapter alleged to have been committed by any person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof the Court is satisfied, on the evidence adduced before it, that such manufacturer or agent is also concerned in that offence, then, the Court may, notwithstanding anything contained in sub-sections (1), (2) and (3) of section 319 of the Code of Criminal Procedure, 1973 (2 of 1974), proceed against him as though a prosecution had been instituted against him under section 32. |

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| Compounding of 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: | **32B.** (1) Notwithstanding anything contained in the Code of Criminal Procedure, 1973, (2 of 1974) any offence punishable under clause (b) of sub-section (1) of section 13, section 28 and section 28A of this Act (whether committed by a company or any officer thereof), not being an offence punishable with imprisonment only, or with imprisonment and also with fine, may, either before or after the institution of any prosecution, be compounded by the Central Government or by any State Government or any officer authorised in this behalf by the Central Government or a State Government, on payment for credit to that Government of such sum as that Government may, by rules made in this behalf, specify: |
| | Provided that such sum shall not, in any case, less or exceed the maximum amount of the fine which may be imposed under this Act for the offences so compounded: | Provided that such sum shall not, in any case, exceed the maximum amount of the fine which may be imposed under this Act for the offence so compounded: |
| | Provided further that in cases of subsequent offences, 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. | Provided further that in cases of subsequent offences, the same shall not be compoundable.<br><br>**Note**:- 1940 Act does not permit compounding of subsequent offences. |
| | (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) Where an offence is compounded under sub-section (1), no proceeding or further proceeding, as the case may be, shall be taken against the offender in respect of the offence so compounded and the offender, if in custody, shall be released forthwith. |
| | (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. | **Note**:- 1940 Act does not permit compounding of subsequent offences. |
| 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. | **2019 Rules**<br>**19**. (1) No person or institution or organisation shall conduct clinical trial of a new drug or investigational new drug,—<br>(i) except in accordance with the permission granted by the Central Licencing Authority; and<br>(ii) without the protocol there of having been approved by the Ethics |

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| | *Explanation:* For the removal of doubt, it is hereby declared that the person includes sponsor, clinical research organization, any other organisation or investigator. | Committee for clinical trial registered in accordance with the provisions of rule 8.<br>(2) Every person associated with the conduct of clinical trial of a new drug or investigational new drug shall follow the general principles and practices as specified in the First Schedule.<br>(3) No person or institution or organisation shall conduct clinical trial of a new drug or investigational new drug except in accordance with the procedure prescribed under the provisions of the Act and these rules.<br><br>**2019 Rules**<br>**31**. (1) No bioavailability or bioequivalence study of any new drug or investigational new drug shall be conducted in human subjects by any person or institution or organisation except in accordance with the provisions of the Act and these rules.<br>(2) No person or institution or organisation shall conduct bioavailability or bioequivalence study of a new drug or investigational new drug in human subjects except in accordance with the permission granted by the Central Licencing Authority and without the protocol thereof having been approved by the Ethics Committee registered under rule 8.<br>(3) Every person associated with the conduct of bioavailability or bioequivalence study of a new drug or investigational new drug shall follow the general principles and practices as specified in the First Schedule. |
| | (2) A new drug shall continue to be a new drug for the purposes of this Act for such period as may be prescribed. | **2019 Rules**<br>**2(1)(w)** Explanation.— The drugs, other than drugs referred to in sub-clauses (iv) and (v), shall continue to be new drugs for a period of four years from the date of their permission granted by the Central Licencing Authority and the drugs referred to in sub-clauses (iv) and (v) shall always be deemed to be new drugs; |
| 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. | **2019 Rules**<br>40. (1) Where an injury occurs to any subject during clinical trial or bioavailability and bioequivalence study of a new drug or an investigational new drug, the sponsor, shall provide free medical management to such subject as long as required as per the opinion of investigator or till such time it is established that the injury is not related to the clinical trial or bioavailability or bioequivalence study, as the case may be, whichever is earlier |

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| | (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. | **2019 Rules**<br>39. (2)Where permanent disability or any other injury occurs to a trial subject during a clinical trial or bioavailability or bioequivalence study, the trial subject shall be provided financial compensation by the sponsor or its representative, who has obtained permission to conduct the clinical trial or bioavailability or bioequivalence study, in accordance with the procedure specified in rule 42. |
| | (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. | **2019 Rules**<br>39. (1) Where any death of a trial subject occurs during a clinical trial or bioavailability or bioequivalence study, the legal heir of the trial subject shall be provided financial compensation by the sponsor or its representative, who has obtained permission to conduct the clinical trial or bioavailability or bioequivalence study, in accordance with the procedure specified in rule 42. |
| 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. | **2019 Rules, Rule 11(i) provides that the functions of the Ethics Committee include: "**oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules …;**"** |
| | (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. | **7.** Constitution of Ethics Committee for clinical trial.— (1) The Ethics Committee shall have a minimum of seven members from medical, non-medical, scientific and non-scientific areas with at least,— (i) one lay person; (ii) one woman member; (iii) one legal expert; (iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian. |
| | (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. | **11.** Functions of Ethics Committee.— The Ethics Committee for clinical trial shall perform the following functions for a person, institution or organization; namely:— (i) review and accord approval to a clinical trial, bioavailability or bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, ~~Good Clinical Practices Guidelines and other applicable regulations;~~ |

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| 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. | **2019 Rules**<br>**14.** Suspension or cancellation of registration of Ethics Committee for clinical trial.— (1) Where Central Licencing Authority is of the opinion that any Ethics Committee fails to comply with any provision of the Act or these rules, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. |
| | (2) Where an Ethics Committee is debarred, its permission or registration shall be deemed to have been revoked. | **14(3)(v)** debar its members to oversee any clinical trial in future for such period as may be considered appropriate by the Central Licencing Authority.<br><br>**Note**: 2019 Rules does not have a similar provision for deemed revocation. |
| 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. | **2019 Rules**<br>**29.** Inspection of premises relating to clinical trial.— The person or the institution or the organisation permitted to conduct clinical trial ~~under rule 22 in Form CT-06 or rule 23 in Form CT-4A~~ including his representatives and investigator, shall allow any officer authorised by the Central Licencing Authority, who may, if considered necessary, be accompanied by an officer authorised by the State Licencing Authority, to enter the premises and clinical trial site with or without prior notice to inspect, search or seize, any record, statistical result, document, investigational drug and other related material~~; and reply to queries raised by the inspecting authority in relation to conduct of such clinical trial.~~ |
| | (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. | **2019 Rules**<br>**29.** Inspection of premises relating to clinical trial.— ~~The person or the institution or the organisation permitted to conduct clinical trial under rule 22 in Form CT-06 or rule 23 in Form CT-4A including his representatives and investigator, shall allow~~ any officer authorised by the Central Licencing Authority, ~~who may, if considered necessary, be accompanied by an officer authorised by the State Licencing Authority, to enter the premises and clinical trial site with or without prior notice to inspect, search or seize, any record, statistical result, document, investigational drug and other related material;~~ and reply to queries raised by the inspecting authority in relation to conduct of such clinical trial. |

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| 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. | **13.** Maintenance of records by Ethics Committee for clinical trial.— (1) The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial. |
| 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. | **Note**: 1940 Act does not prescribe penalties for violations tailored for clinical trial. |
| 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, | **2019 Rules**<br>30. (1) Where any person or institution or organisation to whom permission has been granted under rule 22 in Form CT-06 or rule 23 in Form CT-4A fails to comply with any provision of the Act and these rules, the Central Licencing Authority may, after giving an opportunity to show cause and after affording an opportunity of being heard, by an order in writing, take one or more of the following actions, namely:— |
| | (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; | (i) issue warning in writing describing the deficiency or defect observed during inspection or otherwise, which may affect adversely the right, or well- being of a trial subject or the validity of clinical trial conducted; |
| | (b) direct that study may be rejected or discontinued; | (ii) reject the results of clinical trial; |
| | (c) suspend or cancel the clinical trial permission; | (iii) suspend for such period as considered appropriate or cancel the permission granted under rule 22 in Form CT-06 or rule 23 in Form CT-4A; |

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| | (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. | (iv) debar the investigator or the sponsor including his representatives to conduct any clinical trial in future for such period as considered appropriate by the Central Licencing Authority. |
| | (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. | (2) Where a person or an institution or an organisation to whom permission has been granted under rule 22 in Form CT06 or rule 23 in Form CT-4A or the sponsor is aggrieved by the order of the Central Licencing Authority, the person or the institution or the organisation may, within a period of sixty working days of the receipt of the order, make an appeal to the Central Government and that Government may, after such enquiry, as deemed necessary, and after affording an opportunity of being heard, pass such order in relation thereto as may be considered appropriate in the facts and circumstances of the case. |
| 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: | **Note**: No equivalent provision in the 2019 Rules. |
| | 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, a pproval, 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. | |
| Power of Central Government to make rules for Chapter | **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: | **33**. (1) The Central Government may, after consultation with or on the recommendation of the Board and after previous publications by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter: |

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| IV. | 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. | 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,— | (2) Without prejudice to the generality of the foregoing power, such rules may— |
| | *(a)* standards of cosmetics under clause (b) of sub-section (1) of section 33; | **Note**: New clause |
| | *(b)* the manner of labelling a drug under clause (b) of section 35; | (j) regulate the mode of labelling packed drugs ~~or cosmetics~~, and prescribe the matters which shall or shall not be included in such labels |
| | (*c*) the colour which a drug may bear or contain for purposes of colouring under clause of section 36; | (dd) prescribe under clause (d) of section 17A the colour or colours which a drug may bear or contain for purposes of colouring; |
| | *(d)* the manner of labelling a cosmetic under clause (b) of section 38; | (j) regulate the mode of labelling packed ~~drugs or~~ cosmetics, and prescribe the matters which shall or shall not be included in such labels |
| | *(e)* the colour which a cosmetic may bear or contain for purposes of colouring under clause (d) of section 40; | (dda) prescribe under clause (d) of section 17E the colour or colours which a cosmetic may bear or contain for the purposes of colouring |
| | *(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; | **Note**: New clause |
| | *(g)* other effect which a drug may have under sub-clause (iv) of clause (a) of sub-section (1) of section 41; | **Note**: New clause |
| | *(h)* the form and manner of issue of license or permission under section 41; | **Note**: New clause |
| | *(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; | (k) prescribe the conditions to be observed in the packing in bottles, packages or other containers, of imported drugs 1 [or cosmetics] 3 [including the use of packing material which comes into direct contact with the drugs]; |

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| | *(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; | (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; |
| | *(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; | (g) prescribe the conditions subject to which small quantities of drugs may be manufactured for the purpose of examination, test or analysis; |
| | *(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; | **Note**: New clause |
| | *(m)* the manner for grant of permission or approval by the Central Licensing Authority under Sub-section (3) of section 41; | **Note**: New clause |
| | *(n)* pre-clinical and clinical data requirements of new drugs to be abbreviated, deferred or waived off under sub-section (4) of section 41; | **Note**: New clause |
| | *(o)* the records, registers and other documents to be kept and maintained under section 43; | (ee) prescribe the records, registers or other documents to be kept and maintained under section 18B; |
| | *(p)* qualifications of Government Analyst under section 45; | (b) prescribe the qualifications and duties of Government Analysts ~~and the qualifications of Inspectors~~ |
| | *(q)* qualifications, experience and duties of Drugs Control Officer under section 46; | (b) prescribe ~~the qualifications and duties of Government Analysts and~~ the qualifications of Inspectors |
| | *(r)* the manner of certifying copies or extracts of record, register or other documents under sub-section (3) of section 47; | (eeb) prescribe the manner in which copies are to be certified under sub-section (2A) of section 22; |
| | *(s)* the form and manner of taking sample of drug or cosmetic under section 48; | **Note**: New clause |
| | *(t)* the manner in which the report of the Government Analyst may be challenged under sub-section (1) of section 52; | **Note**: New clause |
| | *(u)* the procedure for further actions on the report of the Government Analyst under sub-section (2) of section 52; | **Note**: New clause |
| | *(v)* the manner of submission of application under section 53; | **Note**: New clause |

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| | *(w)* extent and manner to determine the sum under sub-section (1) of section 71; | (r) sum which may be specified by the Central Government under section 32B. |
| | *(x)* the conditions subject to which and the form and the manner in which the permission may be granted under section 72; | **Note**: New clause |
| | *(y)* the period for which a new drug shall continue to be a new drug under sub-section (2) of section 72; | **Note**: New clause |
| | *(z)* the manner of providing compensation under section 73; | **Note**: New clause |
| | *(za)* the manner of constitution of the Ethics Committee under sub-section (1) of section 74; | **Note**: New clause |
| | *(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; | **Note**: New clause |
| | *(zc)* the data, record, register and other documents to be maintained under section 77; | **Note**: New clause |
| | *(zd)* the manner of imposing penalty by the adjudicating officer under section 79. | **Note**: New clause |
| Chapter not 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. | **33A**. Save as otherwise provided in this Act, nothing contained in this Chapter shall apply to Ayurvedic, Siddha Siddha or Unani drugs. |

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| | ***A. Board and Committee*** | |
| Application of Chapter V. | **85.** The Chapter V shall apply to Ayurveda, Siddha, Sowa-Rigpa, Unani and Homeopathy drugs. | **33B.** Application of Chapter IVA.—This Chapter shall apply only to Ayurvedic, Siddha and Unani drugs. |
| | **86.** Definitions **[…]** | |
| 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.- | **33C.** (1) The Central Government shall, by notification in the Official Gazette and with effect from such date as may be specified therein, constitute a Board to be called the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board to advise the Central Government and the State Governments on Technical matters arising out of this Chapter and to carry out the other functions assigned to it by this Chapter. |
| | (2) the Board shall consist of the following members, namely:- | (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 | (iii) the principal officer dealing with Indian systems of medicine in the Ministry of Health, ex officio; |
| | (ii) the CEO, National Medicinal Plant Board, Ex officio | **Note**: New clause |
| | (iii) the Drugs Controller General of India, ex officio | (ii) the Drugs Controller, India, ex officio; |
| | (iv) the Deputy Drug Controller Ayush, ex officio | **Note**: New clause |
| | (v) An officer in Directorate General of Health Services dealing with Ayurveda, Siddha, Sowa-Rigpa, Unani, Homoeopathy Drugs, ex officio | (i) the Director General of Health Services ex officio; |
| | (vi) the Director of the Pharmacopoeia Commission of Indian system of Medicine and Homoeopathy, ex officio; | **Note**: New clause |
| | (vii)The Director or representative of Indian Pharmacopoeia Commission, Ex officio; | **Note**: New clause |
| | (viii) The head of Scientific Research Board constituted under section 89. | **Note**: New clause |
| | (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 | |

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| | Pharmacologists. | |
| | (x) one expert from Department of Animal Husbandry | **Note**: New clause |
| | (xi) one representative from Department of Pharmaceutical | **Note**: New clause |
| | (xii) one person to be nominated by Central Government from the medical institution involved in conduct of Clinical trial | **Note**: New clause |
| | (xiii) one person from Department of Science and Technology. | **Note**: New clause |
| | (xiv) one person holding the appointment of Government Analyst under section 105, to be nominated by the Central Government; | (v) one person holding the appointment of Government Analyst under section 33F, to be nominated by the Central Government; |
| | (xv) one Pharmacognocist to be nominated by the Central Government; | (vi) one Pharmacognocist to be nominated by the Central Government; |
| | (xvi) one Phyto-chemist to be nominated by the Central Government; | (vii) 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 | **Note**: New clause |
| | (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-Rigpa sub- committee, one from amongst the members of the Unani sub-committee and one from amongst the members of the Homoeopathy sub-committee; | (viii) four persons to be nominated by the Central Government, two from amongst the members of the Ayurvedic Pharmacopoeia Committee, one from amongst the members of the Unani Pharmacopoeia Committee and one from amongst the members of the Siddha Pharmacopoeia Committee; |
| | (xix) one expert each in Dravyaguna, ILM-UL-ADVIA, Gunapadam, and Homoeopathy Materia Medica to be nominated by the Central Government; | (ix) one teacher in Darvyaguna, and Bhaishajya Kalpana, to be nominated by the Central Government;<br><br>(x) one teacher in ILM-UL-ADVIA and TAKLIS-WA-DAWASAZI, to be nominated by the Central Government;<br><br>(xi) one teacher in Gunapadam 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; | (xii) three persons, one each to represent the Ayurvedic, Siddha and Unani 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. | **Note**: New clause |
| | (xxii) five persons, one each from among the Registered Medical practitioners of Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy | (xiii) three persons, one each from among the practitioners of Ayurvedic, Siddha and Unani Tibb systems of medicine to be nominated by the |

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| | drugs system of medicine to be nominated by the Central Government. | Central Government. |
| | | **Note**: The 2022 Bill excludes (iv) the Director of the Central Drugs Laboratory, Calcutta ex officio; |
| | (3) The Central Government shall appoint a member of the Board as its Chairman; | (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; | (4) The nominated members of the Board shall hold office for three years but shall be eligible for renomination. |
| | (5) The functions of the Board may be exercised notwithstanding any vacancy therein; | (6) 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 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; | **Note**: New clause |
| | (8) The procedure for conduct of business of Board shall be such as may be prescribed. | (5) The Board may, subject to the previous approval of the Central Government, make bye - laws fixing a quorum and regulating its own procedure and conduct of all business to be transacted by it. |
| 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. | **33D**. (1) The Central Government may constitute an Advisory Committee to be called the Ayurvedic, Siddha and Unani Drugs Consultative Committee to advise the Central Government, the State Governments and the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board on any matter for the purpose of securing uniformity throughout India in the administration of this Act in so far as it relates to Ayurvedic, Siddha or Unani drugs. |
| | (2) The Central Government shall nominate the Chairperson to the committee. | Comment- New Sub-section |
| | (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. | (2) The Ayurvedic, Siddha and Unani Drugs Consultative Committee shall consist of two persons to be nominated by the Central Government as representatives of that Government and not more than one representative of each State to be nominated by the State Government concerned. |
| | (4) The Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy Drugs | (3) The Ayurvedic, Siddha and Unani Drugs Consultative Committee |

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| | Consultative Committee shall meet as and when required to do so by the Central Government. | shall meet when required to do so by the Central Government and shall regulate its own procedure. |
| | (5) The Ayurveda, Siddha, Sowa Rigpa, Unani, Homeopathy Drugs, Medical Devices and Cosmetics Consultative Committee shall have power to regulate its own procedure. | (3) The Ayurvedic, Siddha and Unani Drugs Consultative Committee shall meet when required to do so by the Central Government and shall regulate its own procedure. |
| 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. | **Note**: New clause. As an aside, there are research councils constituted under the AYUSH Ministry to promote research and development of traditional medicines for Ayurveda, Unani, Siddhi, Homeopathy, and Yoga and Naturopathy. See; https://main.ayush.gov.in/1083-2/ |
| | (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. | **Note**: New clause. |
| | (3) The Chairperson of the Board shall be nominated by the Central Government. | **Note**: New clause. |
| | (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. | **Note**: New clause. |
| | (5) The Board shall have its infrastructure including laboratories or may adopt or authorise such other laboratories to undertake its functions. | **Note**: New clause. |
| 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. | **Note**: New clause. |
| The Central Drugs Laboratory and State drug | **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:-<br><br>(a) Central Drug Laboratories for - | **Note**: New clause. |

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| laboratory for Ayurveda, Siddha, Sowa Rigpa, Unani, Homeopathy. | (i) testing and analysis of Ayurveda, or Siddha, or Sowa-Rigpa, or Unani or Homoeopathy Drugs and cosmetics;<br>(ii) functioning as an appellate authority or centre;<br>(iii) carrying out other functions assigned.<br><br>(b) Central Medical Devices testing centres relating to Ayurveda, or Siddha, or Sowa-Rigpa, or Unani or Homoeopathy systems of Medicine for:-<br>(i) testing and evaluation of medical devices;<br>(ii) functioning as an appellate centre;<br>(iii) carrying out other functions assigned.<br>in such manner as prescribed. | |
| | (2)The State Government may, by notification, establish or designate;<br>(a) State drugs laboratory for —-<br>(i) testing and analysis of Drugs and cosmetics of Ayurveda, or Siddha, or Sowa-Rigpa, or Unani or Homoeopathy<br>(ii) carrying out other functions assigned.<br>(b) State Medical devices testing centres relating to Ayurveda, or Siddha, or Sowa- Rigpa, or Unani or Homoeopathy systems of Medicine for:-<br>(i) testing and evaluation of medical devices;<br>(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 | **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— | **Note**: Medicinal Boards already exists at the Central and state level.<br><br>The National Medicinal Plants Board was setup on 24th November 2000 under Ministry of AYUSH. *The primary mandate of NMPB is to develop an appropriate mechanism for coordination between various ministries/ departments/ organizations in India and implements support policies/programs for overall (conservation, cultivation, trade and export) growth of medicinal plants sector both at the Central /State and* |

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| cultivation and facilitation Centre for medicinal plant. | | *International level.* See: www.nmpb.nic.in |
| | (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. | **Note**: New clause. |
| | (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. | **Note**: New clause. |
| | (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. | **Note**: New clause. |
| | (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. | **Note**: New clause. |
| | (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. | **Note**: New clause. |
| | (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. | **Note**: New clause. |
| | ***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— | **Note**: New clause. |
| | (a) in relation to Ayurveda, Unani, Siddha, Sowa-Rigpa and Homoeopathy drugs shall be the standards specified in the Sixth Schedule. | **Note**: New clause. |
| | (b) the cosmetic of Ayurveda, Siddha, Sowa-Rigpa, Unani, and Homeopathy complies with such standard as may be prescribed. | **Note**: New clause. |
| | (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, | **Note**: New clause. |

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| | 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. | **Note**: New clause. |
| 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— | **33E.** Misbranded drugs.—For the purposes of this Chapter, an Ayurvedic, Siddha or Unani drug shall be deemed to be misbranded— |
| | (a) if it is so coloured, coated, powdered or polished that damage is concealed, or if it is made to appear of better or greater therapeutic value than it really is; or | (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 | (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. | (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 cosmetic in 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:- | **Note**: 1940 Act does not regulate misbranded *cosmetics*. |
| | (a) if it is not labelled in the prescribed manner; or | **Note**: New clause. |
| | (b) if its label or container or anything accompanying the cosmetic bears any statement, which is false or misleading in any particular. | **Note**: New clause. |
| Adulterated drugs in relation to Ayurvedic, | **97.** (1) For the purposes of this Chapter, an Ayurvedic, Sowa Rigpa, Siddha Unani or Homoeopathic drug shall be deemed to be adulterated,- | **33EE.** For the purposes of this Chapter, an Ayurvedic, Siddha or Unani drug shall be deemed to be adulterated,— |
| | (a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or | (a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or |

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| Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic. | (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 | (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 | (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 | (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 | (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. | (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. | 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, | **Note**: 1940 Act does not regulate adulterated *cosmetics*. |
| | (a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or | **Note**: New clause. |
| | (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 | **Note**: New clause. |
| | (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 | **Note**: New clause. |
| | (d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or | **Note**: New clause. |
| | (e) if it contains any harmful or toxic substance which may render it injurious to health; or | **Note**: New clause. |
| | (f) if any substance has been mixed therewith so as to reduce its quality or strength. | **Note**: New clause. |
| Spurious | **99.** For the purposes of this Chapter, an Ayurvedic, Homoeopathic, | **33EEA.** Spurious drugs.—For the purposes of this Chapter, an |

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| drugs in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic. | Sowa Rigpa, Siddha or Unani drug shall be deemed to be spurious— | Ayurvedic, Siddha or Unani drug shall be deemed to be spurious— |
| | (a) if it is sold, or offered or exhibited for sale, under a name which belongs to another drug; except the classical formulation of Ayurveda, Siddha, Sowa Rigpa or Unani bearing the same name but different formulation or | (a) if it is sold, or offered or exhibited for sale, under a name which belongs to another drug; or |
| | (b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or | (b) if it is an imitation of, or is 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 | (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 | (d) if it has been substituted wholly or in part by any other drug or substance; or |
| | (e) if it purports to be the product of a manufacturer of whom it is not truly a product. | (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. | **Note**: New clause. |
| | *Explanation*: -<br>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.<br>*(a)* For the purpose of clause (f), certain substances like musk, elephant tusk, certain medicinal plants are prohibited for protection of those species. | **Note**: New clause. |
| Spurious Cosmetic in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and | **100.** For the purposes of this Chapter, an Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy cosmetic shall be deemed to be spurious | **Note**: 1940 Act does not regulate spurious *cosmetics*. |
| | (a) if it is manufactured under a name which belongs to another cosmetic; or | **Note**: New clause. |
| | (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 | **Note**: New clause. |

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| Cosmetic. | (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 | **Note**: New clause. |
| | (d) if it purports to be the product of a manufacturer of whom it is not truly a product. | **Note**: New clause. |
| 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. | **Note**: New clause. |
| | (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. | **33EEB**. No person shall manufacture for sale or for distribution any Ayurvedic, Siddha and Unani 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. | **Note**: New clause. |
| | (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. | **Note**: New clause. |
| 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- | **Note: Prohibitions contained in Clause 102 of the 2022 Bill does not cover cosmetics**<br>**33EEC.** 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— | (a) manufacture for sale or for distribution— |
| | (i) any misbranded, adulterated or spurious Ayurvedic, Homoeopathic, Sowa Rigpa, Siddha or Unani drug; | (i) any misbranded, adulterated or spurious Ayurvedic, 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 | (ii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true list of all the |

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| | in it; and | 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; | (iii) any Ayurvedic, 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; | (b) sell, stock or exhibit or offer for sale or distribute any Ayurvedic, Siddha or Unani drug which has been manufactured in contravention of any of the provisions of this Act, or any rule made thereunder, |
| | (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:<br><br>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: | (c) manufacture for sale or for distribution, any Ayurvedic, Siddha or Unani drug except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter by the prescribed authority :<br><br>Provided that nothing in this section shall apply to Vaidyas and Hakims who manufacture Ayurvedic, Siddha or Unani drug for the use of their own patients : |
| | Provided further that nothing in this section shall apply to the manufacture, subject to the prescribed conditions, of small quantities of any Ayurvedic, Siddha, Sowa Rigpa, Unani or Homoeopathic drug for the purpose of examination, test or analysis. | Provided further that nothing in this section shall apply to the manufacture, subject to the prescribed conditions, of small quantities of any Ayurvedic, Siddha or Unani drug for the purpose of examination, test or analysis. |
| | (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. | **Note**: New clause. |
| | (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. | **Note**: New clause. |
| | (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: | **Note**: New clause. |
| | (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. | **Note**: New clause. |

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| | (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. | **Note**: New clause. |
| 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. | Comment- New Provision |
| 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. | **33EED**. Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied on the basis of any evidence or other material available before it that the use of any Ayurvedic, Siddha or Unani drug is likely to involve any risk to human being 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 expendient 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. | **33F.** (1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas as may be assigned to them by the Central Government or the State Government, as the case may be. |
| | (2) Notwithstanding anything contained in sub-section (1), neither the Central Government nor a State Government shall appoint as a Government Analyst any official not serving under it without the previous consent of the Government under which he is serving. | (2) Notwithstanding anything contained in sub-section (1), neither the Central Government nor a State Government shall appoint as a Government Analysts 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. | (3) No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be a Government Analysts under this section. |
| Drugs Control | **106.** (1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, | **33G**. (1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, |

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| Officers under Chapter V. | 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. | having the prescribed qualifications to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be. |
| | (2) The powers which may be exercised by 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. | (2) The powers which may be exercised by an Inspector and the duties which may be performed by him and the conditions, limitations or restrictions subject to which such powers and duties may be exercised or performed shall be such as may be prescribed. |
| | (3) No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be a Drugs Control Officer under this section. | (3) No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be an Inspector under this section. |
| | (4) Every 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. | (4) Every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860) and shall be officially subordinate to such authority as the Government appointing him may specify in this behalf. |
| | (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. | **Note**: New clause. |
| 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. | **33H**. The provisions of sections 22, 23, 24 and 25 and the rules, if any, made thereunder shall, so far as may be, apply in relation to an Inspector and a Government Analyst appointed under this Chapter as they apply in relation to an Inspector and a Government Analyst appointed under Chapter IV, subject to the modification that the references to "drug" in the said sections, shall be construed as references to Ayurvedic, Siddha or Unani drug. |
| Penalty for manufacture, sale, etc., of Ayurvedic, Homoeopathic, Sowa Rigpa, Siddha or Unani drug in contravention of | **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 — | **33-I.** Whoever himself or by any other person on his behalf— (1) manufactures for sale or for distribution, — |
| | (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. | **Note**: New clause. |
| | (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 | **Note**: New clause. |

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| this Chapter | Schedule, shall be punishable with fine not exceeding one lakh rupees. | |
| | (c) any Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs—<br>(i)deemed to be adulterated under Section 97,<br>(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; | (a) any Ayurvedic, Siddha or Unani drug—<br>(i) deemed to be misbranded under section 33E,<br>(ii) deemed to be adulterated under section 33EE, or<br>(iii) without a valid licence or in violation of any of the conditions thereof, as required under section 33 EEC, shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than twenty thousand rupees or three times the value of the drugs confiscated, whichever is more; |
| | (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: | (b) any Ayurvedic, Siddha or Unani drug deemed to be spurious under section 33EEA, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and with fine which shall not be less than fifty thousand rupees or three times the value of the drugs confiscated, whichever is more:<br><br>Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than one year and of fine of less than fifty thousand rupees or three times the value of the drugs confiscated, whichever is more; or |
| | (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. | (c) any Ayurvedic, Siddha or Unani drug in contravention of the provisions of any notification issued under section 33EED shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to fifty thousand rupees or three times the value of the drugs confiscated, whichever is more. |
| | 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 | **Note**: 1940 Act contains an identical Proviso – but limited to spurious medicines.<br><br>The portion highlighted [or] is a typographical error. Copied the Proviso from 33-I(1)(b) of 1940 Act. |
| | (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. | (2) Contravenes any other provisions of this Chapter or of section 24 as applied by section 33H or any rule made under this Chapter, shall be punishable with imprisonment for a term which may extend to six months and with fine which shall not be less than ten thousand rupees. |
| Penalty for manufacture, sale, etc., of | **109.** Whoever himself or by any other person on his behalf— | **Note**: New clause. 1940 Act does not deal with cosmetics. |
| | (1)manufactures for sale or for distribution, or sells, or stocks or exhibits or offer for sale or distributes- | **Note**: New clause. |

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| Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy cosmetics in contravention of this Chapter | (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; | **Note**: New clause. |
| | (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; | **Note**: New clause. |
| Compounding of certain offences relating to Ayurveda, Siddha, Sowa- Rigpa, Unani, Homeopathyd rugs 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. | **Note**: New clause. |
| | 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. | **Note**: New clause. |
| | (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. | **Note**: New clause. |
| | (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. | **Note**: New clause. |
| Penalty for subsequent | **111.** Whoever having been convicted of an offence,— | **33J.** Whoever having been convicted of an offence,— |
| | (1) under clause (a) of sub-section (1) of section 108 is again convicted | **Note**: No equivalent provision in 1940 Act to deal with not of standard |

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| offences in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic. | 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. | quality medicines specified in the Eighth Schedule of 2022 Bill. |
| | (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. | (a) under clause (a) of sub-section (1) of section 33-I is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to two years and with fine which shall not be less than fifty thousand rupees or three times the value of the drugs confiscated, whichever is more;<br><br>**Note**: Clause 108(1)(b) of 2022 Bill also covers non-standard medicines. |
| | (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: | (b) under clause (b) of sub-section (1) of section 33-I is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than two years but which may be extend to six years and with fine which shall not be less than one lakh rupees or three times the value of the drugs confiscated, whichever is more: |
| | Provided that the Court may, for any adequate and special reasons to be mentioned in the 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. | Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than two years and of fine of less than one 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. | (c) under sub-section (2) of section 33-I is again convicted of an offence under that sub-section, shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than twenty thousand rupees or three times the value of the drugs confiscated, whichever, is more. |
| 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. | **33K.** Where any person has been convicted under this Chapter, the stock of the Ayurvedic, Siddha or Unani drug, in respect of which the contravention has been made, shall be liable to confiscation. |
| | (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 | **Note**: 1940 Act does not contain an enabling provision for recall. |

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| | 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. | **33KA.** Disclosure of name of manufacturer, etc. — Every person, not being the manufacturer manufacturer of any Ayurvedic, Siddha or Unani drug or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and . other particulars of the person from whom he acquired the Ayurvedic, Siddha or Unani drug. |
| Maintenance of records and furnishing of information in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathi c 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. | **33KB.** Every person holding a licence under clause (c) of section 33EEC shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any 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. | **Note**: New clause |
| Application of provisions to Government departments in relation to Ayurvedic, Siddha, Sowa Rigpa, Unani and | **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. | **33L**. Application of provisions to Government departments.—The provisions of this Chapter except those contained in section 33K shall apply in relation to the manufacture for sale, sale, or distribution of any Ayurvedic, Siddha or Unani] drug by any department of Government as they apply in relation to the manufacture for sale, sale, or distribution of such drug by any other person. |

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| Homoeopathic drugs and Cosmetic. | | |
| 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. | **Note**: New clause |
| | (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. | **33M**. (1) No prosecution under this Chapter shall be instituted except by an Inspector with the previous sanction of the authority specified under sub-section (4) of section 33G. |
| | (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. | (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: | **33N.** (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. | 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,— | (2) Without prejudice to the generality of the foregoing power, such rules may— |

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| | (a) the manner of functions of laboratories and centres under sub-section (1) of section 91; | **Note**: New clause |
| | (b) provide for the establishment of laboratories for testing and analysing Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs; | (a) provide for the establishment of laboratories for testing and analysing Ayurvedic, Siddha or Unani drugs; |
| | (c) the manner of carrying out the safety and efficacy evaluation of Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs under section 116; | **Note**: New clause |
| | (d) prescribe the qualifications and duties of Government Analysts and the qualifications of Drugs Control Officers; | (b) prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors; |
| | (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; | (c) prescribe the methods of test or analysis to be employed in determining whether any Ayurvedic, Siddha or Unani drug is labelled with the true list of the ingredients which it is purported to contain: |
| | (f) specify any substance as a poisonous substance; | (d) 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; | (e) prescribe the forms of licences for the manufacture for sale of Ayurvedic, Siddha or Unani drugs and for sale of processed Ayurvedic, Siddha or Unani drugs, the form of application for such 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 thereunder 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; | (f) prescribe the conditions to be observed in the packing of Ayurvedic, Siddha and Unani drugs including the use of packing material which comes into direct contact with the drugs, regulate the mode of labelling packed drugs and prescribe the matters which shall or shall not be included in such labels; |
| | (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 | (g) prescribe the conditions subject to which small quantities of Ayurvedic, Siddha or Unani drugs may be manufactured for the purpose of examination, test or analysis; 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; | [(gg) prescribe under clause (d) of section 33EE the colour or colours which an Ayurvedic, Siddha or Unani drug may bear or contain for purposes of colouring; |

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| | (k) prescribe the standards for Ayurveda, Siddha, Sowa-Rigpa, Unani, Homeopathy drugs under section 93; | (gga) prescribe the standards for Ayurvedic, Siddha or Unani drugs under section 33EB; |
| | (l) prescribe the records, registers or other documents to be kept and maintained; | (ggb) prescribe the records, registers or the documents to be kept and maintained under section 33KB; and |
| | (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; | **Note**: New clause |
| | (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; | **Note**: New clause |
| | (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.; | **Note**: New clause |
| | (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; | **Note**: New clause |
| | (q) prescribe the manner in which the drugs of Ayurveda, Siddha, Sowa-Rigpa, Unani and Homeopathy with poisonous ingredients are to be retailed; | **Note**: New clause |
| | (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; | **Note**: New clause |
| | (s) prescribe the requirements relating to export as under section 124; and | **Note**: New clause |
| | (t) any other matter which is to be or may be prescribed under this Chapter. | (h) 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. | **33-O.** The Central Government, after consultation with the Board and after giving, by notification in the Official Gazette, not less than three months' notice of its intention so to do, may, by a like notification, add to or otherwise amend the First Schedule for the purposes of this Chapter and thereupon the said Schedule shall be deemed to be amended accordingly. |
| | ***C. Import of Drugs and Cosmetics*** | |
| Standard quality in relation to | **120.** (1) For the purpose of this Chapter, the expression 'standard quality" means— | **Note**: 1940 Act does not regulate import of traditional medicines. |
| | a. in relation to an imported Ayurveda or Siddha or Sowa-Rigpa or | **Note**: New clause |

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| Ayurvedic, Siddha, Sowa Rigpa, Unani and Homoeopathic drugs and Cosmetic. | 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. | **Note**: New clause |
| | (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. | **Note**: New clause |
| | (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. | **Note**: New clause |
| 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. | **Note**: New clause |
| Modified application of Chapter III in relation to import of Ayurveda, Unani, Siddha, Sowa-Rigpa , Homoeopathy | **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 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 " | **Note**: New clause |

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| drugs or cosmetics, etc. | 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”. | **Note**: New clause |
| 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. | **Note**: New clause |