Be it enacted by Parliament in the Seventy First year of the Republic of India as follows: -

An Act to establish independent, autonomous Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic (AYUSSH) Medicines Regulatory Authority of India for laying down science-based standards and to regulate import, manufacture, sale, and distribution of Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic (AYUSSH) Medicines with a view to ensure availability of standard, safe and efficacious medicines.

Chapter I
Introductory

1) **Short title, extent, and commencement**: - This Act may be called as the Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic (AYUSSH) Medicines Act, 2020.

2) It extends to the whole of India.

3) It shall come into force on such date as the Central Government may by notification in official gazette appoint:

   Provided that different dates may be appointed for different provisions of this Act, and any reference to any such provision to the commencement of this Act shall be construed as a reference to the coming into force of that provision.

4) **Application of other laws not barred.** - The provisions of this Act shall be in addition to, and not in derogation of the any other law for the time being in force.

5) **Definitions.** — In this Act, unless there is anything repugnant in the subjects or context,

   (a) "Ayurvedic, Siddha, Unani and Sowa Rigpa Medicines" 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 and process described in, the authoritative books of Ayurvedic, Siddha and Unani and Sowa Rigpa medicine, specified in the First Schedule

   (b) "the Board" means the Ayurvedic, Siddha, Unani, Sowa Rigpa and Homeopathic Medicines Technical Advisory Board constituted under Section ------

   (c) "Government analyst" means: -

   (i) In relation to Ayurvedic, Unani, Siddha and Sowa Rigpa medicine a Government Analyst appointed by the Central Government or a State Government under Section -------

   (ii) In relation to Homoeopathic medicines a Government Analyst appointed by the Central Government or a State Government under Section ---

   (e) "AYUSSH Medicine Regulatory Officer" means - an officer appointed by the Central

Government or a State Government under Section ----------

(f) "Manufacture" in relation to any AYUSSH medicine includes any process or part of a process for making, altering, ornamenting, finishing, packing, labeling, breaking up or otherwise treating or adopting any medicine with a view to its sale or distribution but does not include the compounding or dispensing of any medicine, or the packing of any medicine in the ordinary course of retail business and to manufacture shall be construed accordingly.

(g) "to import" with its grammatical variations and cognate expressions means to bring into India.

(h) "Proprietary medicine" means all formulations containing only such ingredient(s) mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani or Sowa Rigpa system of medicine specified in the First Schedule and is approved by the State Licensing Authority based on the therapeutic rationale and scientific evidence, 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);

(i) New Ayurvedic, Unani, Siddha or Sowa Rigpa medicines - For the purpose of this Act, new AYUSSH medicines shall mean and include: -

(a) Any ingredient or formulation not included in any authoritative book of Ayurvedic, Unani, Siddha and Sowa Rigpa system of medicine listed in First Schedule and has not been used in the country for any significant extent and not supported by documentary usage in India for at least a period of 30 years, under the conditions prescribed, recommended or suggested and has not been recognized as safe and effective by the Central Licensing Authority.

(b) Any formulation containing ingredient or ingredients listed in the authoritative books of Ayurvedic, Unani, Siddha and Sowa Rigpa system of Medicines but is proposed to be manufactured and marketed for new claim not specified in the authoritative books.

(c) Any extract or any formulation containing ingredient or ingredients listed in the authoritative books of Ayurvedic, Unani, Siddha and Sowa Rigpa system but is proposed to be manufactured by using a method different than specified in the authoritative books.

(d) Any AYUSSH medicine covered by the definition under Section 5 (a) or 5 (h) which is now proposed to be manufactured and marketed in a new dosage form except those already licensed or new drug delivery system.

Explanation:- AYUSSH New medicine shall continue to be considered as new medicine for a period of four years from the date of its first approval or its inclusion in respective Pharmacopoeia or Authoritative books listed in First Schedule.

(j) Balya /Poshak/ Muquawi/ Unavuporutkal / Positive health Promoter means those formulations having ingredients mentioned in books of First Schedule of this Act and

recommended for promotional and preventive health.

(k) **Saudarya Prasadak** (**Husane afza**)/ **Azhagh-Sadhan** formulation having ingredients mentioned in Books of First Schedule of this Act and recommended for oral, skin, hair and body care.

(l) **Aushadh Ghana (Medical plant extracts – dry /wet**) extract obtained from plant mentioned in books of First Schedule of the Act including Aqueous or hydro-alcohol.

(m) Homeopathic medicines include any drug which is recorded in Homoeopathic proving or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative Homoeopathic literature of India and abroad and which is prepared according to the techniques of Homoeopathic pharmacy and covers combination of ingredients of such Homoeopathic medicines but does not include a medicine which is administered by parenteral route.

(n) New Homoeopathic means:-

(i) A Homoeopathic medicine which is not specified in the Homoeopathic Pharmacopoeia of India or the United States of America or the United Kingdom or the German Homoeopathic Pharmacopoeia; or

(ii) Which is not recognized in authoritative Homoeopathic literature as efficacious under the conditions recommended; or

(iii) A combination of Homoeopathic medicines containing one or more medicines which are not specified in any of the pharmacopoeias referred to in clause (i) as Homoeopathic medicines and also not recognized in authoritative Homoeopathic literature as efficacious under the conditions recommended.

(o) **Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic (AYUSSH) Medicines Regulatory Authority** means authority established under Section ----of the Act.

(p) Chairperson means Chairperson of the Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic (AYUSSH) Medicines Regulatory Authority.

(q) Drugs Controller General India (AYUSSH) means an officer having prescribed qualification and experience appointed by the Central Government.

(r) Director of AYUSSH Medicine means Director of Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic Medicines having prescribed qualification and experience appointed by the State Government.

(s) Central Licensing Authority means the Drugs Controller General India (AYUSSH) or the officer to whom power is delegated.

(t) State Licensing Authority means Director of AYUSSH Medicines or the officer to whom power is delegated.

(u) AYUSSH Medicine Testing Laboratory means any drug laboratory or institute established by the Central Government or State Government.

(v) Central AYUSSH Medicine Testing Laboratory means

(i) In relation to Ayurvedic, Unani, Siddha and Sowa Rigpa medicines the Pharmacopeial Laboratory of Indian Medicines, Ghaziabad or any other laboratory declared to be Central AYUSSH Medicine Testing Laboratory by the Central Government.

(ii) In relation to Homoeopathic medicines the Homoeopathic Pharmacopoeia Laboratory, Ghaziabad or any other laboratory declared to be Central AYUSSH Medicine Testing Laboratory by the Central Government.

(w) State Government includes the administrator of a Union Territory appointed by the President under article 239 of the Constitution.

(x) Improvement notice means notice issued by the Central Licensing Authority or the State Licensing Authority, as the case may be.

(y) Prescribed' means prescribed by rules made under this Act.

(z) "Notified Body" means a body corporate or other legal entity accredited by the National Accreditation Board or certification bodies or any other Accreditation Body as a body competent to carry out the audit of manufacturing site, assessment of compliance of Good Manufacturing Practices and conditions of licenses.

Provided that the National Accreditation Board for Certification Bodies under the Quality Council of India, registered under the Societies Registration Act, 1860 (21 of 1860) set up by the Ministry of Commerce and Industry in the Government of India shall Act as the National Accreditation Body for the purposes of accrediting Notified Bodies till such time any other body for the purpose is notified, with immediate effect.
[Note: -- Awaiting modified definition of National Body from Dr. Anil Johri and Dr. Rana]

(za) "Marketer" means a person who as an agent or in any other capacity adopts any AYUSSH medicine manufactured by another manufacturer under an agreement for marketing of such medicine by labeling or affixing his name on the label of the medicine with a view for its sale and distribution.

CHAPTER II

Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic (AYUSSH) Medicine Regulatory Authority

6) Establishment of Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic (AYUSSH) Medicines Regulatory Authority

a) The Central Government shall by notification in the official gazette constitute an authority to be known as Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic

(AYUSSH) Medicines Regulatory Authority.

b) Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic (AYUSSH) Medicines Regulatory Authority shall be body corporate by the name aforesaid having perpetual succession and a common seal with power, subject to the provisions.

c) Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic (AYUSSH) Medicines Regulatory Authority shall consist of a Chairperson, Drugs Controller General India (AYUSSH) and not more than seven Members to be appointed by the Central Government by notification in the Official Gazette.

d) The headquarters of the AYUSSH Medicine Regulatory Authority shall be at Delhi.

e) The AYUSSH Medicine Regulatory Authority may, by notification in the Official Gazette, establish its offices at such other places in India as it considers necessary.

f) The Chairperson and Members of the Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic (AYUSSH) Medicines Regulatory 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 Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic Medicines Industry, research or teaching, or public administration, finance or law.

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 Additional Secretary or Joint Secretary respectively to the Government of India or any equivalent post in the Central Government or a State Government or a Public Sector Undertaking.

g) The Drugs Controller General India (AYUSSH) shall be Member Secretary of the Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic Medicines Regulatory Authority.

7) No act or proceeding of the Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic (AYUSSH) Medicines Regulatory Authority shall be invalidated merely by reason of -

(a) any vacancy in, or any defect in the constitution of, the Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic (AYUSSH) Medicines Regulatory Authority.

(b) any defect in the appointment of a person as a Member of the Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic (AYUSSH) Medicines Regulatory Authority.

8) Ayurvedic, Unani, Siddha, Sowa Rigpa and Homeopathic (AYUSSH) Medicines Regulatory 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.

9) **Selection Committee for selection of Chairperson and Members of AYUSSH Authority**.

(1) The Central Government shall, for the purpose of selection of the Chairperson and the Members, constitute a Selection Committee consisting of –

(a) Cabinet Secretary – Chairperson,
(b) Secretary-in-charge of the Ministry of AYUSSH responsible for administration of this Act as the convener– Member,
(c) Secretary-in-charge of the Ministry of Health -- Member
(d) Secretary-in-charge of Legislative and Personnel– Members,
(e) Chairman of the Public Enterprises Selection Board –Member,

(2) The Central Government shall, within two months from the date of occurrence of any vacancy by reason of death, resignation, or removal of the Chairperson or a Member authority and three months before the superannuation or completion of the term of office of the Chairperson or any Member of that Authority, make a reference to the Selection Committee for filling up of the vacancy.

(3) The Selection Committee shall finalise the selection of the Chairperson and Members within two months from the date on which the reference is made to it.

(4) The Selection Committee shall recommend a panel of two names for every vacancy referred to it.

(5) Before recommending any person for appointment as a Chairperson or other Member of the Authority, the Selection Committee shall satisfy itself that such person does not have any financial or other conflicting interest, which is likely to affect prejudicially his functions as a Chairperson or a Member.

10) **Term of Office, salary, allowances and other conditions of service of Chairperson and Members of AYUSSH Medicine Regulatory Authority**

a.The Chairperson and the members other than *ex officio* Members shall hold office for a term of three years from the date on which they enter upon their offices, and shall be eligible for re-appointment for a further period of three years:
Provided that the Chairperson and any Member shall not hold office as such after he has attained the age of seventy years.

b. The salary and allowances payable to, and the other terms and conditions of service of the Chairperson and Members other than *ex-officio* Members shall be such as may be prescribed by the Central Government.

c.The Chairperson and every Member shall, before entering upon his office, make and subscribe to an oath of office and of secrecy in such form and in such manner and before such authority as may be prescribed by the Central Government.

d. Notwithstanding anything contained in sub-section the Chairperson or any Member may –
i) relinquish his office by giving in writing to the Central Government a notice of not less than three months; or
ii) be removed from his office in accordance with the provisions of section 11.

e.The Chairperson or any Member ceasing to hold office as such shall not represent any person before the Authority or any State Authority in any manner for at least two years.

11) **Removal of Chairperson and Members of the AYUSSH Medicine Regulatory Authority.**

1. Notwithstanding anything contained in sub-section (a) of section 10, the Central Government may, by order, remove from office the Chairperson or any other Member, if the Chairperson or as the case may be, such other Member, -
   (a) has been adjudged an insolvent; or
   (b) has been convicted of an offence which, in the opinion of the Central Government, involves moral turpitude; or
   (c) has become physically or mentally incapable of acting as a Member; or
   (d) has acquired such financial or other interests as is likely to affect. prejudicially his functions as a Member; or
   (e) has so abused his position as to render his continuance in office prejudicial to the public interest.

2. No Member shall be removed under clauses (d) and (e) of sub-section (1) unless he has been given a reasonable opportunity of being heard in the matter.

3. No appointment of the Chairperson or other Member of the AYUSSH Medicine Regulatory Authority shall be invalid merely by reason of any vacancy in the Selection Committee.

12) **Officers and other employees of Ayurvedic, Unani, Siddha, Sowa Rigpa and Homoeopathic (AYUSSH) Medicines Regulatory Authority.**

(1) Drugs Controller General India (AYUSSH) shall be the Member-Secretary of the Authority.
(2) The Authority may, with the approval of the Central Government, determine the number, nature and categories of other officers and employees required to the Authority in the discharge of its functions.
(3) The salaries and allowances payable to and other conditions of service of the officers and other employees shall be such as may be specified by regulations by the Authority with the approval of the Central Government.

13) The Central Government may, after due appropriation made by the Parliament by law in this behalf, make to the AYUSSH Medicine Regulatory Authority grants of such sums of money as are required by it.

14) **Powers and Functions of the Drugs Controller General India (AYUSSH)**

(1) The Drugs Controller General India (AYUSSH) shall exercise the powers conferred upon him under this Act and the rules framed thereunder and assigned to him.

(2) The Drugs Controller General India (AYUSSH) shall be the legal representative of the

AYUSSH Medicine Regulatory Authority and shall be responsible for –

a) Coordinating and communicating with Directorate with Directors of AYUSSH Medicine at state level to ensure effective and uniform implementation of Act.
b) Approval of New AYUSSH Medicines.
c) the day-to-day administration of the Authority.
d) drawing up of proposal for the Authority's work programs in consultation with the AYUSSH Medicine Technical Advisory Board.
e) implementing the work programs and the decisions adopted by the Authority.
f) ensuring the provision of appropriate scientific, technical and administrative support for the Scientific Committee.
g) ensuring that the Authority carries out its tasks in accordance with the requirements of its users, in particular about the adequacy of the services provided and the time taken.
h) the preparation of the statement of revenue and expenditure and the execution of the budget of the Authority; and
i) developing and maintaining contact with the Central Government, and for ensuring a regular dialogue with its relevant committees.

(3) Every year, the Drugs Controller General India (AYUSSH) shall submit to the Authority for approval-

(a) a general report covering all the activities of the Authority in the previous year;
(b) programs of work;
(c) the annual accounts for the previous year; and
(d) the budget for the coming year.

(4) The Drugs Controller General India (AYUSSH) shall, following adoption by the Authority, forward the general report and the programs to the Central Government and shall have them published.

(5) The Drugs Controller General India (AYUSSH) shall approve all financial expenditure of the Authority and report on the Authority's activities to the Central Government.

(6) The Drugs Controller General India (AYUSSH) shall have administrative control over the officers and other employees of the Authority.

15) **AYUSSH Medicine Scientific Committee.**

a. The AYUSSH Regulatory Authority shall constitute separate Scientific Committees for Ayurvedic, Unani, Siddha, Sowa Rigpa and Homoeopathic medicines.

b. Each such scientific committee shall consist of six independent scientific experts in the respective field and these six experts shall select one of them to be Chairperson.

c. The Scientific Committee shall be responsible for providing the scientific opinions to the AYUSSH Medicines Technical Advisory Board, and shall have the powers, where necessary, of organizing public hearings.

d. The Scientific Committee shall be responsible for the general co-ordination necessary to ensure consistency of the scientific opinion procedure.

e. The Scientific Committee shall provide opinion on multi-sectoral issues and place such opinion before the AYUSSH medicines Technical Advisory Board.

f. Wherever necessary, the Scientific Committee may set up working groups and, in such cases, it shall draw on the expertise of those working groups when establishing scientific opinion.

16) **Duties and functions of AYUSSH Medicine Regulatory Authority.**

a. It shall be the duty of the AYUSSH Medicine Regulatory Authority to regulate and monitor the manufacture, distribution, sale and import of Ayurvedic, Unani, Siddha, Sowa Rigpa, Homoeopathic Medicines to ensure standard, safe and efficacious medicines.

b. The AYUSSH Medicine Regulatory Authority shall recommend to the Central Government: -
   i. Standards for Ayurvedic, Unani, Siddha, Sowa Rigpa, Homoeopathic Medicines.
   ii. The Central AYUSSH Medicine Testing Laboratory to function as the appellate laboratories for testing Ayurvedic, Unani, Siddha, Sowa Rigpa, Homoeopathic Medicines.
   iii. Measures to regulate manufacture for sale or for distribution or stock or exhibition for sale, sale and distribution of Ayurvedic, Unani, Siddha, Sowa Rigpa, Homoeopathic Medicines.
   iv. Standards for Good Manufacturing Practices and Good Laboratory Practices and other such practices.
   v. The procedure for approval of new Ayurvedic, Unani, Siddha, Sowa Rigpa, Homoeopathic Medicines.
   vi. Amounts of fees and other charges payable under this Act.

c. Without prejudice to the provisions of clause (a) and clause (b)the AYUSSH Medicine Regulatory Authority will have powers to issue regulations for giving effect to the provisions of the Act and for speedy and uniform implementation of the Act. such regulations may specify –
   i. Guidelines in relation to Ayurvedic, Unani, Siddha, Sowa Rigpa, Homoeopathic Medicines and specifying an appropriate system for enforcing various standards notified under this Act.
   ii. Declare the list of excipients from time to time permitted to be used in Ayurvedic, Unani, Siddha, Sowa Rigpa, Homoeopathic Medicines.
   iii. the procedure and guidelines for recognition of Notified Bodies engaged in certification of Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) for manufacturers.
   iv. the procedure and guidelines for recognition of laboratories and notification of the accredited laboratories.
   v. conduct survey of enforcement and administration of this Act in the country.

d. The AYUSSH Medicine Regulatory Authority shall also –

i. provide scientific advice and technical support to the Central Government and the State Governments in matters of framing the policy and rules in areas which have a direct or indirect bearing on standards, safety and efficacy of Ayurvedic, Unani, Siddha, Sowa Rigpa, Homoeopathic Medicines.
ii. establish a system of network of organisations with the aim to facilitate a scientific co-operation framework by the co-ordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the AYUSSH Medicine Regulatory Authority's responsibility.
iii. provide scientific and technical assistance to the Central Government and the State Governments for improving co-operation with international organisations;
iv. take all such steps to ensure that the public, consumers, interested parties and all levels of panchayats receive rapid, reliable, objective, and comprehensive information through appropriate methods and means.
v. organize training programs on various aspects such as Good Manufacturing Practices, Good Laboratory Practices, Good Distribution Practices, Good Raw Material Procurement Practices and various aspects affecting standards, safety and efficacy of Ayurvedic, Unani, Siddha, Sowa Rigpa, Homoeopathic Medicines.
vi. undertake any other task assigned to it by the Central Government to carry out the objects of this Act;
vii. promote general awareness in respect of rational use of medicines.

e) The AYUSSH Medicine Regulatory Authority may from time to time give such directions on matters relating to standards, safety, and efficacy of AYUSSH medicines and for effective and uniform implementation of the Act and rules thereunder to the Director of AYUSSH Medicine, who shall be bound by such directions while exercising his powers under this Act.

f) The AYUSSH Medicine Regulatory Authority shall not disclose or cause to be disclosed to third party's confidential information that it receives for which confidential treatment has been requested and has been acceded, except for information which must be made public if circumstances so require, in order to protect public health.

17) **Proceedings of AYUSSH Medicine Regulatory Authority.**

a. The AYUSSH Medicine Regulatory Authority shall meet at the head office or any of its offices at such time as the Chairperson may direct, and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be specified by regulations.

b. If the Chairperson is unable to attend a meeting of the AYUSSH Medicine Regulatory Authority, any other Member nominated by the Chairperson in this behalf and, in the absence of such nomination or where there is no Chairperson, any Member chosen by the Members present from amongst themselves, shall preside at the meeting.

c. All questions which come up before any meeting of the AYUSSH Medicine Regulatory Authority shall be decided by most votes of the Members present and voting, and in the event of an equality of votes, the Chairperson or the person presiding over the meeting shall have the right to exercise a second or casting vote.

d. All orders and decisions of the AYUSSH Medicine Regulatory Authority shall be authenticated by the Member Secretary.

e. The AYUSSH Regulatory Authority may invite the Chairperson of the Scientific Committee to attend its meetings but without a right to vote.

f. No act or proceedings of the AYUSSH Medicine Regulatory Authority shall be questioned or invalidated merely on the ground of existence of any vacancy or defect in the constitution of AYUSSH Medicine Regulatory Authority

CHAPTER III
AYUSSH Medicines Technical Advisory Board, AYUSSH Medicines Consultative Committee and Central AYUSSH Medicine Testing Laboratory

18) **Ayurvedic, Unani, Siddha, Sowa Rigpa and Homoeopathic Medicines Technical Advisory Board.**-

(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, Unani, Siddha, Sowa Rigpa and Homoeopathic Medicines Technical Advisory Board to advise the Central Government, AYUSSH Medicine Regulatory Authority and the State Governments on technical matters arising out of this Chapter and to carry out the other functions assigned to it by this Chapter.

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

(i) The Director-General of Health Services, ex officio.
(ii) The Drugs Controller, India, ex officio.
(iii) The Drugs Controller General India (AYUSSH) ex-officio.
(iv) The Director Central AYUSSH Medicine Testing Laboratory for Ayurvedic, Unani, Siddha, Sowa Rigpa Medicine and Homoeopathic Medicine, ex-officio.
(v) one Pharmacognocist to be nominated by the Central Government.
(vi) one Phyto-chemist to be nominated by the Central Government.
(vii) Four persons to be nominated by the Central Government, one from amongst the members of the Ayurvedic Pharmacopoeia Committee, one from amongst the members of the Unani Pharmacopoeia Committee and one from amongst the members of the Siddha Pharmacopoeia Committee and one from amongst member of Homoeopathic pharmacopoeia.
(viii) One expert from the field of Sowa Rigpa;

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

(x) one teacher in ILM-UL-ADVIA and TAKLIS-WADAWASAZI, to be nominated by the Central Government.

(xi) One teacher in Gunapadam to be nominated by the Central Government.

(xii) One teacher from Homoeopathic Medicine.

(xiii) Four persons, one each to represent the Ayurvedic, Siddha, Unani, and Homoeopathic medicine industry, to be nominated by the Central Government.

(xiv) Five persons, one each from among the practitioners of Ayurvedic, Siddha, Unani Sowa Rigpa and Homoeopathic systems of medicine to be nominated by the Central Government.

(xv) Three Director of AYUSSH Medicine from State Governments to be nominated by the Central Government.

(xvi) Three Government Analysts to be nominated by Central Government.

(xvii) One representative from National Medicinal Plant Board.

(xviii) One representative from B.I.S.

(xix) Director General of Central Council of Research in Ayurvedic Medicine.

(xx) Director General of Central Council of Research in Siddha Medicine.

(xxi) Director General of Central Council of Research in Unani Medicine.

(xxii) Director General of Central Council of Research in Homoeopathic Medicine.

(3) The Central Government shall appoint a member of the Board as its Chairman.

(4) The nominated members of the Board shall hold office for three years but shall be eligible for renomination.

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

(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.

19) **The Ayurvedic, Siddha, Unani, Sowa Rigpa and Homoeopathic (AYUSSH) Medicine Consultative Committee**. -

(1) The Central Government may constitute an advisory Committee to be called the Ayurvedic, Siddha, Unani, Sowa Rigpa and Homoeopathic Medicine Consultative Committee to advise the Central Government, the State Governments and the Ayurvedic, Siddha, Unani, Sowa Rigpa and Homoeopathic Medicine 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, Unani, Sowa Rigpa and Homoeopathic Medicine 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.

(3) The Ayurvedic, Siddha, Unani, Sowa Rigpa and Homoeopathic Medicine Consultative Committee shall meet when required to do so by the Central Government and shall regulate its own procedure.

20) **AYUSSH Medicine Testing Laboratory** – The Central Government and State Government shall establish AYUSSH Medicine Testing Laboratory in each state well equipped for testing of AYUSSH medicines and the existing laboratory shall be upgraded accordingly.

21) **The Central AYUSSH Medicine Testing Laboratory**–

(1) The Central Government shall, as soon as may be, establish Central AYUSSH Medicine Testing 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 thereunder.

Provided that the Central Government may declare any existing laboratory as the Central AYUSSH Medicine Testing Laboratory in respect of Ayurvedic, Unani, Siddha and Sowa Rigpa and Homoeopathic Medicines and the functions of the Director, Central AYUSSH Medicine Testing Laboratory in respect of such medicines or class of medicines shall be exercised by the Director of that institute or of that other laboratory.

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

(a) The functions of the Central AYUSSH Medicine Testing Laboratory.
(b) The procedure for the submission to the said Laboratory of samples of AYUSSH medicines for analysis or test, the forms of the Laboratory's reports thereon and the fees payable in respect of such reports.
(c) Such other matters as may be necessary or expedient to enable the said Laboratory to carry out its functions.
(d) The matters necessary to be prescribed for the purposes of the proviso to sub-section (1).

CHAPTER - IV

22. Standards of quality - (1) The expression "standard quality" means-

(a) in relation to Ayurvedic, Unani or Siddha medicines
  (i) included in Ayurvedic Pharmacopeia, Unani Pharmacopeia or Siddha Pharmacopoeia, that such medicine complies with the standards set out in the respective pharmacopeia,
  (ii) in relation to a Ayurvedic, Unani or Siddha medicines not included in Ayurvedic Pharmacopeia, Unani Pharmacopeia or Siddha Pharmacopoeia, that such medicine complies with such standard as may be prescribed.
  (iii) In relation to New Ayurvedic, Unani, Siddha or Sowa Rigpa medicines that such medicines comply with the standards as

(b) In relation to Sowa Rigpa medicines that such medicines comply with such standards as may be prescribed.

(c) In relation to Homoeopathic medicines:-
  (i) Included in Homoeopathic Pharmacopeia of India Standards of identity, purity and strength specified in the edition of the Homoeopathic

Pharmacopoeia of India for the time being in force and such other standards as may be prescribed.

(ii) Not included in Homoeopathic Pharmacopoeia of India but which are included in Homoeopathic Pharmacopoeia of United States of America or United Kingdom or German Homoeopathic Pharmacopoeia Standards of identity, purity and strength specified in the edition of such Pharmacopoeia for the time being in force in which they are given, and such other standards as may be prescribed.

(iii) Not included in the Homoeopathic Pharmacopoeia of India or Homoeopathic Pharmacopoeia of United States of America or United Kingdom or German Homoeopathic Pharmacopoeia. The formula or list of ingredients displayed in the prescribed manner on the label of the container and such other standards as may be prescribed.

(iv) In relation to New Homoeopathic medicines that such medicines comply with the standards as prescribed

23. Misbranded Medicines. An Ayurvedic, Siddha, Unani, Sowa Rigpa and Homoeopathic medicines shall be deemed to be misbranded-

(e) if it is so coloured, coated, powdered, or polished that damage is concealed, or if it is made to appear of better or greater therapeutic value than it really is; or

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

(g) if it is manufactured using excipients which are not permitted in the Act or the Rules made thereunder.

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

(i) if its label or container or anything accompanying the AYUSSH medicine bears any statement, design or device which makes any false claim for the AYUSSH medicine or which is false or misleading in any.

24. Adulterated Medicines. - An Ayurvedic, Siddha, Unani, Sowa Rigpa or Homoeopathic medicines shall be deemed to be adulterated, —

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

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

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

d. if it contains any medicine not recognized by Ayurvedic, Siddha, Unani, Sowa Rigpa or Homoeopathic system of medicines.

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

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

Explanation. - For the purpose of clause (a), AYUSSH medicine shall not be deemed to consist, in whole or in part, of any decomposed substance only by reason of the fact that such decomposed substance is the result of any natural decomposition of the AYUSSH medicine:

Provided that such decomposition is not due to any negligence on the part of the manufacturer of the AYUSSH medicine or the dealer thereof and that it does not render the AYUSSH medicine injurious to health.

25. Spurious medicines. - An Ayurvedic, Siddha, Unani, Sowa Rigpa or Homoeopathic medicines shall be deemed to be spurious-

a. if it is sold, or offered or exhibited for sale, under a name which belongs to another AYUSSH medicine; or

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

c. if the label or container bears the name of an individual or company purporting to be the manufacturer of the AYUSSH medicine, which individual or company is fictitious or does not exist; or

d. if it has been substituted wholly or in part by any other ATYSSH medicine or substance; or

e. if it purports to be the product of a manufacturer of whom it is not truly a product.

26. Prohibition of manufacture and sale of certain Ayurvedic, Siddha, Unani, Sowa Rigpa and Homoeopathic Medicines. -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 not of standard quality, misbranded, adulterated or spurious Ayurvedic, Siddha, Unani, Sowa Rigpa or Homoeopathic Medicines.

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 Unani, Sowa Rigpa and Homoeopathic Medicines in contravention of any of the provisions of this Chapter or any rule made thereunder;

b. sell, stock or exhibit or offer for sale or distribute any Ayurvedic, Siddha, Unani, Sowa Rigpa and Homoeopathic Medicines which has been imported or manufactured in contravention of any of the provisions of this Act, or any rule made thereunder;

c. sell, stock or exhibit or offer for sale or distribute any Ayurvedic, Siddha, Unani, Sowa Rigpa Medicine except and in accordance with the conditions of, a registration certificate issued for such purpose under this Chapter or in contravention of any or the provisions of this Act, or any rule made thereunder.

d. sell, stock or exhibit or offer for sale or distribute any Homoeopathic Medicine except and in accordance with the conditions of license issued for such purpose under this Chapter or in contravention of any or the provisions of this Act, or any rule made thereunder.

e. manufacture for sale or for distribution, any Ayurvedic, Siddha, Unani, Sowa Rigpa and Homoeopathic Medicines, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter.

f. manufacture for sale or for distribution, any New Ayurvedic, Siddha, Unani, Sowa Rigpa and Homoeopathic Medicine, unless it is approved by the Central Licensing Authority or any other authority authorized by the Central Government.

Provided that nothing in this section shall apply to Vaidyas and Hakims who manufacture Ayurvedic, Siddha, Unani, Sowa Rigpa Medicine 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, Unani, Sowa Rigpa Medicine for the purpose of examination, test, or analysis.

27. Pleas. –

(1) Save as hereinafter provided in this section, it shall be no defense in a prosecution under this Chapter to prove merely that the accused was ignorant of the nature, substance or quality of the AYUSSH medicine in respect of which the offence has been committed or of the circumstances of its manufacture or import, or that a purchaser, having bought only for the purpose of test or analysis, has not been prejudiced by the sale.

(2) For the purposes of Section 26 ATYSSH medicine shall not be deemed to be misbranded or adulterated or spurious or to be below standard quality only by reason of the fact that-

a. there has been added thereto some innocuous substance or ingredient because the same is required for the manufacture or preparation of the AYUSSH medicine as an article of commerce in a state fit for carriage or consumption, and not to increase the bulk, weight, or measure of the ATYSSH medicine or to conceal its inferior quality or other defects; or

b. in the process of manufacture, preparation, or conveyance some extraneous substance has unavoidably become intermixed with it: provided that this clause shall not apply in relation to any sale or distribution of the ATYSSH medicine occurring after the vendor or distributor became aware of such intermixture.

(3) A person, not being the manufacturer of a ATYSSH medicine or his agent for the distribution thereof or marketer, shall not be liable for a contravention of Section 26 if he proves-

(a) that he acquired the AYUSSH medicine from a duly licensed manufacturer or from distributor or dealer thereof holding necessary registration certificate

(b) that he did not know and could not, with reasonable diligence have ascertained that the AYUSSH medicine in any way contravened the provisions of that section; and

(c) that the AYUSSH medicine, while in his possession, was safely stored and remained in the same state as when he acquired it.

28. Government Analysts. -

(1) The Central Government or 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 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 AYUSSH medicine shall be appointed to be a Government Analyst under this section.

29. AYUSSH Medicine Regulatory Officers –

(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 qualification, to be AYUSSH Medicine Regulatory Officer 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 AYUSSH Medicine Regulatory Officer

and the duties which may be performed by him and the conditions, limitations, or restrictions subject to which such powers and duties may be exercised or performed shall be such as may be prescribed

(3) No persons who has any financial interest in the manufacture or sale of any AYUSSH medicine shall be appointed to be an AYUSSH Medicine Regulatory Officer under this section.

(4) Every AYUSSH Medicine Regulatory Officer 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 this behalf.

30. Powers of AYUSSH Medicine Regulatory Officer –

(1) Subject to the provisions of Section 31 and of any rules made by the Central Government in this behalf, an AYUSSH Medicine Regulatory Officer may, within the local limits of the area for which he is appointed

a) inspect,
   (i) any premises wherein any AYUSSH medicine is being manufactured and the means employed for standardizing and testing the AYUSSH medicine.
   (ii) any premises wherein any ATYSSH medicine is being sold, or stocked or exhibited or offered for sale, or distributed.

b) take samples of any AYUSSH medicine, -
   (i) which is being manufactured or being sold or is stocked or exhibited or offered for sale or is being distributed.
   (ii) from any person who is in the course of conveying, delivering or preparing to deliver such AYUSSH medicine to a purchaser or a consignee.

c) at all reasonable times, with such assistance, if any, as he considers necessary, -
   (i) search any person, who, he has reason to believe, has secreted about his person, any AYUSSH medicine in respect of which an offence under this Chapter has been, or is being, committed; or
   (ii) enter and search any place in which he has reason to believe that an offence under this Chapter has been, or is being, committed; or
   (iii) stop and search any vehicle, vessel or other conveyance which, he has reason to believe, is being, used for carrying any ATYSSH medicine in respect of which an offence under this Chapter has been, or is being, committed, and order in writing the person in possession of the ATYSSH medicine in respect of which the offence has been, or is being, committed, not to dispose of any stock of such AYUSSH medicine for a specified period not exceeding twenty days, or, unless the alleged offence is such that the defect may be removed by the possessor of the AYUSSH medicine, seize the stock of such ATYSSH medicine and any substance or article by means of which the offence has been, or is being, committed or which may be employed for the commission of such offence;

Provided that he shall record the reason in writing as to why he has decided to seize the stock of AYUSSH medicine and shall obtain prior permission from his immediate superior officer as far as it may be practicable.

d) examine any record, register, document or any other material object found with any person, or in any place, vehicle, vessel or other conveyance referred to in clause (c), and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act or the rules made thereunder.

e) require any person to produce any record, register or other document relating to the manufacture for sale or for distribution, stocking, exhibition for sale, offer for sale or distribution of any AYUSSH medicine in respect of which he has reason to believe that an offence under this Chapter has been or is being, committed.

f) exercise such other powers as may be necessary for carrying out the purposes of this Chapter or any rules made thereunder.

(2) The provisions of the Code of Criminal Procedure, 1973 (2 of 1974), shall, so far as may be, apply to any search or seizure under this Chapter as they apply to any search or seizure made under the authority of a warrant issued under Section 94 of the said Code.

(3) Every record, register or other document seized under clause (d) or produced under clause (e) shall be returned to the person, from whom they were seized or who produced the same, within a period of twenty days of the date of such seizure or production, as the case may be, after copies thereof or extracts therefrom certified by that person, in such manner as may be prescribed, have been taken.

(4) If any person willfully obstructs an AYUSSH Medicine Regulatory Officer in the exercise of the powers conferred upon him by or under this Chapter, or refuses to produce any record, register or other document when so required under clause (e) of sub-section (1) he shall be punishable with imprisonment which may extend to three years, or with fine, or with both.

31. Procedure of AYUSSH Medicine Regulatory Officer. -

(1) Where an AYUSSH Medicine Regulatory Officer takes any sample of AYUSSH medicine under this Chapter, he shall tender the fair price thereof and may acquire a written acknowledgement therefor.

(2) Where the price tendered under sub-section (1) is refused, or where the AYUSSH Medicine Regulatory Officer seizes the stock of any AYUSSH medicine under clause (c) of Section 30, he shall tender a receipt therefor in the prescribed form.

(3) Where an AYUSSH Medicine Regulatory Officer takes a sample of AYUSSH medicine for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he willfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked :

Provided that where the sample is taken from premises whereon the ATYSSH medicine is being manufactured, it shall be necessary to divide the sample into three portions only:

Provided further that where the AYUSSH medicine is made up in containers of small volume, instead of dividing a sample as aforesaid, the ATYSSH Medicine Regulatory Officer may, and if the AYUSSH medicine be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four of the said containers after suitably marking the same and, where necessary, sealing them.

(4) The AYUSSH Medicine Regulatory Officer shall restore one portion of a sample so divided or one container to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows-

(i) one portion or container he shall forthwith send to the Government Analyst for test or analysis.

(ii) the second he shall produce to the Court before which proceedings, if any, are instituted in respect of the ATYSSH medicine and

(iii) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under Section 33.

(5) Where an AYUSSH Medicine Regulatory Officer takes any action under clause (c) of Section 30,—

(a) he shall use all dispatch in ascertaining whether or not the AYUSSH medicine contravenes any of the provisions of Section 27 and, if it is ascertained that the AYUSSH medicine does not so contravene, forthwith revoke the order passed under the said clause or, as the case may be, take such action as may be necessary for the return of the stock seized.

(b) if he seizes the stock of the ATYSSH medicine, he shall as soon as be, inform a Judicial Magistrate and take his orders as to the custody thereof;

(c) without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the ATYSSH medicine, he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.

(6) Where an ATYSSH Medicine Regulatory Officer seizes any record, register, document or any other material object under clause (e) of sub-section (1) of Section 30, he shall as soon as be, inform a Judicial Magistrate and take his orders as to the custody thereof.

32. Reports of Government Analysts. –

(1) The Government Analyst to whom a sample of any ATYSSH medicine has been submitted for test or analysis under sub-section (4) of Section 31, shall deliver to the AYUSSH Medicine Regulatory Officer submitting it a signed report in triplicate in the prescribed form.

(2) The AYUSSH Medicine Regulatory Officer on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken and another copy to the person, if any, whose name, address and other particulars have been disclosed under Section 33 and shall retain the third copy for use in any prosecution in respect of the sample.

(3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken or the person whose name, address and other particulars have been disclosed under Section 34 has, within twenty- eight days of the receipt of a copy of the report, notified in writing the AYUSSH Medicine Regulatory Officer or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

(4) Where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused cause the sample of the AYUSSH Medicine Regulatory Officer produced before the Magistrate under sub-section (4) of Section 31 to be sent for test or analysis to the Central AYUSSH Medicine Testing Laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of, the Director of the Central AYUSSH Medicine Testing Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.

(5) The cost of a test or analysis made by the Central ATYSSH Medicine Testing Laboratory under sub- section (4) shall be paid by the complainant or accused as the Court shall direct.

33. Disclosure of name of manufacturer, etc.- Every person, not being the manufacturer of any AYUSSH medicine or his agent for the distribution thereof, shall if so required, disclose to the ATYSSH Medicine Regulatory Officer the name, address,

and other particulars of the person from whom he acquired the AYUSSH medicine.

34. Maintenance of records and furnishing of information. - Every person, holding a licence and/or registration certificate under clause (c),(d),(e) of section 26 shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act.

35. Persons bound to disclose place where AYUSSH medicines are manufactured or kept. - Every person for the time being in charge of any premises whereon any ATYSSH medicine is being manufactured or is kept for sale or distribution shall, on being required by an ATYSSH Medicine Regulatory Officer so to do, be legally bound to disclose to the ATYSSH Medicine Regulatory Officer the place where the AYUSSH medicine is being manufactured or is kept, as the case may be.

36. Purchaser of AYUSSH medicine enabled to obtain test or analysis. - Any person or any recognized consumer association, whether such person is a member of that association or not, shall, on application in the prescribed manner and on payment of the prescribed fee, be entitled to submit for test or analysis to a Government Analyst any AYUSSH medicine purchased by him or it and to receive a report of such test or analysis signed by the Government Analyst.

Explanation. - For the purposes of this section and Section 44, "recognised consumer association" means a voluntary consumer association registered under the Companies Act, 1956 (1 of 1956), or any other law for the time being in force.

37. Power of Central Government to regulate, restrict or prohibit manufacture, etc., of Ayurvedic, Siddha, Unani, Sowa Rigpa, Homoeopathic medicine in public interest.- Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied on the basis of any evidence or other material available before it that the use of any Ayurvedic, Siddha, Unani, Sowa Rigpa, Homoeopathic medicine is likely to involve any risk to human beings or animals or that any such medicine does not have the therapeutic value claimed or purported to be claimed for it and that in the public interest it is necessary or expedient so to do then, that Government may, by notification in the Official Gazette, regulate, restrict or prohibit the manufacture, sale or distribution of such medicine.

38. Power of Central Government to regulate, restrict or prohibit import of AYUSSH medicines in public interest. – Without prejudice to any other provision contain in this Chapter if the Central Government is satisfied that use of any ATYSSH medicine is likely to involve any risk to human being or animals or that any ATYSSH medicine does not have the therapeutic value claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do then, that Government may, by notification in the official gazette, regulate, restrict or prohibit the import of such ATYSSH medicine.

39. Penalty for manufacture, sale, etc., of Ayurvedic, Siddha, Unani, Sowa Rigpa, Homoeopathic medicine in contravention of this Chapter. - Whoever, himself or by any other person on his behalf,

(1) manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes, —

(a) any AYUSSH medicine deemed to be adulterated under Section 24 or spurious under Section 25 and which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt within the meaning of Section 320 of the Indian Penal Code (45 of 1860), solely on account of such AYUSSH medicine being adulterated or spurious as the case may be, shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to imprisonment of seven years and shall also be liable to fine which shall not be less than one lakh rupees or three times value of the ATYSSH medicines confiscated, whichever is more;

(b) any AYUSSH medicine deemed to be adulterated under Section 24 or deemed to be spurious under Section 25 but not being a ATYSSH medicine 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 and with fine which shall not be less than fifty thousand rupees or three times the value of the AYUSSH medicines 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 two years and of fine of less than fifty thousand rupees.

(c) any AYUSSH medicine without license required under Section 26(e) or the registration certificate required under Section 26(c) shall be punishable with imprisonment for a term which shall not be less than one year, but which may extend to imprisonment for three years and with fine which shall not be less than twenty thousand rupees or three times the value of the ATYSSH medicines 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 one year.

(d) any AYUSSH medicine, other than that referred to in clause (a) or clause (b) or clause (c), in contravention of any other provision of this Chapter or any rule made thereunder, shall be punishable with imprisonment for a term which shall not be less than one year, but which may extend to two years and with fine which shall not be less than twenty thousand rupees:

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

(e) any ATYSSH medicine in contravention of the provisions of any notification issued under section 37 shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to fifty thousand rupees or three times the value of the drugs confiscated, whichever is more

40. Penalty for non-disclosure of the name of the manufacturer, etc.— Whoever contravenes the provisions of Section 33 or Section 35 shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than twenty thousand rupees or with both.

41. Penalty for manufacture, etc. of AYUSSH medicine in contravention of Section 37.-Whoever himself or by any other person on his behalf manufactures or sells or distributes any AYUSSH medicine in contravention of the provisions of any notification issued under Section 38, shall be punishable with imprisonment for a term which may extend to three years and shall also be liable to fine which may extend to five thousand rupees.

42. Penalty for use of Government Analyst's report for advertising. -Whoever uses any report of a test or analysis made by the Central ATYSSH Medicine Testing Laboratory or by a Government Analyst, or any extract from such report, for the purpose of advertising any ATYSSH medicine, shall be punishable with fine which may extend to twenty thousand rupees

43. Penalty for subsequent offences. –

(1) Whoever having been convicted of an offence: -

(i) Under clause (a) of Section 39 is again convicted under that clause shall be punishable with imprisonment for a term which shall not be less than three years but may extend to ten years and with fine which shall not be less than two lakh rupees or three times the value of the ATYSSH medicines confiscated, whichever is more.

(ii) under clause (b) of Section 40 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 seven years and with fine which shall not be less than one lakh rupees or three times the value of the ATYSSH medicines confiscated, whichever is more:

(iii) under clause (c) of Section 39 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 and with fine which shall not be less than fifty thousand rupees or three times the value of the ATYSSH medicines confiscated, whichever is more.

(iv) under clause (d) of Section 39 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 and with fine which shall not be less than twenty thousand rupees or three times the value of the ATYSSH medicines confiscated, whichever is more.

(v) under clause (e) of Section 39 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 five years and with fine which shall not be less than one lakh rupees or three times the value of the ATYSSH medicines confiscated, whichever is more

(2) Whoever having been convicted of an offence under Section 40 is again convicted of an offence under that Section shall be punishable with imprisonment for a term which may extend to two years and with fine which shall not be less than fifty thousand rupees.

(3) Whoever having been convicted of an offence under Section 41 is again convicted of an offence under that Section shall be punishable with imprisonment for a term which shall not be less than one year but may extend to three years and with fine which shall not be less than fifty thousand rupees.

(4) Whoever having been convicted of an offence under Section 42 is again convicted of an offence under that Section shall be punishable with imprisonment for a term which may extend to three years and with fine which shall not be less than fifty thousand rupees.

44. Cognizance of offences.-

(1) No prosecution under this Chapter shall be instituted except by

(a) an AYUSSH Medicine Regulatory Officer with the previous sanction of the controlling authority appointed by the Central or State Government as the case may be, or

(b) any person aggrieved, or

(c) a recognized consumer association whether such person is a member of that association or not.

(2) No Court inferior to that of a Metropolitan Magistrate or of a Judicial Magistrate of the first class shall try an offence punishable under this Chapter

(3) Nothing contained in this Chapter shall be deemed to prevent any person from being prosecuted under any law or any Act or omission which constitutes an offence against this chapter.

45. Adjudication: - The offences except those related to adulterated and spurious AYUSSH medicine may be adjudicated as provided as under:-

(1) For the purposes of adjudication under this Chapter, retired Additional Session Judge of the district where the alleged offence is committed, shall be notified by the State Government or the Central Government as the Adjudicating Officer for adjudication in the manner as may be prescribed by the Central Government.

(2) The Adjudicating Officer shall, after giving the person a reasonable opportunity for making representation in the matter, and if, on such inquiry, he is satisfied that the person has committed the contravention of provisions of this Act or the rules or the regulations made thereunder, impose such penalty as he thinks fit in accordance with the provisions relating to that offence.

(3) The Adjudicating Officer shall have the powers of a Civil Court and –

(a) All proceedings before him shall be deemed to be judicial proceedings within the meaning of sections 193 and 228 of the Indian Penal Code [45 of 1860]

(b) Shall be deemed to be a Court for the purposes of sections 345 and 346 of the Code of Criminal Procedure, 1973 [2 of 1974]

(4) While adjudicating the quantum of penalty under this Chapters, the Adjudicating Officer shall have due regard to the guidelines specified below.

General provisions relating to penalty – While adjudicating the quantum of penalty under this Chapter, the Adjudicating Officer or the Tribunal, as the case may be, shall have due regard to the following: -

(a) The amount of gain or unfair advantage, wherever quantifiable, made because of the contravention,

(b) The amount of loss caused or likely to cause to any person because of the contravention,

(c) The repetitive nature of the contravention,

(d) Whether the contravention is without his knowledge and

(e) Any other relevant factor.

46. Establishment of Appellate Tribunal

(1) The Central Government or the State Government may by notification, establish one or more tribunals to be known as the Appellate Tribunal to hear appeals from the decisions of the Adjudicating Officer.

(2) The Central Government or the State Government shall prescribe, the matters and areas in relating to which the Tribunal may exercise jurisdiction.

(3) The Tribunal shall consist of one person only hereinafter referred to as the Presiding Officer of the Tribunal to be appointed, by notification, by the Central Government or the State Government, as the case may be:

PROVIDED that no person shall be qualified for appointment as the Presiding Officer to the Tribunal unless he has been a Principal District and Session Judge.

(4) The qualifications, appointment, term of office, salary and allowances, resignation and removal of the Presiding Officer shall be such as may be prescribed by the Central Government.

(5) The procedure of appeal and powers of the Tribunal shall be such as may be prescribed by the Central Government.

47. Confiscation.- (1) Where any person has been convicted under this Chapter, the stock of the Ayurvedic, Siddha, Unani, Sowa Rigpa, Homoeopathic medicine in respect of which the contravention has been made, 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 AYUSSH Medicine Regulatory Officer or otherwise and after such inquiry as may be necessary that the AYUSSH medicine is not of standard quality or is a misbranded, adulterated or spurious AYUSSH medicines, such medicines, shall be liable to confiscation.

48. Application of provisions to Government departments. -The provisions of this Act except those contained in Section 48 shall apply in relation to the manufacture for sale, sale, or distribution of any Ayurvedic, Siddha, Unani, Sowa Rigpa, Homoeopathic medicine by any department of Government as they apply in relation to the manufacture for sale, sale or distribution of such AYUSSH medicine by any other person

49. Power of Central Government to make rules. -

(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) provide for the establishment of laboratories for testing and analyzing Ayurvedic, Siddha, Unani, Sowa Rigpa, Homoeopathic medicine.

(b) prescribe the qualifications and duties of Government Analysts and the qualifications of AYUSSH Medicine Regulatory Officer

(c) prescribe the methods of test or analysis to be employed in determining whether any Ayurvedic, Siddha, Unani, Sowa Rigpa, Homoeopathic medicine 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 licenses or registration certificate for the manufacture for sale of Ayurvedic, Siddha, Unani, Sowa Rigpa, Homoeopathic medicine, and

for sale of processed Ayurvedic, Siddha, Unani, Sowa Rigpa, Homoeopathic medicine, the form of application for such licenses or registration certificate, the conditions subject to which such licenses may be issued, the authority empowered to issue the same and the fees payable therefor and provide for the cancellation or suspension of such licenses or registration certificate 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, Unani, Sowa Rigpa, Homoeopathic medicine including the use of packing material which comes into direct contact with the AYUSSH medicines, regulate the mode of labelling packed AYUSSH medicines 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, Unani, Sowa Rigpa, Homoeopathic medicine may be manufactured for the purpose of examination, test, or analysis.

(h) prescribe the fees for the inspection of premises for the purpose of grant or renewal of licenses, wherein any ATYSSH medicine is being or is proposed to be manufacture.

(i) Prescribe the way copies are to be certified under sub-Section 3 of Section 30

(j) Specify the diseases or ailment which an ATYSSH medicine may not purport to claim to prevent, cure or mitigate or such other effects which an ATYSSH medicine may not purport or claim to have.

(k) To prohibit misleading or exaggerated advertisement.

(l) Regulate the mode of labeling of AYUSSH medicines and prescribe the matter which shall or shall not be included in such labels.

(m) prescribe the colour or colours which an Ayurvedic, Siddha, Unani, Sowa Rigpa, Homoeopathic medicine may bear or contain for purposes of colouring;

(n) prescribe the standards of Ayurvedic, Siddha, Unani, Sowa Rigpa, Homoeopathic medicine under section 22.

(o) prescribe the records, registers, or other documents to be kept and maintained under section 34 and

(p) prescribe the powers and duties of AYUSSH Medicine Regulatory Officers and qualifications of the authority to which such ATYSSH Medicine Regulatory Officer shall be subordinate and specify the ATYSSH medicines or classes of AYUSSH medicines in relation to which, and the conditions, limitation, or restrictions subject to which, such powers and duties may be exercised or performed.

(q) Prescribe the forms of report to be given by the Government Analyst and the manner of application for test or analysis under Section 32 and the fees payable thereunder.

(r) Specify the offences against this chapter or any Rule made thereunder in relation to which an order of confiscation may be made under Section 48.

(s) Provide for the exemption, conditionally or otherwise, from all or any of the provisions of this chapter or the Rules made thereunder, or any specified AYUSSH medicine or class of ATYSSH medicines.

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

50. Power to amend First Schedule. - ATYSSH Medicine Regulatory Authority after consultation with the Board and after giving, by notification in the Official Gazette, not less than three months' notice of its intention so to do, may, by a like notification, add to or otherwise amend the First Schedule for the purposes of this Chapter and thereupon the said Schedule shall be deemed to be amended accordingly.

CHAPTER – V
MISCELLANEOUS

51. Power to give directions. - AYUSSH Medicine Regulatory Authority may give such directions to any State Government and Central Licensing Authority, State Licensing Authority and officers subordinate to such authority as may appear to the AYUSSH Medicine Regulatory Authority to be necessary for carrying into execution in the State any of the provisions of this Act or of any rule or order made thereunder.

52. Offences by companies. -(1) Where an offence under this Act has been committed by a company, every person who at the time the offence was committed, was in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly :

Provided that the person responsible for releasing the batch AYUSSH medicine for sale and distribution of AYUSSH medicine and in case of sale establishments the concerned person in-charge of such establishment, nominated by the company as responsible person shall be liable for contravention in respect of such manufacturing unit or establishment.

Provided further that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a Company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation. -For the purposes of this section -

(a) "company" means a body corporate, and includes a firm or other association of individuals; and

(b) "director" in relation to a firm means a partner in the firm**.**

53. Offences by Government departments. -Where an offence under this Act or Rules made thereunder has been committed by any department of Government, such authority as is specified by the Central Government or State Government to be in charge of manufacture, sale or distribution of AYUSSH medicines or where no authority is specified, the head of the department, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this section shall render any such authority or person liable to any punishment provided under this Act or Rules made thereunder if such authority or person proves that the offence was committed without its or his knowledge or that such authority or person exercised all due diligence to prevent the commission of such offence.

54. Penalty for vexatious search or seizure. -Any ATYSSH Medicine Regulatory Officer exercising powers under this Act or the Rules made thereunder, who, —

(a) without reasonable ground of suspicion searches any place, vehicle, vessel,

or other conveyance; or

(b) vexatiously and unnecessarily searches any person; or

(c) vexatiously and unnecessarily seizes any AYUSSH medicine, or any substance or article, or any record, register, document or other material object; or

(d) commits, as such AYUSSH Medicine Regulatory Officer, any other act, to the injury of any person without having reason to believe that such act is required for the execution of his duty, shall be punishable with fine which may extend to one thousand rupees.

55. Publication of sentences passed under this Act.-(1) If any person is convicted of an offence under this Act, the Court before which the conviction takes place shall, on application made to it by the ATYSSH Medicine Regulatory Officer, cause the offender's name, place of residence, the offence of which he has been convicted and the penalty which has been inflicted upon him, to be published at the expense of such person in such newspapers or in such other manner as the Court may direct.

(2) The expenses of such publication shall be deemed to form part of the costs relating to the conviction and shall be recoverable in the same manner as those costs are recoverable.

56. Magistrate's power to impose enhanced penalties. -Notwithstanding anything contained in the Code of Criminal Procedure, 1973 (2 of 1974), it shall be lawful for any Metropolitan Magistrate or any Judicial Magistrate of the first class to pass any sentence authorised by this Act in excess of his powers under the said Code.

57. Certain offences to be tried summarily. - Notwithstanding anything contained in the Code of Criminal Procedure, 1973, all offences under this Act, punishable with imprisonment for a term not exceeding three years, other than an offence relating to spurious and adulterated AYUSSH medicine, shall be tried in summary way by a Judicial Magistrate of the first class specially empowered in this behalf by the State Government or by a Metropolitan Magistrate and the provisions of Sections 262 to 265 (both inclusive) of the said Code shall, as far as may be, apply to such trial:

Provided that, in the case of any conviction in a summary trial under this section, it shall be lawful for the Magistrate to pass a sentence of imprisonment for a term not exceeding one year:

Provided further that when at the commencement of, or in the course of, a summary trial under this section it appears to the Magistrate that the nature of the case is such that a sentence of imprisonment for a term exceeding one year may have to be passed or that it is, for any other reason, undesirable to try the case summarily, the Magistrate shall, after hearing the parties, record an order to that effect and thereafter recall any witness who has been examined and proceed to hear or rehear the case in the manner provided by the said Code.

58. Protection of action taken in good faith. - No suit, prosecution or other legal proceedings shall lie against any person for anything which is in good faith done or intended to be done under this Act.

59. Rules to be laid before parliament.-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 immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so however that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

60. Repeal and Savings –

(1) With effect from such date as the Central Government may appoint in this behalf, the sections under The Drugs and Cosmetics Act, 1940 (Act 23 of 1940) to the extent as applicable to the Ayurvedic, Unani, Siddha, Homoeopathic medicines, shall stand repealed.

Provided that such repeal shall not affect the sections under The Drugs and Cosmetics Act, 1940 (Act 23 of 1940) to the extent as applicable to the Ayurvedic, Unani, Siddha, Homoeopathic medicines to:

(i) the previous operations of the sections under repeal or anything duly done or suffered there under; or

(ii) any right, privilege, obligation or liability acquired, accrued or incurred under any of the sections under repeal; or

(ii) any penalty, forfeiture or punishment incurred in respect of any offences committed against the sections under repeal; or

(iv) any investigation or remedy in respect of any such penalty, forfeiture, or punishment, and any such investigation, legal proceedings or remedy may be instituted, continued or enforced and any such penalty, forfeiture or punishment may be imposed, as if this Act had not been passed:

(2) If there is any other law for the time being in force in any State, corresponding to this Act, the same shall upon the commencement of this Act, stand repealed and in such case, the provisions of section 6 of the General Clauses Act, 1897(10 of 1897) shall apply as if such provisions of the State law had been repealed.

(3) Notwithstanding the repeal of the aforesaid sections, the licences issued under any such rule, which are in force on the date of commencement of this Act, shall continue to be in force till the date of their expiry for all purposes, as if they had been issued under the provisions of this Act or the rules or regulations made thereunder.

(4) Notwithstanding anything contained in any other law for the time being in force, no court shall take cognizance of an offence under the repealed Act after the expiry of a period of three years from the date of the commencement of this Act.

61. Power to remove difficulties.

(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 may appear to be necessary, for removing the difficulty:

Provided that no order shall be made under this section after of the expiry of the period of three years from the date of 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.

THE FIRST SCHEDULE
[See Section 5(a)]
A. - AYURVEIDC AND SIDDHA SYSTEMS

Sr. no.	Name of book	Sr no	Name of book
1.	Arogya Kalpadruma	35	Vaidya Chintamani
2	Arka Prakasha	36	Vaidyaka Shabda Sindu
3	Arya Bhishak	37	Vaidyaka Chikitsa Sara
4	Ashtanga Hridaya	38	Vaidya Jiwan
5	Bhaishajya Ratnvali	39	Basava Rajeeyam
6	Bharat Bhaishajya Ratnakara	40	Yoga Ratnakara
7	Bhava Prakasha	41	Yoga Tarangini
8	Brihat Nighantu Ratnakara	42	Yoga Chintamani
9	Charaka Samhita	43	Kashyapasamhita

10	Chakra Datta	44	Bhelasamhita
11	Gada Nigraha	45	Vishwanathachikitsa
12	Kupi Pakva Rasayana	46	Vrindachikitsa
13	Nighantu Ratnakara	47	Ayurvedachintamani
14	Rasa Chandanshu	48	Abhinavachintamani
15	Rasa Raja Sundara	49	Ayurveda-ratnakar
16	Rasaratna Samuchaya	50	Yogaratnasangraha
17	Nighantu Ratnakara	51	Rasamrita
18	Rasa Chandanshu	52	Dravyagunanighantu
19	Rasa Raja Sundara	53	Rasamanjari
20	Rasaratna Samuchaya	54	Bangasena
21	Rasatantra Sara Va Siddha Prayoga Sangraha -Part I	54-A	Ayurvedic Formulary of India and its parts
21-A	Rasatantra Sara va siddha prayog samgraha part II (Edition 2006)	54-B	Ayurveda Sara Samgraha
22	Rasa Tarangini	54-C	Ayurvedic Pharmacopeia of India
23	Rasa Yoga Sagara	54-D	Ayurvedic Pharmacopeia of India and its parts
24	Rasa Yoga Ratnakara		**Siddha**
25	Rasa Yoga Samgraha	55	Siddha Vaidya Thirattu
26	Rasendra Sara Samgraha	56	Therayar Maha Karisal
27	Rasa Pradipika	57	Brahma Muni Karukkadai (300)
28	Sahasrayoga	58	Bhogar (700)
29	Sarvaroga Chikitsa Ratnam	59	Pulppani (500)
30	Sarvayoga Chikitsa Ratnam	60	Agasthiyar Paripuranam (400)
31	Sharangadhara Samhita	61	Therayar Yamagam
32	Siddha Bhaishajya Manimala	62	Agasthiyar Chenduram(300)
33	Siddha Yoga Samgraha	63	Agasthiyar (500)
34	Sushruta Samhita	64	Athmarakshmrutham

Sr. no.	Name of book	Sr no	Name of book
65	Agasthiyar Pin (80)	76	Chimittu Rathna (Rathna) Churukkam.
66	Agasthiyar Rathna Churukkam	77	Nagamuni (200)
67	Therayar Karisal (300)	78	Agasthiyar Chillari Kovai
68	Veeramamuni Nasa Kandam	79	Chikicha Rathna Deepam
69	Agasthiyar (600)	80	Agasthiyaar Nayana Vidhi
70	Agasthiyar Kanma Soothiram	81	Yugi Karisal (151)
71	18 Siddhar's Chillari Kovai	82	Agasthiyar Vallathi (600)
72	Yogi Vatha Kaviyam	83	Therayar Thaila Varkam
73	Therayar Tharu	84	Siddha Formulary of India(Part I)
74	Agasthiyar Vaidya Kaviyam (1500)	85	Siddha Pharmacopoeia of India and its parts]
75	Bala Vagadam		

B. UNANI TIBB SYSTEM

Sr. no.	Name of book	Sr. no.	Name of book
1	Karabadin Qadri	9	Sanat-ul-Taklis
2	Karabadin Kabir	10	Mifta-ul-Khazain
3	Karabadin Azam	11	Madan-ul-Aksir
4	Ilaj-ul-Amraz	12	Makhzan-ul-Murabhat
5	Al Karabadin	13	National Formulary of Unani
6	Biaz Kabir, Vol. II	14	Unani Pharmacopoeia of India
7	Karabadin Jadid		
8	Kitab -ul-Taklis		