(31.12.2014)

Subject: Placing the draft Drugs and Cosmetics (Amendment) Bill, 2015 in public domain

The Department of Health and Family Welfare proposes to introduce the Drug and Cosmetics (Amendment) Bill, 2015 in the Budget Session of the Parliament. The said is placed in public domain with a view to elicit the comments/views of the stakeholders including the general public. The comments/views may be forwarded to Dr. Shailendra Kumar, Director (Drugs), Department of Health and Family Welfare, Room No-301 'D' Wing, 3rd Floor, Nirman Bhawan, New Delhi-110011 or emailed at anita.tripathi76@nic.in latest by January 12, 2015.

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THE DRUGS AND COSMETICS (AMENDMENT) BILL, 2015

	A BILL further to amend the Drugs and Cosmetics Act, 1940.	
	BE it enacted by Parliament in the Sixty-fifth Year of the Republic of India as follows: -	
	1. (1) This Act may be called the Drugs and Cosmetics (Amendment) Act, 2014. (*2*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint: Provided that different dates may be appointed for different provisions of this Act and any reference in any such provision to the commencement of this Act shall be construed as a reference to the coming into force of that provision.	Short title and commencement.
23 of 1940.	**2.** In the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the principal Act), for the long title, the following shall be substituted, namely: - "An Act to regulate the import, manufacture, distribution and sale of drugs, cosmetics and medical devices, to ensure their safety, efficacy, quality and conduct of clinical trials and for matters connected therewith or incidental thereto".	Amendment of long title.
	3. In the principal Act, in the preamble, for the portion beginning with the words "WHEREAS it is expedient" and ending with the words "and cosmetics", the following shall be substituted, namely: - "WHEREAS it is expedient to regulate the import, manufacture, distribution and sale of drugs, cosmetics, medical devices and conduct of clinical trials and for matters connected therewith or incidental thereto;".	Amendment of preamble.
.	**4.** In section 1 of the principal Act, in sub-section (1), for the words "and Cosmetics", the words ", Cosmetics and Medical Devices" shall be substituted.	Amendment of section 1.
	5. Throughout the principal Act, for the word "Inspector" wherever it occurs, the words "Drugs Control Officer" shall be substituted.	Substitution of words "Drugs Control Officer" for word "Inspector".
2 of 1930. 61 of 1985.	**6**. In section 2 of the principal Act, for the words and figures "the Dangerous Drugs Act, 1930", the words and figures "the Narcotic Drugs and Psychotropic Substances Act, 1985" shall be substituted.	Amendment of section 2.
	7. For section 3 of the principal Act, the following section shall be substituted, namely: - '3. In this Act, unless there is anything repugnant in the subject or context, -	Substitution of new section for section 3.

	(a)"Ayurvedic, Siddha or Unani drug" includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine, specified in the First Schedule; (b) "bioavailability study" means a study to assess the rate and extent to which the active drug is absorbed from a pharmaceutical formulation and becomes available in the systemic circulation or availability of drug at the site of action; (c) "bioequivalence study" means a study to establish the absence of a significant difference in the rate and extent of absorption of an active drug from a pharmaceutical formulation in comparison to the reference formulation having the same active drug when administered in the same molar dose under similar conditions; (d) "Board" means- (i) in relation to drug other than those specified in sub-clause (iii) or cosmetic, the Drugs Technical Advisory Board constituted under section 5; (ii) in relation to Medical Devices, the Medical Devices Technical Advisory Board constituted under section 5A; (iii) in relation to Ayurvedic, Siddha or Unani drug, the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board constituted under section 33C; (e) "Central Drugs Laboratory" means a laboratory established or designated by the Central Government under section 6; (f) "Central Licensing Authority" for the purposes of this Act means the Drugs Controller General of India; (g) "clinical trial" means- (i) in respect of drugs, any systematic study of new drug or investigational new drug or bioavailability or bioequivalence study of any new drug in human participants to generate data for discovering or verifying its clinical, pharmacological, including pharmacodynamic and pharmacokinetic, or adverse effects with the objective of determining safety, efficacy or tolerance of the drug; (ii) in respect of cosmetics, the systematic study, including dermatological study of any new cosmetic on human participants to generate data for discovering or verifying its adverse effects with the objective of determining safety, efficacy or tolerance of the cosmetic; (iii) in respect of medical devices, the systematic clinical investigation or study of an investigational medical device or a new medical device in, or on human participants to assess the safety or performance or effectiveness of the medical device; (h) "clinical trial protocol" means a document containing background, objective, rationale, design, methodology including performance, management, adverse event, withdrawal and statistical consideration of a clinical trial; (i) "cosmetic" means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic or new cosmetic;	Definitions.

	(j) "drug" includes- (i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes; (ii) such substances, other than food, intended to affect structure or any function of the human body or intended to be used for the destruction of vermin, insects or microbes which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification; (iii) all substances intended for use as components of a drug including empty gelatin capsules; and (iv) any new drug for which licence has been granted by the Central Licensing Authority under sub-section (2) of section 18; (k) "Drugs Control Officer" means– (*i*) in relation to any medical device, the Drugs Control Officer appointed by the Central Government under section 7H; (*ii*) in relation to drug other than those specified in sub-clause (iii) or cosmetic, a Drugs Control Officer appointed by the Central Government or a State Government under section 21; (iii) in relation to Ayurvedic, Siddha or Unani drug, a Drugs Control Officer appointed by the Central Government or a State Government under section 33G; *Explanation*.- For the purposes of this Act, the controlling officer and any other officer senior to the Drugs Control Officer shall be deemed to be the Drugs Control Officer; (l) "Drugs Controller General of India" means an officer appointed by the Central Government under section 33Q; (m) "Ethics Committee" means the Ethics Committee constituted under section 4E; (n) "Government Analyst" means- (i) in relation to drugs other than specified in sub-clause (ii), cosmetics and medical devices, a Government Analyst appointed by the Central Government or a State Government under section 20; and (ii) in relation to Ayurvedic, Siddha, Unani drug, a Government Analyst appointed by the Central Government or a State Government under section 33F; (o) "import" within its grammatical variations and cognate expressions means to bring into India; (p) "Indian Pharmacopoeia" means the official book of standards for drugs which specifies the standards of identity, purity and strength for the drugs mentioned therein;	

(q) "investigational new drug" means new chemical entity or substance which is under investigation in a clinical trial regarding its safety and efficacy;

(r) "investigational new medical device" means a new device which is an object of a clinical investigation or research or development involving one or more human participants to determine the safety and the effectiveness of a device;

(s) "investigator" means a person permitted to conduct clinical trial by the Central Licensing Authority under section 4A;

(t) "manufacture"-

(*i*) in relation to any drug , or any cosmetic, except human blood and its components, includes any process for making, altering, ornamenting, finishing, labeling, packing, breaking up or otherwise treating or adapting any drug or cosmetic with a view to sell, stock or distribute or market but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic in the ordinary course of retail business;

(*ii*) in relation to human blood and its components includes any process of collection, processing, storage, labeling, packing and testing for its use or distribution for transfusion in human beings;

(iii) in relation to medical device, includes any process for designing, making, assembling, configuring, finishing, packing, sterilising, labeling, refurbishing, or adapting with a view to sell, stock or distribute or market but does not include assembling or adapting by Registered Medical Practitioner, a device already approved for use, for an individual patient;

(u) "manufacturer" means a person who himself or through any other person on his behalf manufactures drug, cosmetic or medical device;

(v) "medical device" includes-

(i) any instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including the software, intended by its manufacturer to be used specially for human beings or animals for one or more of the specific purposes of,-

(A) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
(B) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
(C) investigation, replacement or modification or support of the anatomy or of a physiological process;
(D) supporting or sustaining life;
(E) disinfection of medical devices;
(F) control of conception;

which does not achieve primary intended action in or on the human body or animals by any pharmacological or immunological or metabolic means, but which may be assisted in its intended function by such means;

(ii) an accessory to such an instrument, apparatus, appliance, material or other article;

(iii) in vitro diagnostic medical device including a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination;

(w) "new cosmetic" means any cosmetic containing ingredients which have not been established as safe for use in cosmetics;

(x) "new drug" means-

	(i) a drug, including bulk drug substance, which has not been used in the country to any significant extent under the specified conditions, recommended or suggested in the labelling thereof and has not been recognised as effective and safe by the Central Licensing Authority for the expected claims and its limited use, if any; *(ii)* a drug approved by the Central Licensing Authority for certain claims, which is proposed to be marketed with modified or new claims, namely, indications, route of administration, dosage and dosage form, including sustained release and novel drug delivery systems; *(iii)* a fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in a marketed combination is proposed to be changed, with certain claims, namely, indications, route of administration, dosage, dosage form, including sustained release and novel drug delivery systems; *(iv)* vaccines, recombinant Deoxyribonucleic Acid (r-DNA) derived products, living modified organisms, monoclonal anti-bodies, stem cells, gene therapeutic products and xenografts which are intended to be used as drugs; (y) "new medical device" means a device which has not been approved by the Central Licensing Authority; (z) "notification" means a notification published in the Official Gazette and the word "notified" shall be construed accordingly; (za) " proprietary medicine" means- (i) in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause *(a)*; *(ii)* in relation to any other systems of medicine, a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorised in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board constituted under section 5; (zb) "prescribed" means prescribed by rules made under this Act; (zc) "sponsor" includes a person, a company or an institution responsible for the initiation, financing and management of a clinical trial; (zd) "State Drugs Laboratory" means laboratory established or designated by the State Government under section 6; (ze) "State Licensing Authority" for the purposes of this Act means the State Drugs Controller by whatever name called; (zf) "Schedule" means Schedule appended to the Act.'.	

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Insertion of new Chapter IA	**8**. After Chapter I of the principal Act, the following Chapter shall be inserted, namely: -	
	"CHAPTER IA. CLINICAL TRIALS.	
No clinical trial without permission.	**4A.** (1) No person, sponsor, clinical research organisation or any other organisation or investigator, shall conduct any clinical trial in respect of a new drug, investigational new drug, notified category of new medical device and investigational new medical device, new cosmetic, 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 in such form and manner as may be prescribed. (2) Subject to the provisions of sub-section (1), no person shall initiate or conduct any clinical trial unless it is approved by the Ethics Committee constituted under section 4E in such manner as may be prescribed. (3) New drug shall continue to be a new drug for the purposes of this Act for such period as may be prescribed. (4) The fee for the purposes of this section shall be such as may be notified by the Central Government.	
Determination regarding injury or death.	4B. Whether the injury or death of a person in the course of a clinical trial, has been caused due to such clinical trial or not, shall be determined by such authority and in such manner as may be prescribed.	
Medical treatment and compensation for injury or death due to clinical trial.	4C. (1) Where a participant is injured or disabled in a clinical trial, the person or body permitted under section 4A and the sponsor shall provide such medical treatment and compensation in such manner as may be prescribed.	
	(2) Where death of a participant is caused due to clinical trial, the person or a body permitted under section 4A and the sponsor shall provide to his legal heir, such compensation, in such manner as may be prescribed.	
Deferm	4D. Notwithstanding anything contained in this Chapter, the Central Licensing	

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ent of clinical data requirements by the Central Licensing Authority.	Authority may, in public interest, abbreviate, defer or waive off the pre-clinical and clinical data requirements for approval of clinical trial of drugs in case of life threatening or serious diseases or diseases of special relevance to the country.	
Registration of Ethics Committee.	4E. The Ethics Committee, constituted in such manner as may be prescribed, for the purpose of giving approval to a clinical trial protocol and other related matters, shall be registered with the Central Licensing Authority in such manner as may be prescribed.	
Functions and responsibilities of Ethics Committee	4F. (1) The Ethics Committee shall grant its approval to the clinical trial protocol and other related documents in such manner as may be prescribed.	
	(2) The Ethics Committee shall be responsible to oversee the conduct of clinical trial, safeguard the rights, safety and well being of all trial participants enrolled in the clinical trial.	
	(3) The Ethics Committee shall make periodic review of the trial, based on the study of progress reports furnished by the investigators, and monitor internal audit reports furnished by the Sponsor, or by visiting the study sites in such manner as may be prescribed.	
	(4) The Ethics Committee shall have power to revoke its approval granted under sub-section (1) of section 4F to a clinical trial protocol and other related documents, for reasons to be recorded in writing and communicated to the Investigator and to the Central Licensing Authority.	
	(5) The Ethics Committee shall perform such other functions and responsibilities as may be prescribed.	
Action against	4G. (1) Where the Central Licensing Authority is satisfied that the Ethics Committee is not able to discharge its functions and responsibility under this Act,	

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Ethics Committee	the Central Licensing Authority shall suspend or cancel its registration granted under section 4E.	
	(2) On the suspension or cancellation of the registration of the Ethics Committee under sub-section (1), the Central Licensing Authority shall review the approval granted by the Ethics Committee for continuance or otherwise of the clinical trial in such manner as may be prescribed.	
	(3) If the registration of the Ethics Committee is cancelled under sub-section (1), every member of such Committee shall be disqualified to be a member of any other Ethics Committee for a period of two years.	
Inspection by Drugs Control Officer.	4H. (1) The Drugs Control Officer or any other officer authorised by the Central Licensing Authority shall have the power to enter with or without prior notice into any premises related to clinical trial to inspect the facilities, record, data, documents, books, drugs including investigational new drugs, notified category of medical devices and cosmetics. (2) The officer empowered under sub-section (1) shall have the power to seek clarifications, information and record regarding clinical trial or matters relating thereto.	
Disclosure of name, address, etc. of persons involved in clinical trials	4-I. Every person, sponsor, clinical research organisation or any other organisation or investigator 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, the names, addresses and other particulars of the persons involved in conducting clinical trials and participants in the clinical trial.	
Maintenance of record and furnishing information.	4J. Every person, sponsor, clinical research organisation or any other organisation or investigator 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.	

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Penalty for conducting clinical trial of any drug or investigational new drug or any notified category of medical device or investigational medical device without permission.	4K. Whoever himself, or by any other person on his behalf, conducts clinical trial of,- (i) any new drug or investigational new drug, in contravention of section 4A and the rules made thereunder, shall be punishable with imprisonment which may extend to three years or fine which may extend to five lakh rupees or both; (ii) any notified category of new medical device and investigational new medical device, in contravention of section 4A and the rules made thereunder, shall be punishable with imprisonment which may extend to two years or fine of three lakh rupees or both.	
Penalty for repeat offence.	4L. Whoever, having been convicted under section 4K, is again convicted under that section, 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 fifteen lakh rupees.	
Penalty for conducting clinical trial of cosmetics	4M. Whoever, himself or by any other person on his behalf, conducts clinical trials with cosmetics in contravention of section 4A shall be punishable with imprisonment for a term which may extend to one year or fine which shall not be less than two lakh rupees.	

without permission.		
Penalty for repeated offence regarding cosmetics clinical trials.	4N. Whoever having been convicted under section 4M, is again convicted under that section, shall be punishable with imprisonment for a term which shall not be less than two years and shall also be liable to fine which shall not be less than three lakh rupees.	
Penalty for violation of conditions of permission	4-O. Whoever, himself or by any other person on his behalf, conducts clinical trials with any new drug or investigational new drug or notified category of new medical device and investigational new medical device or new cosmetics in contravention of the conditions of permission issued under section 4A and rules made thereunder,- (a) which causes adverse affects on the body of participants shall be punishable with imprisonment for a term which may extend to one year or fine which may extend to three lakh rupees or both; (b) which does not cause any adverse affect on the body of participant shall be liable for a penalty, which shall not be less than fifty thousand rupees but which may extend to two lakh rupees, to be imposed by the Central Licencing Authority.	
Penalty for repeated offence for conditions of permission	4P. Whoever, having been convicted of an offence,- (a) under clause (a) of section 4-O, is again convicted of an offence under that section, shall be punished with imprisonment for a term which shall not be less than one year and fine which shall not be less than five lakh rupees; and (b) under clause (b) of section 4-O, is again adjudged to have contravened the conditions specified therein shall be liable for a penalty, which shall not be less than two lakh rupees and which may extend to three lakh rupees to be imposed by the Central Licensing Authority.	
Penalty for	4Q. Whoever is responsible to provide compensation for clinical trial related to injury, disability or death under section 4C fails to do so, shall be punishable with	

failure to provide compensation	imprisonment which may extend to one year and fine which may not be less than twice the amount of the compensation.	
Penalty for contravention of any provision of this chapter.	4R. Whoever initiates or conducts clinical trial of any new drug, or investigational new drug, or notified category of new medical device and investigational new medical device, or new cosmetic, in contravention of any provisions under this Chapter, except the provisions of sections 4A to 4-I, both inclusive, and the rules made under this Act shall be liable for penalty which shall not be less than fifty thousand rupees to be imposed by the Central Licensing Authority.	
Confiscation of stock, medical device or cosmetcis.	4S. Where any person has been convicted for contravention of any provision of this Chapter or any rule made under this Act, the stock of the new drug, investigational new drug, notified category of new medical device and investigational new medical device or new cosmetic in respect of which the contravention has been made and implement, machinery, vehicle, vessel or other conveyances used in or for the purposes of conducting such clinical trial shall be liable to be confiscated.	
Cognizance of offence.	4T. (1) No prosecution under this Chapter shall be instituted, except on a complaint made by,-	
	(*a*) a Drugs Control Officer or any other officer duly authorised in this behalf by the Drugs Controller General India; or	
	(*b*) a Gazetted officer of the Central Government authorised by that Government by an order made in this behalf; or	
	(*c*) the person aggrieved; or	
	(*d*) any recognised consumer association.	
	(2) Nothing contained in this Chapter shall be deemed to prevent any person from being prosecuted under any other law for the time being in force for any act or omission which constitute an offence under this Chapter.	
Power of Central Government to	4U. The Central Government may, after consultation with 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 to provide for,-	

make rules.		
	(a) the form and manner for conducting clinical trial under section 4A;	
	(*b*) the norms and procedure for approval of any clinical trial by the Ethics Committee under sub-section (*1*) of section 4F;	
	(c) the manner in which the Central Licensing Authority shall review the approval granted by the Ethics Committee for continuance of clinical trial under sub-section (2) of section 4G;	
	(d) the norms and procedures for deciding whether injury or death of a trial participant has been caused due to clinical trial, under section 4B;	
	(e) the norms and procedures for providing medical treatment to the trial participants under section 4C;	
	(f) the norms and procedures for registration of Ethics Committees under section 4E;	
	(g) additional functions and responsibilities of the Ethics Committee under sub-section (*5*) of section 4F; and	
	(h) the norms and procedures for conducting inspections relating to conduct of clinical trials under sections 4H and 4-I:	
	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.	
Chapter not to apply to Ayurvedic, Homeopathy, Siddha or Unani drugs	4V. Nothing contained in this Chapter shall apply to Ayurvedic, Siddha or Unani drugs.".	
Substitution of new Chapter heading for Chapter II heading.	**9**. In Chapter II of the principal Act, for the Chapter heading, the Chapter heading "TECHNICAL ADVISORY BOARDS, CENTRAL DRUGS LABORATORIES AND CONSULTATIVE COMMITTEE" shall be substituted.	

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Amendment of section 5.	**10**. In section 5 of the principal Act,-	
	(a) in sub-section (1),-	
	(i) for the words and brackets "as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board)", the words "by notification, constitute a Board to be called the Drugs Technical Advisory Board" shall be inserted;	
	(b) for sub-section (2) to sub-section (7), the following sub-sections shall be substituted, namely:-	
	"(2) The Board shall consist of the following members, namely:-	
	(i) the Director General of Health Services, *ex officio*, who shall be Chairperson;	
	(ii) the Drugs Controller General of India, *ex officio*, who shall be Member Secretary;	
	(iii) one Director of the Central Drugs Laboratory to be nominated by the Central Government, *ex officio*;	
	(iv) one expert to be nominated by the Department of Animal Husbandry and Dairy;	
	(v) three experts to be nominated by rotation by the Central Government from amongst persons who are in charge of drugs control in the State Government;	
	(vi) one expert, to be nominated by the Executive Committee of the Pharmacy Council of India, from amongst teachers in pharmaceutical sciences;	
	(*vii*) one expert, to be nominated by the authority established for regulating the medical education, from amongst teachers in medicine or therapeutics;	
	(viii) two persons to be nominated by the Central Government from the pharmaceutical industry;	
	(i*x*) one pharmacologist to be nominated by the Department of Health Research;	
	(*x*) one person to be nominated by the Central Council of the Indian Medical Association;	
	(*xi*) one expert to be nominated by the Central Council of the Indian Pharmaceutical Association;	
	(*xii*) two Government Analysts to be nominated by rotation by the Central Government;	
	(*xiii*) the Director of the National Institute of Biologicals, *ex officio*;	
	(*xiv*) the Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, *ex officio*;	
	(*xv*) one expert to be nominated by the Department of Pharmaceuticals;	

	(*xvi*) one expert to be nominated by the Department of Bio-technology;	
	(*xvii*) one expert to be nominated by the Central Government from the medical institutions involved in the conduct of clinical trials;	
	(*xviii*) one person to be nominated by Union Ministry dealing with Consumer Affairs from amongst consumer associations.	
	(3)The nominated members of the Board shall hold office for a period of three years but shall be eligible for re-nomination: Provided that no member shall be eligible for nomination for more than two consecutive terms. Provided further that a member nominated under sub-section (1) by virtue of his holding an office in the Government shall hold office on Board so long as he holds the appointment of the office by virtue of which he was nominated to the Board.	
	(4) The procedure for conduct of business of the Board shall be such as may be prescribed.	
	(*5*) The Board may constitute sub-committees and may appoint to such sub-committees, persons who are not members of the Board for such periods not exceeding three years, as it may decide, for the consideration of particular matters.	
	(*6*) The functions of the Board may be exercised notwithstanding any vacancy therein.	
Insertion of new section 5A.	**11**. After section 5 of the principal Act, the following section shall be inserted, namely:-	
Constitution of Medical Devices Technical Advisory Board.	"5A. (*1*) The Central Government shall, by notification, constitute a Board to be called the Medical Devices Technical Advisory Board to advise the Central Government and State Governments on technical matters pertaining to medical devices, arising out of administration of this Act and to carry out other functions assigned to it by or under this Act.	
	(*2*) The Board shall consist of the following members, namely:-	
	(*a*) the Director General, Indian Council of Medical Research, *ex officio*, who	

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	shall be the Chairperson;	
	(*b*) the Drugs Controller General of India, *ex officio*, who shall be the Member Secretary;	
	(*c*) one expert each from the following, having qualifications and experience in the field of medical devices, to be nominated by-	
	(*i*) the Department of Science and Technology;	
	(*ii*) the Department of Atomic Energy;	
	(*iii*) the Department of Electronic and Information Technology;	
	(iv) the Central Government testing laboratories responsible for testing of medical devices;	
	(v) the Department of Pharmaceuticals;	
	(*vi*) the Bureau of Indian Standard;	
	(*vii*) the Defence Research and Development Organisation;	
	(viii) one expert to be nominated by the Indian Pharmacopoeial Commission or any other standards setting body as may be constituted by or with approval of the Central Government;	
	(*d*) one expert from the field of biomedical technology from recognised technical educational institutions, to be nominated by the Central Government;	
	(*e*) one expert from the field of biomaterial or polymer technology from recognised technical educational institutions, to be nominated by the Central Government;	
	(*f*) one person to be nominated by Union Ministry dealing with Consumer Affairs from amongst consumer associations;	
	(*g*) one pharmacologist to be nominated by the Central Government from recognised medical or research institute in the field of medical devices;	
	(*h*) one expert to be nominated by the Central Government from recognised medical or research institute from amongst person involved in conduct of clinical trials;	
	(i) four experts to be nominated by the Central Government from the medical device industry including in-vitro diagnostics industry.	
	(3)The nominated members of the Board shall hold office for a period of three years but shall be eligible for re-nomination: Provided that no member shall be eligible for nomination for more than two consecutive terms. Provided further that a member nominated under sub-section (1) by virtue of his holding an office in the Government shall hold office on Board so long as he holds the appointment of the office by virtue of which he was nominated to the Board.	
	(4) The procedure for conduct of business of the Board shall be such as may be	

	prescribed.	
	(*5*) The Board may constitute sub-committees and may appoint to such sub-committees, persons who are not members of the Board for such periods not exceeding three years, as it may decide, for the consideration of particular matters.	
	(*6*) The functions of the Board may be exercised notwithstanding any vacancy therein.	
Amendment of section 6.	**12**. In section 6 of the principal Act,-	
	(*a*) for sub-section (*1*), the following sub-sections shall be substituted, namely:-	
	"(1) The Central Government may, by notification, establish or designate Central Drugs Laboratories under the control of a Director, to be appointed by the Central Government, to carry out such functions as may be prescribed.	
	(1A) The Central Government may, by notification, designate any Central Drugs Laboratory or any other laboratory,-	
	(*a*) for testing of drugs or cosmetics or medical devices; or	
	(*b*) as an Appellate Laboratory for testing of drugs or cosmetics or medical devices.	
	(IAB) The State Government may, by notification, establish or designate State drugs laboratories or any other laboratories to carry out such functions as may be prescribed.";	
	(*b*) in sub-section (*2*),-	
	(*i*) in clause (a), after the word "Laboratory", the words "State Drugs Laboratory" shall be inserted; (ii) in clause (*d*), for the words, figures and letter "under Chapter IV or Chapter IVA of samples of drugs or cosmetics", the words, figures and letters "under Chapter IIA, Chapter III, Chapter IV or Chapter IVA of samples of drugs or cosmetics or medical devices" shall be substituted.	
Substitution of new section for section 7.	**13**. For section 7 of the principal Act, the following section shall be substituted, namely:-	
Drug, Cosmet	7. (1) The Central Government may constitute a consultative committee to be called the Drugs, Cosmetics and Medical Devices Consultative Committee to	

ic and Medical Devices Consultative Committee.	advise the Central Government, the State Governments, the Drugs Technical Advisory Board and the Medical Device Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of this Act.	
	(2) The Drug, Cosmetic and Medical Devices Consultative Committee shall consist of two representatives of the Central Government to be nominated by the 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, cosmetics and medical devices. (3) The Drug, Cosmetic and Medical Devices Consultative Committee shall meet as and when required to do so by the Central Government and shall have power to regulate its own procedure. (4) The Drugs Controller General of India shall be the Chairperson of the Drug, Cosmetic and Medical Devices Consultative Committee.".	
Insertion of new Chapter IIA.	**14.** After section 7A of the principal Act, the following Chapter shall be inserted, namely:-	
	"CHAPTER IIA. IMPORT, MANUFACTURE, SALE AND DISTRIBUTION OF NOTIFIED CATEGORY OF MEDICAL DEVICE.	
	7B. (1) The classification, standards, manufacturing, testing, distribution, labeling, packaging, essential requirements for quality, safety and performance, adverse events, post marketing surveillance, conformity assessment bodies, exemptions, procedure to regulate notified category of medical device, manner and conditions of licence shall be such as may be prescribed.	
	(2) The fee for the purposes of this section shall be such as may be notified by the Central Government.	
	7C. For the purposes of this Chapter, a medical device shall be deemed to be misbranded if it,-	
	(a) is configured so as to conceal any damage or made to appear of better or greater functional value or made to appear of lesser risk than it really is; or	
	(b) is not labeled or packed in the prescribed manner; or	

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	(c) bears label, container, statement, design or device which makes any false claim; or	
	(d) does not comply with the prescribed colour additives.	
	7D. For the purposes of this Chapter, a medical device shall be deemed to be adulterated if it,-	
	(*a*) consists, in whole or in part, of rusted or corroded or filthy or putrid or decomposed substance; or	
	(*b*) is not prepared or stored in such manner and conditions as may be prescribed; or	
	(*c*) contains any harmful or toxic substance or component or software or parts thereof which may render it dangerous to use or injurious to health; or	
	(*d*) is having any substance or component or software or part thereof mixed or added thereto or substituted or removed therefrom so as to reduce its quality or strength or performance or safety which may render it dangerous to use or injurious to health; or	
	(*e*) is having a pack or container composed, in whole or in part, of any deleterious substance which may render it dangerous to use or injurious to health.	
Spurious medical device.	7E. For the purposes of this Chapter, a medical device shall be deemed to be spurious if it,-	
	(a) is having the label or pack or the container bearing the name of an individual or firm or company purporting to be the manufacturer of the device, which individual or a firm or a company is fictitious or does not exist; or	
	(b) purports to be the product of a manufacturer of product whom it is not actually a product.	
Prohibition of import or manufacture and sale of medical devices.	7F. (*1*) save as otherwise provided in sub-section (4), no person shall himself or by any other person on his behalf import or manufacture for sale for distribution or for marketing, sell, stock, exhibit, offer for sale or distribute any notified category of medical device,-	
	(*i*) which does not conform to such standards of quality, safety and	

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	performance as may be prescribed;	
	(*ii*) which is misbranded, adulterated or spurious;	
	(iii) software, part, component or instrument accompanying to which is not having details displayed in such manner as may be prescribed;	
	(iv) which by means of any statement, design or accessory accompanying it or by any other means, purports or claims to cure any such disease or ailment, or to have any such other effect as may be prescribed;	
	(*v*) which is containing any component that may render it unsafe or harmful beyond what is declared, for use under the directions indicated therein or recommended therefor;	
	(*vi*) which is in contravention of any of the provisions of this Chapter or rules made there under,	
	except under and in accordance with a licence issued under this Chapter by the Central Licensing Authority or the State Licensing Authority, as the case may be:	
	Provided that nothing contained in clause (i) to (vi) shall apply to import or manufacture of any notified category of medical device in small numbers for the purposes of examination, test, analysis, demonstration, not on human beings, or for personal use subject to such conditions as may be prescribed:	
	Provided further that the Central Government may, in consultation with the Medical Devices Technical Advisory Board, by notification permit, subject to any conditions specified therein, the import or manufacture of any notified category of medical device not approved by the Central Government or not of standard quality for sale or for distribution.	
	(*2*) No person shall himself or by any other person on his behalf sell or stock or distribute or exhibit or offer for sale any notified category of medical device referred to in sub-section (1) which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made there under.	
	(3) No person shall himself or by any other person on his behalf sell, or stock or exhibit or offer for sale, or distribution any notified category of medical device,	
	except under and in accordance with a licence issued under this Chapter by the State Licensing Authority:	
	(4) On and from the commencement of the Drugs and Cosmetics (Amendment) Act, 2014, the Central Licensing Authority shall have exclusive power to issue a licence for the manufacture for sale or distribution or marketing of any medical device in such manner as may be prescribed.	
Application of law relating	7G. (*1*) The law for the time being in force relating to customs and goods, the import of which is prohibited by the Customs Act, 1962 or rules made or notifications issued there under or any other law for the time being in force shall, subject to the provisions of section 7J, section 7K and section 7L of this Act,	

to sea customs and powers of Customs Officers.	apply in respect of notified category of medical device, the import of which is prohibited under this Chapter, and officers of Customs and officers empowered under that Act or law to perform the duties imposed thereby on a Customs Collector and other officers of Customs, shall have the same powers in respect of such notified category of medical device 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 notified category of medical device, the import of which is prohibited under this Chapter or any other law for the time being in force and shall forthwith report such detention to the Drugs Controller General of India and, if necessary, forward the package or sample of any suspected medical device found therein to the Laboratory prescribed for the purpose:	
	Provided that in the event of that package or sample of that notified category of medical device found in contravention of any of the provisions of this Chapter or any rule made thereunder, the same shall not be allowed to be imported from that or any other port of entry in the country.	
	7H. (*1*) The Central Government or a State Government may, by notification, for the purposes of this Chapter, appoint such persons, as it thinks fit, having such qualifications and experience as may be prescribed to be the Drugs Control Officers for such areas as may be assigned to them.	
	(*2*) The powers and duties of the Drugs Control Officer shall be such as may be prescribed.	
	(*3*) No person who has any financial interest in the import, manufacture or sale or distribution of notified category of medical devices shall be appointed to be a Drugs Control Officer under this section.	
45 of 1860.	(*4*) Every Drugs Control Officer shall be subordinate to such authority having the prescribed qualifications and experience and deemed to be a public servant within the meaning of section 21 of the Indian Penal Code.	
Power of Central Government to	7-I. (1) Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that the use of any notified category of medical device is likely to involve any risk to human beings or animals or that any such medical device does not have the functional value claimed or purported to be claimed for it or which is not safe or effective for use or for which there is	

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regulate, restrict or prohibit import or manufacture, sale or distribution of notified category of medical device in public interest.	no functional justification and that in the public interest it is necessary or expedient so to do, then, it may, by notification, regulate, restrict or prohibit the import, manufacture, sale or distribution of such medical device. (2) The notification issued under sub-section (1) shall be laid, as soon as may be after it is made, before each House of Parliament.	
Offences for import or manufacture, sale or distribution of medical device in contravention of this Chapter.	7J. Whoever, himself or by any other person on his behalf, import or manufacture for sale or for distribution or market, or sell, or stock or exhibit or offer for sale any notified category of medical device,-	
	(a) deemed to be adulterated under section 7D or spurious under section 7E 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 such bodily harm which amount to grievous hurt within the meaning of section 320 of the Indian Penal Code, solely on account of such medical device shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to seven years and shall also be liable to fine which shall not be less than five lakh rupees or three times the value of the device whichever is more and in case of failure to pay fine, liable to imprisonment upto one year:	45 of 1860.
	Provided that the fine imposed under this clause shall be paid to the person who had been administered such medical device:	
	Provided further that where the use of such medical device caused death of a person who was administered such medical device, the fine imposed shall be paid to his legal heir;	
	(b) deemed to be adulterated under section 7D but not being a device referred to in clause (*a*), or misbranded under section 7C, or without a valid licence as required under clause (*c*) of section 7F, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and shall be liable to fine which shall not be less than one lakh rupees or three times the value of the medical device, whichever is more:	
	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 year or of fine of less than one lakh rupees;	
	(c) deemed to be spurious under section 7E, but not being a device referred to in clause (a) shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to five years or shall also be liable to fine which shall not be less than two lakh rupees or three times the value of the device, whichever is more or both;	
	(d) other than a device 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 liable to pay penalty which shall not be less than one lakh rupees to be imposed by the Central Licensing Authority.	
Penalty for import or manufacture, etc. of medical	7K. Whoever himself, or by any other person on his behalf, imports or manufactures or sells or distributes any notified category of medical device in contravention of the provisions of any notification issued under section 7-I, shall be punishable with imprisonment which may extend to five years and with fine which may extend to five lakh rupees.	

device in contravention of section 7-1.		
Penalty for repeat offence.	7L. (*1*) Whoever having been convicted of an offence,-	
	(i) under clause (a) of section 7J, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than five years but which may extend to seven years and shall also be liable to fine which shall not be less than five lakh rupees;	
	(ii) under clause (b) of section 7J, 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 five years or shall also be liable to fine which shall not be less than two lakh rupees;	
	(iii) under clause (c) of section 7J, 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 but which may extend to seven years and shall also be liable to fine which shall not be less than five lakh rupees;	
	(iv) under clause (d) of section 7J, 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 three years or shall also be liable to fine upto two lakh rupees.	
	(2) Whoever having been found guilty of an offence under section 7K is again found guilty under that clause shall be liable for punishable with imprisonment not less than three years and shall also be liable to fine which may extend to five lakh.	
Confiscation.	7M. (*1*) Where any person is convicted under this Chapter for contravening any of the provisions of this Chapter or any rule made thereunder, the stock of the notified category of medical device in respect of which the contravention has been made in respect of-	
	(*a*) import or manufacture of any device deemed to be misbranded under section 7C or adulterated under section 7D or spurious under section 7E; or	

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	(*b*) import or manufacture for sale, or for distribution, sale, or stocking or exhibiting or offering for sale or distribution of any notified category of medical device without a valid licence as required under clause (b) of sub-section (1) or clause (c) of sub-section (2) of section 7F and any implements or machinery used in such import or manufacture, sale, or distribution and any receptacles, packages or coverings in which such device is contained and the animals, vehicles, vessels or other conveyances used in carrying such device, 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 a Drugs Control Officer or any other officer duly authorised in this behalf or otherwise and after such inquiry as may be necessary, that the device is not of standard quality and required performance shall be liable to confiscation.	
Powers of the Central Government to make rules.	7N. (1) The Central Government may after consultation with or on the recommendation of the Medical Devices Technical Advisory Board and subject to previous publication, by notification, make rules for classification, standards, manufacturing, testing, distribution, labeling, packaging, essential requirements for quality, safety and performance, adverse events, post marketing surveillance, conformity assessment bodies, exemptions and procedure to regulate notified category of medical devices under section 7B: 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.".	
Amendment of section 9B.	**15.** In section 9B of the principal Act, after clause (e), the following clause shall be inserted, namely:- "(f) if it does not contain active ingredient.".	
Insertion of new section 9E.	**16**. After section 9D of the principal Act, the following section shall be inserted, namely:-	
Adulterated cosmetics.	"9E. For the purposes of this Chapter, a cosmetic shall be deemed to be adulterated,-	
	(*a*) if it consists, in whole or in part, of any filthy, putrid or decomposed	

	substance; or	
	(*b*) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or	
	(c) if it contains colour other than those prescribed; or	
	(d) if it contains any harmful or toxic substance which may render it injurious to health.".	
Amendment of section 10.	**17.** In section 10 of the principal Act,-	
	(i) after clause (bb), the following clause shall be inserted, namely:-	
	"(bbb) any adulterated cosmetic;";	
	(ii) in clause (d), the words "patent or" shall be omitted.	
Amendment of section 11.	**18**. In section 11 of the principal Act, in sub-section (2), the following proviso shall be inserted, namely:-	
	"Provided that in the event of that package or sample of that drug or cosmetic found in contravention of any of the provisions of this Chapter or any rule made thereunder, the same shall not be allowed to be imported from that or any other port of entry in the country.".	
Substitution of new section for section 13.	**19.** For section 13 of the principal Act, the following sections shall be substituted, namely:-	
Penalty for import of drugs or cosmetics in contravention	"13. Whoever, himself or by any other person on his behalf, imports,-	

of this Chapter .		
	(a) any drug deemed to be adulterated under section 9A or spurious under section 9B 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 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 imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more:	45 of 1860.
	Provided that the fine imposed under this clause shall be paid to the person who had used the adulterated or spurious drugs:	
	Provided further that where the use of adulterated or spurious drug referred to in this clause has caused the death of a person who used such drug, the fine imposed shall be paid to his legal heir;	
	(b) any drug-	
	(*i*) deemed to be adulterated under section 9A, but not being a drug referred to in clause (a); or	
	(*ii*) without a valid licence as required under clause (c) of section 10,	
	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 one lakh rupees or three times the value of the drugs confiscated, whichever is more:	
	Provided that the court may, for any adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less than three years and of fine of less than one lakh rupees;	
	(c) any drug deemed to be spurious under section 9B, 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 shall also be liable to 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 of fine of less than one lakh rupees;	
	(d) any drug deemed to be misbranded under section 9, shall be liable for penalty which may extend to two lakh rupees to be imposed by the Central Licensing	

	Authority in such manner as may be prescribed.	
	(e) any drug, other than a drug referred to in clause (a) or clause (b) or clause (c) or clause (d), in contravention of the any other provision of this Chapter or any rule made under the Act, shall be liable for penalty which may extend to five lakh rupees to be imposed by the Central Licensing Authority in such manner as may be prescribed.	
	(*f*) any cosmetic deemed to be adulterated under section 9E or spurious under section 9D and which when used by any person is likely to cause bodily harm which causes permanent disability on account of such cosmetics 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 two years but which may extend to imprisonment for five years and shall also be liable to fine which shall not be less than two lakh rupees or three times value of the cosmetics confiscated, whichever is more:	45 of 1860.
	Provided that the fine imposed under this clause shall be paid to the person who had used the adulterated or spurious cosmetic:	
	(*g*) any cosmetic,	
	(i) deemed to be spurious under section 9D or adulterated under section 9E but not being a cosmetic referred to in clause (e);	
	(ii) without a valid licence as required under clause (c) of section 10,	
	shall be punishable with imprisonment for a term which may extend to two years and shall also be liable to fine which shall not be less than fifty thousand rupees;	
	(*h*) any cosmetic other than a cosmetic referred to in clause (*e*) or clause (f), the import of which is prohibited under section 10, or any rule made under this Act, shall be punishable with imprisonment for a term which may extend to one year or shall also be liable to fine which shall not be less than twenty five thousand rupees;	
	(i) any cosmetic deemed to be misbranded under section 9C, shall be liable for penalty which may extend to fifty thousand rupees to be imposed by the Central Licensing Authority in such manner as may be prescribed;	
	(j) any cosmetic, other than a cosmetic referred to in clause (f) or clause (g) or clause (h) or clause (i), in contravention of the any other provision of this Chapter or any rule made under the Act, shall be liable for penalty which may extend to two lakh rupees to be imposed by the Central Licensing Authority in such manner as may be prescribed;	
	(*k*) 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 shall not be less than two years and shall also be liable to fine which shall not be less than fifty thousand rupees.".	

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Penalty for repeat of offence.	13A. Whoever having been convicted of an offence,-	
	(i) under clause (*a*) of section 13 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 five lakh rupees:	
	(*ii*) under clause (*b*) of section 13 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than five years but which may extend to seven years and shall also be liable to fine which shall not be less than two lakh rupees:	
	Provided that the court may, for any adequate and special reason to be recorded in the judgment, impose a sentence of imprisonment for a term of less than five years and of fine of less than two lakh rupees;	
	(*iii*) under clause (*c*) of section 13 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 five lakh rupees;	
	(*iv*) under clause (*d*) and clause *(e)* of section 13 again contravene the provisions of section 9 or any other provision of this Chapter or any rule made under the Act, shall be liable for penalty which may extend to seven lakh rupees to be imposed by the Central Licensing Authority in such manner as may be prescribed;	
	(*v*) under clause (*f*) or clause (*g*) or clause (*h*) of section 13 again contravene the provisions of section 9C or any other provision of this Chapter or any rule made under the Act, shall be liable for penalty which may extend to three lakh rupees to be imposed by the Central Licensing Authority in such manner as may be prescribed;	
	(vi) under clause (k) of section 13 again convicted under that clause, shall be punishable with imprisonment which shall not be less than three year and shall also be liable to fine which shall not be less than one lakh rupees.".	
Amendment of section 17B.	**20.** In section 17B of the principal Act, after clause (e), the following shall be inserted, namely:- "(f) if it does not contain active ingredient.".	
Substitution of	**21**. For section 18 of the principal Act, the following section shall be substituted, namely:-	

new section for section 18.		
Prohibition of manufacture and sale of drugs and cosmetics.	"18. (1) Save as otherwise provided in sub-section (3), no person shall himself or by any other person on his behalf,-	
	(a) manufacture for sale, distribution or marketing, sell, stock, exhibit, offer for sale or distribute any,	
	(*i*) drug which is not of a standard quality, is misbranded, adulterated or spurious;	
	(*ii*) cosmetic which is not of a standard quality, or is misbranded, adulterated or spurious;	
	(*iii*) 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;	
	(*v*) cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;	
	(*vi*) drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made 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 there under;	
	(c) manufacture for sale or for distribution or for market, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic,	
	except under and in accordance with a licence issued under this Chapter by the State Licensing Authority:	

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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:	
	Provided further that the Central Government may, after consultation with the Board, by notification, 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) The licence for the manufacture for sale or distribution or marketing of any new drug shall be issued by the Central Licensing Authority in such manner as may be prescribed.	
	(3) Notwithstanding anything contained in sub-section (1), on and from the commencement of the Drugs and Cosmetics (Amendment) Act, 2014, the Central Licensing Authority shall have exclusive power to issue a licence in respect of manufacture for sale or for distribution or for marketing of drugs specified in the Third Schedule in such manner as may be prescribed;	
	(4) The Central Government, after consultation with the Board, and after previous publication, by notification, may amend the Third Schedule.	
Amendment of section 18A.	**22**. In section 18A of the principal Act, for the words "drug or cosmetic" at both the places where they occur, the words "drug or cosmetic or notified category of medical device" shall be substituted.	
Amendment of section 18B.	**23**. In section 18B of the principal Act, for the words, letter, brackets and figures "clause (c) of section 18", the words, letters, brackets, and figures "clause (*b*) of sub-section (*1*) or clause (*c*) of sub-section (*2*) of section 7F or clause (c) of sub-section (1) of section 18" shall be substituted.	
Amendment of section 19.	**24**. In section 19 of the principal Act,-	
	(a) in sub-section (1), for the words, "this Chapter", the words, figures and letter "Chapter IIA or Chapter III or Chapter IV" shall be substituted;	
	(b) for the words "drug or cosmetic", wherever they occur, the words "drug or cosmetic or notified category of medical device" shall be substituted;	
	(*c*) in sub-section (*2*),-	
	(*i*) for the words and figures "For the purposes of section 18", the words, figures and letter "For the purposes of section 7F, a notified category of medical device shall not be deemed to be misbranded or adulterated or spurious or not of standard quality and for the purposes of section 18" shall be substituted;	
	(*ii*) in clause (*a*), for the word "consumption", the words "use or consumption"	

	shall be substituted;	
	(*d*) in sub-section (*3*), for the word and figures "section 18", the words, figures and letter "section 7F or section 18" shall be substituted.	
Amend ment of section 20.	**25**. In section 20 of the principal Act,-	
	(*a*) in sub-section (*1*), for the words "such drugs or classes of drugs or such cosmetics or classes of cosmetics", the words "such drugs, cosmetics and notified categories of medical devices" shall be substituted;	
	(*b*) in sub-section (*2*), for the words "such drugs or classes of drugs or such cosmetics or classes of cosmetics", the words "such drugs, cosmetics or notified categories of medical devices " shall be substituted;	
	(c) in sub-section (*4*), for the words "import, manufacture or sale of drugs or cosmetics", the words "import, manufacture or sale of drugs or cosmetics or notified categories of medical devices" shall be substituted.	
Amend ment of section 21.	**26**. In section 21 of the principal Act,-	
	(*a*) after sub-section (*4*), the following sub-section shall be inserted, namely:-	
	"(*5*) Any person appointed as the Inspector under this section, before the commencement of the Drugs and Cosmetics (Amendment) Act, 2014, shall, after such commencement, be deemed to have been appointed as the Drugs Control Officer for the purposes of this Chapter and shall continue to discharge his functions as the Drugs Control Officer unless his appointment is terminated or withdrawn.".	
Amend ment of section 22.	**27**. In section 22 of the principal Act,-	
	(*a*) for the words "drug or cosmetic" wherever they occur, the words "drug or cosmetic or notified category of medical device" shall be substituted;	
	(b) for the words "this Chapter", wherever they occur except in clause (*cca*) of sub-section (*1*), the words, figures and letter "Chapter IIA or Chapter IV" shall be substituted;	
	(*c*) in sub-section (1),- (A) in clause (*b*), in sub-clause (*i*), for the words "being manufactured", the words "being imported or manufactured" shall be substituted;	

	(B) in clause (*d*), for the words 'exercise such other powers', the words 'exercise such other powers and perform such functions' shall be substituted;	
	(C) after clause (*d*), the following proviso shall be inserted, namely:– "Provided that in case the stocks of the drugs or cosmetics or notified category of medical devices, and the record, registers, documents or any other material objects connected or related thereto are seized, he shall, as soon as may be, inform the Judicial Magistrate and take his orders as to the custody thereof.".	
Substitution of new section for section 23.	**28**. For section 23 of the principal Act, the following section shall be substituted, namely:-	
Sampling of drug, cosmetic and notified category of medical device.	"23. The Drugs Control Officer or any other officer duly authorised by the Central Government, State Government, the Drugs Controller General India or State Drugs Controller by whatever name called, as the case may be, shall take sample of drug, cosmetic and notified category of medical device for test, analysis and examination under Chapter IIA, Chapter III and Chapter IV in such manner as may be prescribed.".	
Amendment of section 24.	**29**. In section 24 of the principal Act, for the words "drug or cosmetic" at both places, the words "drug, cosmetic or notified category of medical device" shall be substituted.	
Substitution of new section for section 25.	**30**. For section 25 of the principal Act, the following section shall be substituted, namely:-	
Report	"25. (1) The report of the Government Analyst in respect of sample of drug,	

of Government Analyst.	cosmetic and notified category of medical device shall be the conclusive evidence of facts stated therein, unless challenged in such manner as may be prescribed. (2) The procedure for further action on the report of the Government Analyst shall be such as may be prescribed.".	
Amendment of section 26.	**31**. In section 26 of the principal Act, for the words "drug or cosmetic", the words "drug, cosmetic or notified category of medical device" shall be substituted;	
Amendment of section 26A.	**32**. In section 26A of the principal Act,- (a) for the words "this Chapter", the words, letter and figures "Chapter IIA and Chapter IV" shall be substituted; (b) for the words "drug or cosmetic at both the place where they occur", the words "drug, cosmetic or notified category of medical device" shall be substituted.	
Amendment of section 26B.	**33**. In section 26B of the principal Act, for the word "drug" at both the places where it occur, the words "drug or notified category of medical device" shall be substituted.	
Amendment of section 27.	**34**. In section 27 of the principal Act,-	
	(i) in the opening portion, for the words "for distribution,", the words "for distribution or for market," shall be substituted;	
	(*ii*) in clause (*a*), in the second proviso,-	
	(*a*) for the word "relative", the words "legal heir" shall be substituted;	
	(*b*) the "*Explanation*" shall be omitted.	
	(iii) for clause (d), the following clauses shall be substituted, namely:-	
	"(d) any drug deemed to be misbranded under section 17, shall be liable for penalty which may extend to two lakh rupees to be imposed by the Central Licensing Authority or State Licensing Authority, as the case may be, in such manner as may be prescribed.	
	(e) any drug, other than a drug referred to in clause (a) or clause (b) or clause (c) or clause (d), in contravention of the any other provision of this Chapter or any rule made under the Act, shall be liable for penalty which may extend to five lakh rupees to be imposed by the Central Licensing Authority or State Licensing Authority, as the case may be, in such manner as may be prescribed.".	
Amendment of	**35**. In section 27A of the principal Act,-	

section 27A.		
	(a) in the opening portion, for the words "for distribution,", the words "for distribution or for market," shall be substituted;	
	(b) for clause (ii), the following clauses shall be substituted, namely:-	
	"(ii) any cosmetic deemed to be misbranded under section 17C, shall be liable for penalty which may extend to fifty thousand rupees to be imposed by the State Licensing Authority in such manner as may be prescribed.	
	(iii) any cosmetic, other than a drug referred to in clause (i) or clause (ii), in contravention of the any other provision of this Chapter or any rule made under the Act, shall be liable for penalty which may extend to two lakh rupees to be imposed by the State Licensing Authority in such manner as may be prescribed.".	
Amend ment of section 28.	**36**. In section 28 of the principal Act, for the words "may extend to one year or with fine which shall not be less than twenty thousand rupees or with both", the words "shall not be less than three years and shall also be liable to fine which shall not be less than three lakh rupees" shall be substituted.	
Amend ment of section 28A.	**37**. In section 28A of the principal Act, for the words "may extend to one year or with fine which shall not be less than twenty thousand rupees or with both", the words "may extend to three years or fine which may extend to rupees three lakh or both" shall be substituted.	
Amend ment of section 28B.	**38**. In section 28B of the principal Act, for the words "may extend to three years and shall also be liable to fine which may extend to five thousand rupees", the words "shall not be less than three years and shall also be liable to fine which shall not be less than five lakh rupees" shall be substituted.	
Amend ment of section 29.	**39**. In section 29 of the principal Act,-	
	(*a*) for the words "drug or cosmetic", the words "drug, cosmetic or notified category of medical device" shall be substituted;	
	(*b*) for the words "which may extend to five thousand rupees", the words "which shall not be less than fifty thousand rupees" shall be substituted.	
Amend ment of section 30.	**40**. In section 30 of the principal Act,-	
	(i) in sub-section (1), for clause (c), the following clauses shall be substituted, namely:-	
	"(c) under clause (d) and clause (e) of section 27, again make contravention under	

	that clause, shall be liable for penalty which may extend to five lakh rupees to be imposed by the Central Licensing Authority or State Licensing Authority, as the case may be, in such manner as may be prescribed;	
	(d) under clause (i) and clause (ii) of section 27A, again make contravention under that clause, shall be liable for penalty which may extend to three lakh rupees to be imposed by the State Licensing Authority in such manner as may be prescribed.".	
	(*ii*) in sub-section (*1A*), for the words "may extend to two years or with a fine which may extend to two thousand rupees", the words "shall not be less than three years and shall also be liable to fine which shall not be less than ten lakh rupees" shall be substituted;	
	(*iii*) in sub-section (*2*), for the words "may extend to two years, or with fine which shall not be less than ten thousand rupees or with both", the words "shall not be less than two years and shall also be liable to fine which shall not be less than one lakh rupees" shall be substituted;	
	(*iv*) after sub-section (*2*), the following sub-section shall be inserted, namely:-	
	"(*3*) Whoever having been convicted of an offence under section 28A or section 28B is again convicted of an offence under that section 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.".	
Insertion of new section 30A.	**41.** After section 30 of the principal Act, the following section shall be inserted, namely:-	
Power of Central Government and State Government to recover certain amount as	"30A. (1) Where any person liable to pay any amount by way of fine or penalty in pursuance of any order made under the provisions of this Act or the rules made there under default in paying or depositing the whole or any part 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 an arrear of land revenue. (2) Notwithstanding anything contained in any other law for the time being in force, no court, tribunal or other authority shall grant any injunction or make any order prohibiting or restraining any Government from recovering any amount as an arrears of land revenue in pursuance of the provisions of sub-section (1).".	

arrear of land revenue.		
Amendment of section 31.	**42**. In section 31 of the principal Act, in sub-section (*1*), in clause (*ii*), for the words, brackets, letters and figure "clause (c) of section 18", the words and figures "section 18" shall be substituted.	
Amendment of section 31A.	**43**. In section 31A of the principal Act, for the words and figures "this Chapter except those contained in section 31", the words, figures and letter "Chapter IA, Chapter IIA and Chapter IV except those contained in section 4ZM, section7M and section 31" shall be substituted;	
Amendment of section 32.	**44**. In section 32 of the principal Act, for the words "this Chapter" wherever they occur, the words, figures and letter "Chapter IIA or Chapter III or Chapter IV" shall be substituted.	
Insertion of new sections 33Q, 33R, 33S and 33T.	**45**. After section 33P of the principal Act, the following sections shall be inserted, namely:-	
Appoint of Drugs Controller General of India.	"33Q. For the purposes of this Act, the Central Government may, by notification, appoint an officer, having such qualifications and experience as may be prescribed, as the Drugs Controller General of India.	
Appoint of State Drugs Controller.	33R. For the purposes of this Act, a State Government may, by notification, appoint an officer, having such qualifications and experience as may be prescribed, as the State Drugs Controller by whatever name called.	

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Delegation of power of Central Licensing Authority and State Licensing Authority.	33S. (1) The Drugs Controller General of India may, with the approval of the Central Government, by an Order in writing, delegate his powers as Central Licensing Authority to any other officer under his control. (2) The Drugs Controller of a State, by whatever name called, may, with the approval of the State Government, by an Order in writing, delegate his powers as State Licensing Authority to any other officer under his control.	
Appeal to Central Licensing Authority against the decision or action of any subordinate officer.	33T. (1) Where any person is aggrieved by any action or decision of an officer to whom the powers under the provisions of the Act and rules made there under have been delegated, may prefer an appeal to the Central Licensing Authority in such manner as may be prescribed.	
	(2) Where any person is not satisfied with the decision of the Central Licensing Authority under sub-section (1), he may prefer an appeal to the Central Government in such manner as may be prescribed.	
Appeal to State Licensing Author	33U. (1) Where any person is aggrieved by any action or decision of an officer to whom the powers under the provisions of the Act and rules made there under have been delegated, may prefer an appeal to the State Licensing Authority in such manner as may be prescribed.	

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ity against the decision or action of any subordinate officer.		
	(2) Where any person is not satisfied with the decision of the State Licensing Authority under sub-section (1), he may prefer an appeal to the State Government in such manner as may be prescribed.	
Power of Central Government to suspend or cancel any permission, licence or certificate.	33V. (1) The Central Government may suspend or cancel any permission, licence or certificate issued by the Central Licensing Authority or a State Licensing Authority, in public interest and for reasons to be recorded in writing, by notification. (2) Where the Central Government is satisfied that the permission, licence or certificate specified under sub-section (1) is not in accordance with the provisions of this Act and the rules made there under, that Government may, by notification, suspend or cancel such permission, licence or certificate.".	
Amendment of section 34A.	**46**. In section 34A of the principal Act,-	
	(*a*) for the words, figures and letter "Chapter IV or Chapter IVA" at both the places where they occur, the words, figures and letters "Chapter IA, Chapter IIA, Chapter III, Chapter IV or Chapter IVA" shall be substituted;	
	(*b*) for the words "manufacture, sale or distribution of drugs", the words "clinical trial, import, manufacture, sale or distribution of drugs, cosmetics or notified	

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	categories of medical devices" shall be substituted.	
Amendment of section 34AA.	**47**. In section 34AA of the principal Act,-	
	(*i*) in clause (*c*), for the words "any drug or cosmetic", the words "any drug, cosmetic or notified category of medical device" shall be substituted;	
	(*ii*) for the words "one thousand rupees", the words "one lakh rupees" shall be substituted.	
Insertion of new section 34AAA.	**48**. After section 34AA of the principal Act, the following section shall be inserted, namely:-	
Penalty for submission of misleading or wrong information or refusal to furnish information.	"34AAA. Whoever himself or by any other person on his behalf imports, manufactures, stocks, sells, or distributes, or intends to do so, any drug or cosmetic or notified category of medical device and submits misleading or wrong information or refuses to provide correct information in that regard as required by the Licensing Authority under this Act shall be punishable with imprisonment for a term which shall not be less than two years and shall also be liable to fine which shall not be less than one lakh rupees.".	
Insertion of new sections 35A and 35B.	**49**. After section 35 of the principal Act, the following sections shall be inserted, namely:-	

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Convicted person liable for cost of storage.	"35A. Any person convicted for an offence under this Act shall be liable to bear the cost of storage of any article related to such offence, seized under this Act.	
Drugs, cosmetics and medical devices proved spurious, misbranded, adulterated or not of standard qualilty to be distroyed.	35B. The seized spurious or misbranded or adulterated or not of standard quality drugs, cosmetics and notified category of medical devices, having been proved so and after their use as evidence in the case before the court is over, shall be destroyed by the official authority in custody of these products in the manner as may be prescribed and the convicted person shall be liable to bear the cost of destruction of seized articles.".	
Insertion of new section 39.	**50**. After section 38 of the principal Act, the following section shall be inserted namely:-	
Removal of difficulty.	"39. (1) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of this Act as appear to it to be necessary or expedient for removing the difficulty: Provided that no order shall be made under this section after the expiry of a period of three years from the commencement of this Act	

	(2) Every order made under this section shall be laid, as soon as may be after it is made, before each house of Parliament.".	
Amendment of second Schedule.	**51**. In the Second Schedule to the principal Act, against serial No. 1, under column heading "Class of drug", for the words "Patent or proprietary", the word "Proprietary" shall be substituted.	
Insertion of new Third Schedule	**52**. After the Second Schedule to the principal Act, the following Schedule shall be inserted, namely:-	
	"THE THIRD SCHEDULE (See sub-section (6) of section 18) CATEGORIES OF DRUGS FOR WHICH THE CENTRAL LICENSING AUTHORITY IS EMPOWERED TO ISSUE LICENCE AND PERMISSION. 1. antigens and anti-toxins; 2. blood products; 3. cytotoxic substances (anti-cancer drugs); 4. drug products containing modified living organisms; 5. fixed dose combination. 6. gene therapeutic products; 7. hormones and preparations containing hormones; 8. large volume parenterals; 9. monoclonal anti-bodies; 10. recombinant-deoxyribo nucleic acid derived drugs; 11. ribo nucleic acid derived drugs; 12. sera; 13. solution of serum proteins intended for injection; 14. stem cells and cell based drug products; 15. toxins; 16. vaccines; 17. xenografts;	