

**Bill No. LVII of 2007**

THE DRUGS AND COSMETICS (AMENDMENT) BILL, 2007

A

BILL

*further to amend the Drugs and Cosmetics Act, 1940.*

BE it enacted by Parliament in the Fifty-eighth Year of the Republic of India as follows:—

**1.** (1) This Act may be called the Drugs and Cosmetics (Amendment) Act, 2007.

Short title and commencement.

(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.

23 of 1940.

**2.** In the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the principal Act), in section 3,—

Amendment of section 3.

(i) for clause (aa), the following clauses shall be substituted, namely:—

‘(aa) “Central Drugs Authority” means the Central Drugs Authority of India constituted under sub-section (1) of section 5;

(aai) “Chairperson” means the Chairperson of the Central Drugs Authority;

(aaii) “clinical trial” means systematic study of any drug or cosmetic in human subjects 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 or the cosmetic;’;

(ii) in clause (b), for sub-clause (iv), the following sub-clause shall be substituted, namely:—

“(iv) such medical device, medicated device, instrument, apparatus, appliance, material, software necessary for their application, intended for internal or external use in human beings or animals, whether used alone or in combination, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Central Drugs Authority, for the purpose of diagnosis, prevention, monitoring, treatment or mitigation of any disease or disorder; diagnosis, monitoring, treatment, alleviation of or compensation for, any injury or handicap; investigation, replacement or modification of anatomy or physiology; or control of conception, and which does not achieve its intended action primarily by any pharmacological or immunological or metabolic process, but is included in the pharmacopoeias mentioned in the Second Schedule;’;

(iii) after clause (b), the following clauses shall be inserted, namely:—

‘(bb) “Drugs Controller (India)” means the Drugs Controller (India) appointed under sub-section (1) of section 5E;

(bbb) “Fund” means the Fund constituted under sub-section (1) of section 5-I;’;

(iv) in clauses (c) and (e), for the words “Central Government”, wherever they occur, the words “Central Drugs Authority” shall be substituted;

(v) in clause (f), for the words “sale or distribution”, the words “sale or export or distribution” shall be substituted;

(vi) after clause (f), the following clause shall be inserted, namely:—

‘(ff) “Member” means a Member of the Central Drugs Authority and includes the Chairperson;’;

(vii) in clause (h), in sub-clause (ii), for the words “Drugs Technical Advisory Board constituted under section 5”, the words “Central Drugs Authority” shall be substituted.

Insertion of  
new Chapters.

**3.** In the principal Act, after Chapter I, the following Chapters shall be inserted, namely:—

#### ‘CHAPTER IA

##### CENTRAL DRUGS AUTHORITY OF INDIA

Constitution  
of Central  
Drugs Autho-  
rity.

5. (1) The Central Government shall, by notification in the Official Gazette, constitute an Authority to be known as the Central Drugs Authority of India.

(2) The Central Drugs Authority shall be a body corporate by the name aforesaid,

having perpetual succession and a common seal with power, subject to the provisions of this Act, to acquire, hold and dispose of property, both movable and immovable, and to contract, and may, by the said name, sue or be sued.

(3) The Central Drugs Authority shall consist of a Chairperson and not more than five, but at the least three, Members, to be appointed by the Central Government by notification in the Official Gazette.

(4) The headquarters of the Central Drugs Authority shall be at Delhi.

(5) The Central Drugs Authority may, by notification in the Official Gazette, establish its offices at such other places in India as it considers necessary.

5A. The Chairperson and Members of the Central Drugs Authority shall be appointed by the Central Government from amongst persons who have special knowledge of, and at the least fifteen years' professional experience in pharmaceutical industry, research or teaching, or public administration, finance or law: Qualifications of Chairperson and Members.

Provided that a person who is, or has been, in the service of Government shall not be appointed as a Chairperson or Member unless such person has held the post of Secretary or Additional Secretary to the Government of India or any equivalent post in the Central Government or a State Government or a Public Sector Undertaking.

5B. The Chairperson or Member shall hold office as such for a term of three years from the date on which he enters upon his office, and shall be eligible for reappointment for a further term of three years: Term of office of Chairperson and Members.

Provided that the Chairperson or Member shall not hold office as such on attaining the age of seventy years.

5C. The salaries, allowances and pensions payable to, and other conditions of service of, the Members shall be such, as may be prescribed by the Central Government. Salaries, allowances, pensions and other conditions of service of Members.

5D. No act or proceeding of the Central Drugs Authority shall be invalidated merely by reason of—

(a) any vacancy in, or any defect in the constitution of, the Central Drugs Authority;

(b) any defect in the appointment of a person as a Member of the Central Drugs Authority; or

(c) any irregularity in the procedure of the Authority not affecting the merits of the case.

5E. (1) The Central Drugs Authority shall appoint a Drugs Controller (India), and such other officers and employees as it considers necessary for the efficient discharge of its functions and exercise of its powers under this Act. Staff of the Central Drugs Authority.

(2) The salaries, allowances and pensions payable to, and other conditions of service of, the Drugs Controller (India), other officers and employees of the Central Drugs Authority appointed under sub-section (1) shall be such as may be determined by the Central Drugs Authority by regulations.

(3) The Drugs Controller (India) shall be the Secretary of the Central Drugs Authority.

5F. (1) The Central Drugs Authority may issue licences under clause (c) of section 10, clause (c) of section 18 and clause (c) of section 33EEC, and collect fees therefor. Powers and functions of Central Drugs Authority.

(2) The Central Drugs Authority may cancel or suspend any licence issued under sub-section (1).

(3) The Central Drugs Authority shall collect charges for granting permission for conduct of clinical trials in respect of drugs and cosmetics.

(4) The Central Drugs Authority may constitute such committees or sub-committees as it considers essential for the efficient discharge of its functions and exercise of its powers under this Act.

(5) The Central Drugs Authority shall recommend to the Central Government—

(a) standards for drugs and cosmetics;

(b) the Central Drugs Laboratories for the purpose of testing drugs and cosmetics;

(c) measures to regulate import of drugs and cosmetics;

(d) measures to regulate manufacture for sale or for export or for distribution, or sale, stock or exhibition of drugs and cosmetics;

(e) standards for good manufacturing and laboratory practices and other such practices;

(f) measures to regulate clinical trials;

(g) amounts of fees and other charges payable under this Act;

(h) any other measures for the purpose of giving effect to the provisions of this Act.

(6) The Central Drugs Authority shall regulate its own procedure.

5G. (1) The Drugs Controller (India) shall exercise the powers conferred upon him under this Act or the rules framed thereunder or assigned to him by the Central Drugs Authority.

(2) The Drugs Controller (India) shall be the Chief Executive Officer and the legal representative of the Central Drugs Authority, and shall be responsible for—

(a) the day-to-day administration of the Central Drugs Authority;

(b) drawing up of proposals for the work programmes of the Central Drugs Authority;

(c) implementing the work programmes approved and the decisions made by the Central Drugs Authority;

(d) the preparation of the statement of revenue and expenditure and the execution of the budget of the Central Drugs Authority;

(e) the preparation of draft annual report for submission to and approval of the Central Drugs Authority.

(3) The Drugs Controller (India) shall have administrative control over other officers and employees of the Central Drugs Authority.

5H. The Central Government may, after due appropriation made by Parliament by law in this behalf, make to the Central Drugs Authority grants of such sums of money as are required by it.

5-I. (1) There shall be constituted a Fund to be called the Central Drugs Authority of India Fund and there shall be credited thereto—

(a) all grants, fees and charges received by the Central Drugs Authority under this Act; and

Powers and functions of Drugs Controller (India).

Grants by Central Government.

Fund.

(b) all sums received by the Central Drugs Authority from such other sources as may be determined by the Central Government.

(2) The Fund shall be applied for meeting—

(a) the salaries, allowances and pensions payable to the Chairperson and other Members and the administrative expenses, including the salaries, allowances and pensions payable to or in respect of the Drugs Controller (India) and other officers and employees of the Central Drugs Authority; and

(b) the expenses to carry out the objects and purposes of this Act.

5J. (1) The Central Drugs Authority shall maintain proper accounts and other relevant records and prepare an annual statement of accounts in such form as may be prescribed by the Central Government in consultation with the Comptroller and Auditor-General of India. Accounts and audit.

(2) The accounts of the Central Drugs Authority shall be audited by the Comptroller and Auditor-General of India at such intervals as may be specified by him and any expenditure incurred in connection with such audit shall be payable by the Central Drugs Authority to the Comptroller and Auditor-General of India.

(3) The Comptroller and Auditor-General of India and any other person appointed by him in connection with the audit of the accounts of the Central Drugs Authority shall have the same rights and privileges and authority in connection with such audit as the Comptroller and Auditor-General generally has, in connection with the audit of the Government accounts and, in particular, shall have the right to demand the production of books, accounts, connected vouchers and other documents and papers and to inspect any of the offices of the Central Drugs Authority.

(4) The accounts of the Central Drugs Authority as certified by the Comptroller and Auditor-General of India or any other person appointed by him in this behalf, together with the audit report thereon, shall be forwarded annually to the Central Government and that Government shall cause the same to be laid, as soon as may be after it is received, before each House of Parliament.

5K. (1) The Central Drugs Authority shall prepare every year an annual report in such form and manner and at such time as may be prescribed by the Central Government, giving summary of its activities during the previous year and copies of the report shall be forwarded to the Central Government. Annual report.

(2) A copy of the report forwarded under sub-section (1) shall be laid, as soon as may be after it is received, before each House of Parliament.

5L. (1) The Central Government may, after consultation with, or on the recommendation of, the Central Drugs Authority and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter: Power to make rules.

Provided that consultation with the Central Drugs Authority 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 Central Drugs Authority shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Central Drugs Authority may make in relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may provide for the following matters, namely:—

(a) the salaries, allowances and pensions payable to, and other conditions of service of, the Members under section 5C;

(b) the manner and form in which the accounts of the Central Drugs Authority shall be maintained under sub-section (1) of section 5J;

(c) the form and manner in which and the time within which annual report is to be made to the Central Government under sub-section (1) of section 5K.

Power to make regulations.

5M. (1) The Central Drugs Authority may, by notification in the Official Gazette, make regulations consistent with this Act and the rules made thereunder, to discharge its functions and exercise its powers.

(2) In particular, and without prejudice to the generality of the foregoing power, such regulations may provide for the following matters, namely:—

(a) the salaries, allowances and pensions payable to, and other conditions of service of, the Drugs Controller (India) and other officers and employees of the Central Drugs Authority under sub-section (2) of section 5E;

(b) the regulation of the procedure of the Central Drugs Authority under sub-section (6) of section 5F.

## CHAPTER IB

### CLINICAL TRIALS

No clinical trial without permission.

5N. No person shall conduct clinical trials in respect of any drug or cosmetic except under, and in accordance with, the permission granted by the Central Drugs Authority.

Punishment for conducting clinical trial without permission.

5O. (1) Whoever, himself or by any other person on his behalf, conducts clinical trials in contravention of section 5N shall be punished with imprisonment for a term which may extend to five years and with fine which may extend to ten lakh rupees.

(2) Whoever having been convicted of an offence under sub-section (1) is again convicted of an offence under that sub-section, shall be punished with imprisonment for a term which may extend to ten years and with fine which may extend to twenty lakh rupees.

Trial of offences.

5P. (1) No prosecution under section 5-O shall be instituted except upon complaint made in writing in this behalf by an officer authorised by the Central Drugs Authority.

(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 section 5-O.

Power to make rules.

5Q. (1) The Central Government may after consultation with, or on the recommendation of, the Central Drugs Authority 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 Central Drugs Authority 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 Central Drugs Authority shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Central Drugs Authority may make in relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may provide for the form and conditions of the permission under section 5N, the charges payable therefor, and the cancellation or suspension of such permission in any case where any provision of this Act or the rules made thereunder is contravened or any of the conditions subject to which the permission is granted is not complied with.'

- 4.** In the principal Act, in Chapter II, for the Chapter heading “THE DRUGS TECHNICAL ADVISORY BOARD, THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE”, the Chapter heading “THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE” shall be substituted. Substitution of heading of Chapter II.
- 5.** In the principal Act, section 5 shall be omitted. Omission of section 5.
- 6.** In the principal Act, in section 6,—
- (a) for the word “Laboratory”, wherever it occurs, the words “Laboratory or Laboratories” shall be substituted;
- (b) in sub-section (2), for the word “Board”, the words “Central Drugs Authority” shall be substituted.
- 7.** In the principal Act, in section 7,—
- (a) in sub-section (1), for the words “Drugs Technical Advisory Board”, the words “Central Drugs Authority” shall be substituted;
- (b) for sub-section (2), the following sub-section shall be substituted, namely:—
- “(2) the Drugs Consultative Committee shall consist of such number of representatives of the Central Government, industry, consumer associations, academic and research institutions, as may be prescribed and one representative of each State Government to be nominated by the State Government concerned.”;
- (c) after sub-section (3), the following sub-section shall be inserted, namely:—
- “(4) The Central Government may, after consultation with the Central Drugs Authority, make rules prescribing the number of representatives under sub-section (2).”.
- 8.** In the principal Act, section 7A shall be omitted. Omission of section 7A.
- 9.** In the principal Act, in section 8, in sub-section (2), for the word “Board”, the words “Central Drugs Authority” shall be substituted. Amendment of section 8.
- 10.** In the principal Act, in section 10, in the second proviso, for the word “Board”, the words “Central Drugs Authority” shall be substituted. Amendment of section 10.
- 11.** In the principal Act, in section 12,—
- (a) in sub-section (1), for the word “Board”, wherever it occurs, the words “Central Drugs Authority” shall be substituted;
- (b) in sub-section (2), in clause (a), the words “the authority empowered to issue the same” shall be omitted.
- 12.** In the principal Act, in section 16, in sub-section (2), for the word “Board”, the words “Central Drugs Authority” shall be substituted. Amendment of section 16.
- 13.** In the principal Act, in section 18,—
- (a) for the words “manufacture for sale or for distribution”, wherever they occur, the words “manufacture for sale or for export or for distribution” shall be substituted;
- (b) in the second proviso, for the word “Board”, the words “Central Drugs Authority” shall be substituted.
- 14.** In the principal Act, in sections 20 and 21, for the words “Central Government”, wherever they occur, the words “Central Drugs Authority” shall be substituted. Amendment of sections 20 and 21.
- 15.** In the principal Act, in section 22, in sub-section (1), in clause (cca), for the words “manufacture for sale or for distribution”, the words “manufacture for sale or for export or for distribution” shall be substituted. Amendment of section 22.

- Amendment of sections 27 and 27A. **16.** In the principal Act, in sections 27 and 27A, for the words “manufactures for sale or for distribution”, at both the places where they occur, the words “manufactures for sale or for export or for distribution” shall be substituted.
- Amendment of section 31. **17.** In the principal Act, in section 31, in sub-section (1), in clause (ii), for the words “manufacture for sale, or for distribution”, the words “manufacture for sale or for export or for distribution” shall be substituted.
- Amendment of section 33. **18.** In the principal Act, in section 33,—  
 (a) in sub-section (1), for the word “Board”, wherever it occurs, the words “Central Drugs Authority” shall be substituted;  
 (b) in sub-section (2),—  
 (i) clause (b) shall be omitted;  
 (ii) in clause (e),—  
 (A) for the words “manufacture for sale or for distribution”, the words “manufacture for sale or for export or for distribution” shall be substituted; and  
 (B) the words “the authority empowered to issue the same, the qualifications of such authority” shall be omitted;  
 (iii) clause (n) shall be omitted.
- Omission of section 33C. **19.** In the principal Act, section 33C shall be omitted.
- Amendment of section 33D. **20.** In the principal Act, in section 33D,—  
 (a) in sub-section (1), for the words “Ayurveda, Siddha and Unani Drugs Technical Advisory Board”, the words “Central Drugs Authority” shall be substituted;  
 (b) for sub-section (2), the following sub-section shall be substituted, namely:—  
 “(2) the Ayurveda, Siddha and Unani Drugs Consultative Committee shall consist of such number of representatives of the Central Government, industry, consumer associations, academic and research institutions, as may be prescribed and one representative of each State Government to be nominated by the State Government concerned.”
- Amendment of section 33EEB. **21.** In the principal Act, in section 33EEB, for the words “manufacture for sale or for distribution”, the words “manufacture for sale or for export or for distribution” shall be substituted.
- Amendment of section 33EEC. **22.** In the principal Act, in section 33EEC,—  
 (A) in clause (a), for the words “manufacture for sale or for distribution”, the words “manufacture for sale or for export or for distribution” shall be substituted;  
 (B) in clause (c),—  
 (i) for the words “manufacture for sale or for distribution”, the words “manufacture for sale or for export or for distribution” shall be substituted; and  
 (ii) the words “by the prescribed authority” shall be omitted.
- Amendment of sections 33F and 33G. **23.** In the principal Act, in sections 33F and 33G, for the words “Central Government”, wherever they occur, the words “Central Drugs Authority” shall be substituted.
- Amendment of section 33-I. **24.** In the principal Act, in section 33-I, for the words “manufactures for sale or for distribution”, the words “manufactures for sale or for export or for distribution” shall be substituted.



**25.** In the principal Act, in section 33L, for the words “manufacture for sale”, at both the places where they occur, the words “manufacture for sale or for export or for distribution” shall be substituted. Amendment of section 33L.

**26.** In the principal Act, in section 33N,— Amendment of section 33N.

(a) in sub-section (1), for the word “Board”, wherever it occurs, the words “Central Drugs Authority” shall be substituted;

(b) in sub-section (2),—

(i) clause (b) shall be omitted;

(ii) in clause (e),—

(A) for the words “manufacture for sale”, the words “manufacture for sale or for export or for distribution” shall be substituted; and

(B) the words “the authority empowered to issue the same” shall be omitted;

(iii) after clause (f), the following clause shall be inserted, namely:—

“(ff) prescribe the number of representatives under sub-section (2) of section 33 D;”.

**27.** In the principal Act, in section 33-O, for the word “Board”, the words “Central Drugs Authority” shall be substituted. Amendment of section 33-O.

**28.** In the principal Act, for section 38, the following section shall be substituted, namely:— Substitution of new section for section 38.

“38. Every rule and every regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation.”. Rules and regulations to be laid before Parliament.

## STATEMENT OF OBJECTS AND REASONS

The Drugs and Cosmetics Act, 1940 (the Act) is a consumer protection legislation, which is mainly concerned with the standards and quality of drugs and regulates the import, manufacture, sale and distribution of drugs and cosmetics.

2. The Central Government had constituted an Expert Committee under the chairmanship of Dr. R.A. Mashelker, Director General of the Council of Scientific and Industrial Research in January 2003 to undertake a comprehensive examination of drug regulatory issues, including the problem of spurious drugs and to suggest measures to improve the drug administration in the country. The Committee, *inter alia*, recommended setting up of a Central Drugs Authority reporting directly to the Ministry of Health and Family Welfare and a system of centralised licensing. The Central Government considered the recommendations of the Committee and proposes to make amendments in the Act, in order to facilitate setting up of a Central Drugs Authority and introduction of Centralised licensing for manufacture of drugs in pursuance of the said recommendations. The Drugs and Cosmetics (Amendment) Bill, 2007, *inter alia*, provides for:—

(a) substitution of the "Drugs Technical Advisory Board" as well as the "Drugs Technical Advisory Board for Ayurvedic, Siddha and Unani Drugs" by the "Central Drugs Authority";

(b) insertion of a new Chapter IA with a view to providing the constitution of the Central Drugs Authority and other connected or incidental matters;

(c) insertion of a new Chapter IB in the Act, providing for grant of permission for clinical trials, punishment for conducting clinical trial without permission, trial of offences, etc.; and

(d) expansion of the compositions of the Drugs Consultative Committees.

3. Certain consequential changes in the Act are also proposed so as to make it in consonance with proposal for setting up of the Central Drugs Authority.

4. The Bill seeks to achieve the above objects.

NEW DELHI;  
The 7th June, 2007.

ANBUMANI RAMADOSS.

*Notes on clauses*

*Clause 1* relates to short title and commencement of the Act.

*Clause 2* amends section 3 of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the Act) in order to add definitions of the terms "Central Drugs Authority", "Chairperson", "Member", "Drugs Controller (India)", "clinical trial" and "Fund", amend the definition of the term "drug", and substitute the words "Central Government" in the definitions of the terms "Government analyst" and "Inspector" with the words "Central Drugs Authority", the words "sale or distribution" in the definition of the term "manufacture" with the words "sale or export or distribution" and the words "Drugs Technical Advisory Board constituted under section 5" in the definition of the term "patent or proprietary medicine" with the words "Central Drugs Authority".

*Clause 3* inserts a new Chapter, CHAPTER IA titled "CENTRAL DRUGS AUTHORITY OF INDIA" containing proposed new sections 5 to 5M and CHAPTER IB titled "CLINICAL TRIALS" containing proposed new sections 5N to 5Q.

Proposed new section 5 provides for the constitution of the Central Drugs Authority of India, its nature, composition, location of headquarters and power to set up offices in other places in India.

Proposed new section 5A provides for qualifications of Chairperson and Members of the Central Drugs Authority.

Proposed new section 5B provides for the term of office of the Chairperson and Members of the Central Drugs Authority.

Proposed new section 5C gives the power to the Central Government for prescribing the salaries, allowances, pensions payable to, and other conditions of service of, the Chairperson and Members of the Central Drugs Authority.

Proposed new section 5D provides that any vacancy in, or any defect in the constitution of, or any defect in the appointment of the Chairperson or a Member of the Central Drugs Authority or any irregularity in its procedure not affecting the merits of a case, would not invalidate its proceedings.

Proposed new section 5E gives power to the Central Drugs Authority to appoint Drugs Controller (India) and other officers and employees of the Authority and to fix their salaries, allowances and pensions. It also provides that the Drugs Controller (India) shall be the Secretary of the Central Drugs Authority.

Proposed new section 5F enumerates the powers and functions of the Central Drugs Authority.

Proposed new section 5G provides for the powers and functions of the Drugs Controller (India).

Proposed new section 5H provides for grants to be made by the Central Government to the Central Drugs Authority.

Proposed new section 5-I provides for constitution of the Central Drugs Authority of India Fund as well as what shall be credited thereto. It also provides the purposes for which the Fund shall be applied.

Proposed new section 5J provides for maintenance of proper accounts by the Central Drugs Authority and the details regarding procedure for auditing of its accounts.

Proposed new section 5K provides for preparation of an annual report by the Central Drugs Authority, which shall be forwarded to the Central Government and also laid before each House of Parliament.

Proposed new section 5L lays down the power of the Central Government to make rules, in consultation with the Central Drugs Authority, for giving effect to the provisions as contained in CHAPTER IA.

Proposed new section 5M provides for power of the Central Drugs Authority to make regulations for discharge of its functions and exercise of its powers.

Proposed new section 5N prohibits the conduct of clinical trials in respect of any drug or cosmetic without due permission from the Central Drugs Authority.

Proposed new section 5-O provides for punishment for conducting clinical trials without permission.

Proposed new section 5P provides for procedure for trial of offences under section 5-O.

Proposed new section 5Q gives powers to the Central Government to make rules, in consultation with the Central Drugs Authority, to give effect to the provisions of CHAPTER IB.

*Clause 4* provides for substitution of the existing heading of CHAPTER II of the Act with "THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE".

*Clause 5* provides for omission of section 5 of the Act dealing with the Drugs Technical Advisory Board.

*Clause 6* amends section 6 of the Act for substituting the word 'Laboratory' with the words 'Laboratory or laboratories' and the word 'Board' with the words 'Central Drugs Authority'.

*Clause 7* amends section 7 of the Act for substituting the words "Drugs Technical Advisory Board" with the words "Central Drugs Authority". It also provides for change in the composition of the Drugs Consultative Committee.

*Clause 8* omits section 7A of the Act.

*Clauses 9 to 18 and clauses 20 to 27* amend various sections of the Act for replacing the word "Board", wherever it occurs, with the words "Central Drugs Authority", the words "manufacture for sale or for distribution", wherever they occur, with the words "manufacture for sale or for export or for distribution" and the words "Ayurvedic, Siddha and Unani Drugs Technical Advisory Board", wherever they occur, with the words "Central Drugs Authority", and to provide for new composition of the Ayurvedic, Siddha and Unani Drugs Consultative Committee.

*Clause 19* provides for omission of section 33C of the Act dealing with the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board.

*Clause 28* substitutes new section 38 dealing with laying of every rule and every regulation made under the Act before each House of Parliament within a stipulated timeframe.

## FINANCIAL MEMORANDUM

*Clause 3* of the Drugs and Cosmetics (Amendment) Bill, 2007 proposes to insert, *inter alia*, new section 5A in the Drugs and Cosmetics Act, 1940 empowering the Central Government to appoint the Chairperson and Members of the Central Drugs Authority of India and new section 5C in the said Act empowering the Central Government to decide on the salaries, allowances and pensions payable to, and other conditions of service of, the Members of the Central Drugs Authority of India. Some recurring expenditure will be involved in regard to payment of salaries, allowances and pensions payable to the Chairperson and Members of the Central Drugs Authority of India. The exact amount of expenditure involved will depend on the number of Members appointed and will be met out of the revenues of the Central Drugs Authority of India.

2. It is estimated that no expenditure, either of recurring or non-recurring nature, from the Consolidated Fund of India, would be involved.

#### MEMORANDUM REGARDING DELEGATED LEGISLATION

*Clause 3* of the Bill proposes to insert new Chapters IA and IB (containing new sections 5 to 5Q) in the Drugs and Cosmetics Act, 1940. New section 5L proposes to confer power on the Central Government to make rules for giving effect to the provisions of Chapter IA after consultation with, or on the recommendation of, the Central Drugs Authority and after previous publication by notification in the Official Gazette. New section 5M proposes to confer power upon the Central Drugs Authority to make regulations consistent with the said Act and the rules made thereunder to discharge its functions and exercise its powers. New section 5Q proposes to confer power on the Central Government to make rules for giving effect to the provisions of Chapter IB after consultation with, or on the recommendation of the Central Drugs Authority and after previous publication by notification in the Official Gazette. *Clause 7* of the Bill proposes to insert new sub-section (4) in section 7 of the said Act to confer power on the Central Government to make rules for prescribing the number of Central Government's representatives in the Drugs Consultative Committee under sub-section (2) of section 7 of the said Act, after consultation with Central Drugs Authority. *Clause 26(b) (iii)* of the Bill proposes to insert new clause (ff) after clause (f) in sub-section (2) of section 33N of the said Act, to confer power on the Central Government to make rules for the purpose of prescribing the number of Central Government's representatives in the Ayurvedic, Siddha and Unani Drugs Consultative Committee under sub-section (2) of section 33D of the said Act.

These matters are the matters of procedure and administrative detail. Hence, it is not practical to provide for them in the Bill. The delegation of legislative powers is, therefore, normal in character.

ANNEXURE

EXTRACTS FROM THE DRUGS AND COSMETICS ACT, 1940

(23 OF 1940)

*	*	*	*	*
3.	In this Act, unless there is anything repugnant in the subject or context,—			Definitions.
*	*	*	*	*
	(aa) “the Board” means—			
	(i) in relation to Ayurvedic, Siddha or Unani drug, the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board constituted under section 33C; and			
	(ii) in relation to any other drug or cosmetic, the Drugs Technical Advisory Board constituted under section 5;			
*	*	*	*	*
	(b) “drug” includes—			
*	*	*	*	*
	(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;			
	(c) “Government Analyst” means—			
	(i) in relation to Ayurvedic, Siddha or Unani drug, a Government Analyst appointed by the Central Government or a State Government under section 33F; and			
	(ii) in relation to any other drug or cosmetic, a Government Analyst appointed by the Central Government or a State Government under section 20;			
*	*	*	*	*
	(e) “Inspector” means—			
	(i) in relation to Ayurvedic, Siddha or Unani drug, an Inspector appointed by the Central Government or a State Government under section 33G; and			
	(ii) in relation to any other drug or cosmetic, an Inspector appointed by the Central Government or a State Government under section 21;			
	(f) “manufacture” in relation to any drug or cosmetic includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business; and “to manufacture” shall be construed accordingly;			
*	*	*	*	*
	(h) “patent or proprietary medicine”,—			
	(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;’			
*	*	*	*	*

## CHAPTER II

THE DRUGS TECHNICAL ADVISORY BOARD, THE CENTRAL DRUGS LABORATORY AND  
THE DRUGS CONSULTATIVE COMMITTEE

The Drugs  
Technical  
Advisory  
Board.

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 the following members, namely:—

- (i) the Director General of Health Services, *ex officio*, who shall be Chairman;
- (ii) the Drugs Controller, India, *ex officio*;
- (iii) the Director of the Central Drugs Laboratory, Calcutta, *ex officio*;
- (iv) the Director of the Central Research Institute, Kasauli, *ex officio*;
- (v) the Director of the Indian Veterinary Research Institute, Izatnagar, *ex officio*;
- (vi) the President of the Medical Council of India, *ex officio*;
- (vii) the President of the Pharmacy Council of India, *ex officio*;
- (viii) the Director of the Central Drug Research Institute, Lucknow, *ex officio*;
- (ix) two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States;
- (x) one person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian university or a college affiliated thereto;
- (xi) one person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto;
- (xii) one person to be nominated by the Central Government from the pharmaceutical industry;
- (xiii) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;
- (xiv) one person to be elected by the Central Council of the Indian Medical Association;
- (xv) one person to be elected by the Council of the Indian Pharmaceutical Association;
- (xvi) two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government.

(3) The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election:

Provided that the person nominated or elected, as the case may be, under clause (ix) or clause (x) or clause (xi) or clause (xvi) of sub-section (2) shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the Board.

(4) The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.



(5) The Board may constitute sub-committees and may appoint to such sub-committees for such periods, not exceeding three years, as it may decide, or temporarily for the consideration of particular matters, persons who are not members of the Board.

(6) The functions of the Board may be exercised notwithstanding any vacancy therein.

(7) The Central Government shall appoint a person to be Secretary of the Board and shall provide the Board with such clerical and other staff as the Central Government considers necessary.

**6. (1)** The Central Government shall, as soon as may be establish a Central Drugs Laboratory under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by this Act or any rules made under this Chapter: The Central Drugs Laboratory.

Provided that, if the Central Government so prescribes, the functions of the Central Drugs Laboratory in respect of any drug or class of drugs or cosmetic or class of cosmetics shall be carried out at the Central Research Institute, Kasauli, or at any other prescribed Laboratory and the functions of the Director of the Central Drugs Laboratory in respect of such drug or class of drugs or such cosmetic or class of cosmetics shall be exercised by the Director of that Institute or of that other Laboratory, as the case may be.

(2) The Central Government may, after consultation with the Board, make rules prescribing—

(a) the functions of the Central Drugs Laboratory;

\* \* \* \* \*

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

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

(f) the matters necessary to be prescribed for the purposes of the proviso to subsection (1).

**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 matter tending to secure uniformity throughout India in the administration of this Act. The Drugs Consultative Committee.

(2) The Drugs Consultative Committee shall consist of two representatives of the Central Government to be nominated by that Government and one representative of each State Government to be nominated by the State Government concerned.

(3) The Drugs Consultative Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.

**7A.** Nothing contained in sections 5 and 7 shall apply to Ayurvedic, Siddha or Unani drugs. Sections 5 and 7 not apply to Ayurvedic, Siddha or Unani drugs.

**CHAPTER III**

**IMPORT OF DRUGS AND COSMETICS**

**8. (1)** \* \* \* \* \* Standards of quality.

(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.

\* \* \* \* \*

Prohibition of import of certain drugs or cosmetics.

**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 or cosmetic which is not of standard quality;

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

(bb) any adulterated or spurious drug;

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

(d) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof;

(e) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;

(ee) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(f) any drug or cosmetic the import of which is prohibited by rule made under this Chapter:

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

Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the import of any drug or class of drugs not being of standard quality.

\* \* \* \* \*

Power of Central Government to make rules.

**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:

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

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

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

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

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

(cc) prescribe under clause (d) of section 9A, the colour or colours which a drug may bear or contain for purposes of colouring;

(d) specify the diseases or ailments which an imported drug may not purport or claim to prevent, cure or mitigate and such other effects which such drug may not purport or claim to have;

(e) prescribe the conditions subject to which small quantities of drugs, the import of which is otherwise prohibited under this Chapter, may be imported for the purpose of examination, test or analysis or for personal use;

(f) prescribe the places at which drugs or cosmetics may be imported, and prohibit their import at any other place;

(g) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label or container or any specified imported drug or class of such drug, and prohibit the import of the said drug or class of drug after the expiry of a specified period from the date of manufacture;

(h) regulate the submission by importers, and the securing, of samples of drugs or cosmetics for examination, test or analysis by the Central Drugs Laboratory, and prescribe the fees, if any, payable for such examination, test or analysis;

(i) prescribe the evidence to be supplied, whether by accompanying documents or otherwise, of the quality of drugs or cosmetics sought to be imported, the procedure of officers of Customs in dealing with such evidence, and the manner of storage at places of import of drugs or cosmetics detained pending admission;

(j) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter and the rules made thereunder of drugs or cosmetics imported for the purpose only of transport through, and export from, India;

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

(l) regulate the mode of labelling drugs or cosmetics imported for sale in packages, and prescribe the matters which shall or shall not be included in such labels;

(m) prescribe the maximum proportion of any poisonous substance which may be added to or contained in any imported drug, prohibit the import of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder;

(n) require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the label or wrapper of any imported, patent or proprietary medicine containing such drug;

(o) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder, of any specified drug or class of drugs or cosmetic or class of cosmetics.

\* \* \* \* \*

#### CHAPTER IV

##### MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS AND COSMETICS

16. (1) \* \* \* \* \* Standards of quality.

(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.

\* \* \* \* \*

Prohibition of manufacture and sale of certain drugs and cosmetics.

**18.** From such date may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf—

(a) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute—

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

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

(iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredient contained in it together with quantities thereof;

(iv) any drug which by means of any statement design or device accompanying it or by any other means, purports or claims to prevent, cure or mitigate any such disease or ailment, or to have any such other effect as may be prescribed;

(v) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(vi) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;

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

(c) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter:

\* \* \* \* \*

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

Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the 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.

\* \* \* \* \*

Government Analysts.

**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 such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification.

(3) Notwithstanding anything contained in sub-section (1) or sub section (2), neither the Central Government nor a State Government shall appoint as a Government

Analyst any official not serving under it without the previous consent of the Government under which he is serving.

(4) No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be a Government Analyst under sub-section (1) or sub-section (2) of this section.

**21.** (1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be. Inspectors.

(2) The powers which may be exercised by an Inspector and the duties which may be performed by him, the drugs or classes of drugs or cosmetics or classes of cosmetics in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed shall be such as may be prescribed.

(3) No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be an Inspector under this section.

45 of 1860. (4) Every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code, and shall be officially subordinate to such authority, having the prescribed qualifications, as the Government appointing him may specify in this behalf.

**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,— Powers of Inspectors.

\* \* \* \* \*

(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;

\* \* \* \* \*

**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,— Penalty for manufacture, sale, etc., drugs in contravention of this Chapter.

45 of 1860. (a) any drug deemed to be adulterated under section 17A or spurious under section 17B or 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 five years but which may extend to a term of life and with fine which shall not be less than ten thousand rupees;

(b) any drug—

(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 18,

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 five thousand rupees:

Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than one year and of fine of less than five thousand rupees;

(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 three years but which may extend to five years and with fine which shall not be less than five thousand rupees:

Provided that the Court may, for any adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less than three years but not less than one year;

(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:

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.

Penalty for manufacture, sale, etc., of cosmetics in contravention of this Chapter.

**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—

(i) any cosmetic deemed to be spurious under section 17C shall be punishable with imprisonment for a term which may extend to three years and with fine;

(ii) any cosmetic other than a cosmetic referred to in clause (i) above 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 with fine which may extend to one thousand rupees or with both.

Confiscation.

**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 17, adulterated under section 17A or spurious under section 17B; or

(ii) manufacture for sale, or for distribution, sale or stocking or exhibiting or offering for sale, or distribution of any drug without a valid licence as required under 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.

\* \* \* \* \*

Power of Central Government to make rules.

**33.** (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 the relation to the amendment of the said rules.

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

\* \* \* \* \*

(b) prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;

\* \* \* \* \*

(e) prescribe the forms of licences for the manufacture for sale or for Distribution for the sale and for the distribution of drugs or any specified drug or class of drugs or of cosmetics or any specified cosmetic or class of cosmetics, the form of application for such licences may be issued, the authority empowered to issue the same the qualifications of such authority and the fees payable therefor; and provide for the cancellation or suspension of such licences in any case where any provision of this Chapter or the rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with.

\* \* \* \* \*

(n) prescribe the powers and duties of Inspectors and the qualifications of the authority to which such Inspectors shall be subordinate and specify the drugs or classes of drugs or cosmetics or classes of cosmetics in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed;

\* \* \* \* \*

**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.

Ayurvedic,  
Siddha and  
Unani drug  
Technical  
Advisory  
Board.

(2) The Board shall consist of the following members, namely:—

(i) the Director General of Health Services, *ex officio*;

(ii) the Drugs Controller, India, *ex officio*;

(iii) the Principal Officer dealing with, Indian systems of medicine in Ministry of Health *ex-officio*;

(iv) the Director of the Central Drugs Laboratory, Calcutta, *ex officio*;

(v) one person holding the appointment of Government Analyst under section 33F, to be nominated by the Central Government;

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

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

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

(ix) one teacher in Dravyaguna and Bhaishajya Kalpana, to be nominated by the Central Government;

(x) one teacher in ILM-UL-ADVIA and TAKLISWA-DAWASAZI, to be nominated by the Central Government;

(xi) one teacher in Gunapadam to be nominated by the Central Government;

(xii) three persons, on each to represent the Ayurvedic, Siddha and Unani drug industry, to be nominated by the Central Government;

(xiii) three persons, one each from among the practitioners of Ayurvedic, Siddha and Unani Tibb systems of medicine to be nominated by the Central Government.

The Ayurvedic, Siddha and Unani Drugs Consultative Committee.

**33D.** (1) The Central Government may constitute and 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 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.

\* \* \* \* \*

Regulation of manufacture for sale of Ayurvedic, Siddha and Unani drugs.

**33EEB.** No person shall manufacture for sale or for distribution any Ayurvedic, Siddha or Unani drugs except in accordance with such standards, if any, as may be prescribed in relation to that drug.

Prohibition of manufacture and sale of certain Ayurvedic, Siddha and Unani drugs.

**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—

(a) manufacture for sale or for distribution—

(i) any misbranded, adulterated or spurious Ayurvedic, Siddha or Unani drug;

(ii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true list of all the ingredients contained in it; and

(iii) any Ayurvedic, Siddha or Unani drug in contravention of any of the provisions of this Chapter or any rule made thereunder;

\* \* \* \* \*

(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:

Provided that nothing in this section shall apply to Vaidyas and Hakims who manufacture Ayurvedic, Siddha or Unani drug for the use of their own patients:

Provided further that nothing in this section shall apply to the manufacture, subject to the prescribed conditions, of small quantities of any Ayurvedic, Siddha or Unani drug for the purpose of examinations, test or analysis.

Government Analysts.

**33F.** (1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such person as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

(2) Notwithstanding anything contained in sub-section (1), neither the Central Government nor a State Government shall appoint as a Government Analyst any official not serving under it without the previous consent of the Government under which he is serving.

(3) No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be a Government Analyst under this section.

Inspectors.

**33G.** (1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.



(2) The powers which may be exercised by an Inspector and the duties which may be performed by him and the conditions, limitations or restrictions subject to which such powers and duties may be exercised or performed shall be such as may be prescribed.

(3) No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be an Inspector under this section.

45 of 1860.

(4) Every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code and shall be officially subordinate to such authority as the Government appointing him may specify in the behalf.

\* \* \* \* \*

**33-I.** Whoever himself or by any other person on his behalf—

Penalty for manufacture, sale, etc., of Ayurvedic, Siddha or Unani drug in contravention of this Chapter.

(1) manufactures for sale or for distribution,—

(a) any Ayurvedic, Siddha or Unani drug—

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

(ii) without a valid licence as required under clause

(c) of section 33EEC,

shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than two thousand rupees;

(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 five thousand rupees:

Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than one year and of fine of less than five thousand rupees; or

(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 three months and with fine which shall not be less than five hundred rupees.

\* \* \* \* \*

**33L.** 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

Application of provisions to Government Departments.

\* \* \* \* \*

**33N.** (1) The Central Government may, after consultation with, or on the recommendation of, the Board after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:

Power of Central Government to make rules.

\* \* \* \* \*

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

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

(a) provide for the establishment of laboratories for testing and analysing Ayurvedic, Siddha or Unani.

(b) prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;

(c) prescribe the methods of test or analysis to be employed determining whether any Ayurvedic Siddha or Unani drug is labelled with the true list of the ingredients which it is purported to contain;

(d) specify any substance as a poisonous substance;

(e) prescribe the forms of licences for the manufacture drugs for sale of drugs the forms 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.

(f) prescribe the conditions to be observed in the packing of Ayurvedic, Siddha and Unani durgs 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;

(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

(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;

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

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

Power to  
amend First  
Schedule.

**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 the Chapter and thereupon the said Schedule shall be deemed to be amended accordingly.

\* \* \* \* \*

Rules to be  
laid before  
Parliament.

**38.** Every rule made under this Act shall be laid as soon as may be after it is made before each House of Parliament while it is in session for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if before the expiry of the session in which it is so laid or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so however that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

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RAJYA SABHA

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**BILL**

further to amend the Drugs and Cosmetics Act, 1940.

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*(Dr. Ambumani Ramadoss, Minister of Health and Family Welfare)*