Regulatory Requirements for Ayurvedic, Siddha and Unani Drugs : An Overview

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Abstract

The drug legislation in India is governed by Drugs & Cosmetics Act 1940 and Rules 1945. During the British rule the drugs were imported in the country and Government regulated the drugs under the provisions of Poisons Act, 1919 and Dangerous Drug Act, 1930. To strengthen the regulation then Government appointed Drug Enquiry Committee under the chairmanship of Lt. Col. R.N. Chopra in 1931 to enquire into the extent to which drugs and chemicals of impure quality or of defective strength, particularly those recognized by the British Pharmacopoeia, are imported, manufactured and sold in British India and the necessity of controlling such import, manufacture and sale in the public interest and to make recommendations thereof. The committee categorically recommended; (i) Regulate the standards of drugs and medicines including patent and proprietary medicines; (ii) Compilation of a National Pharmacopoeia; (iii) Development of the Pharmacy profession; (iv) Standardization of indigenous drugs and; (v) Development of drug industry.

These recommendations prompted the Government of India to pass the Drugs & Cosmetics Act in 1940, partly implementing the Chopra Committee's recommendations to regulate, manufacture, distribute and sale of drugs in India. The drugs of Ayurvedic, Siddha and Unani are also under regulatory requirements laid in the Act and its compliance is mandatory. This communication provides genesis of the Drugs and Cosmetics Act and a synoptic account of regulatory requirements of ASU drugs in the country to educate and help manufacturers of ISM drugs.

Key words : Regulatory affairs, Drugs & Cosmetics Act 1940 and Rules 1945, Ayurvedic, Siddha and Unani Drugs.

Introduction

Drugs of Ayurvedic, Siddha and Unani systems of medicine are under regulation of Drugs & Cosmetics Act, 1940 and Rules thereunder. Drug regulations are the only tool to ensure the quality, safety and efficacy of drugs. Healthcare industry in the country is being significantly regulated under this Act alongwith other prevalent regulatory norms, it paves the way to ensure the industry to comply all the regulation and laws pertinent to their business. Industry has to tune with the Central Government, State Government and local regulatory agencies for the compliance of regulations. Drugs & Cosmetics Act is Central law regulated at country and State level with defined mechanism.

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Genesis

In the beginning of 20th century, the drug industry was almost non-existent to meet out the demand of drugs. During and after the First World War cheap drugs were imported in the country. Increasing demand of drugs resulted in production of cheaper and inferior drugs by some Indian companies to compete with imported drugs flooded in the market.

To control this situation, the Government passed the Poisons Act and Dangerous Drug Act in 1919 and 1930 respectively. Debates were held in the then legislative assembly and the council of State on the prevalence of spurious and substandard drugs and resolutions were passed urging the Government 'to take immediate measures to control the craze for medicinal drugs, through legislation, thereby ensuring standardization of the preparations and sale of such drugs'. But to have a comprehensive legislation, the Indian Government appointed a Drug Enquiry Committee, under the chairmanship of Lt. Col. R.N. Chopra in 1931, to make recommendations about the ways and means to control production and sale of drugs and pharmaceuticals in the interest of public health.

Chopra Committee made comprehensive recommendations to the Government suggesting the creation of Drug Control Machinery at the Centre with branches in provinces. The Committee also recommended the establishment of well–equipped Central Drugs Laboratory with competent staff and experts. Creation of Central Pharmacy Council and Provincial Council to train young men and women were also suggested by the Chopra committee.

In 1937, Bills were introduced in Central Legislative assembly to give effect to the recommendations of Drug Enquiry Committee to regulate the import of drugs into British India. In turn provincial Government got the resolution passed from the provincial legislative and sent them to the Central Government for getting through the bill to regulate the import, manufacture, distribution and sale of drugs. Bill was introduced in the Central Legislative Assembly and it received the assent of the Governor General on 10th April 1940 with the promulgation of Drugs & Cosmetics Act, 1940.

In 1985 the Narcotic Drugs and Psychotropic Substances Act was enacted by repealing the Dangerous Drugs Act, 1930 and Opium Act, 1878.The Drugs Rules were framed in 1945 to give effect to provision of Act.

Chapter IV-A in the Act comprises the provisions relating to Ayurvedic, Siddha and Unani drugs. It was inserted by Act 13 of 1964 (with affect from 01.02.1969) and substituted by Act of 68 of 1982, S.2 (with effect from 01.02.1983).

Regulatory requirements Law, Act and Rule

Regulatory affairs are concerned to law. Law is a procedure established by custom, agreement, or authority. In other words, it is the body of rules and principles governing the affairs of a society. Law constitutes Acts, Statutes, Amendments, Notifications, Rules and Bills in Parliament, State Laws, Central Acts, Legal Opinions, and Advices.

Legislation that has been passed by both the Houses of Parliament and has been approved by the President is termed as Act. In other words, bills passed in the Parliament become Acts. Act is the intention of law describing its applicability, definitions governing provisions, fines and penalties and the way they are to be applied. Rules are the standard methods and procedures in relation to any provision contained in the act and these are framed by the inherent powers given in the act. In case of any contradiction in Rules and Acts, the provisions of Act prevail and apply accordingly.

Statutory Basis of Drugs and Cosmetics Act & Rules

The Drugs and Cosmetics Act, 1940 & Rules 1945 is the set of rules and regulations governing the regulatory affairs in India. This Act was amended time to time to make it more effective. The list of amending Acts & adaption orders so far is:

i. The Drugs (Amendment) Act, 1955

ii. The Drugs (Amendment) Act, 1960

iii. The Drugs (Amendment) Act, 1962

iv. The Drugs & Cosmetics (Amendment) Act, 1964

v. The Drugs & Cosmetics (Amendment) Act, 1972

vi. The Drugs & Cosmetics (Amendment) Act, 1982

vii. The Drugs & Cosmetics (Amendment) Act, 1995

viii. The Drugs & Cosmetics (Amendment) Act, 2008

The Objectives of the Drugs & Cosmetics Act are:

i. To regulate the import, manufacture and sale of drugs and cosmetics through licensing.

ii. Manufacture, distribution and sale of drugs and cosmetics by qualified personals only.

iii. To prevent manufacture and sale of substandard drugs & cosmetics.

iv. To regulate the manufacture and sale of Ayurvedic, Siddha and Unani drugs.

v. To establish Drugs Technical Advisory Board (DTAB) and Drug Consultative Committee (DCC) for allopathic and allied drugs and cosmetics.

The detail of contents and chapters of Act are summarized in Table 1 & 2.

Table 1 : Contents of Drugs & Cosmetics Act & Rules thereunder

Drugs and Cosmetics Act 1940	Drugs and Cosmetics Rules 1945
Chapter: 5 (I, II, III, IV-A, V)	Parts: 19 (part I to V,VI, VI-A, VII, VII-A, VIII, IX, IX-A, X, X-A, X-B, XI to XV, XV-A, XVI, XVI-A, XVII, XVII & XVIII
Section: 38 (I-1 to 4, II-5 to 7, 7A, III-8 to 15, IV-16-33, 33-A, IV- A, 33-B to 33-O and V-33-P to 38)	Rules: 169 (Rule 9-20, 42-67, 98-101,116-118 omitted)
Schedules: 2 (First and Second)	Schedules & Sub-schedules: 44 (Sch. E, I, L., W omitted)

Table 2 : Chapters of Drugs & Cosmetics Act and their details

Chapters	Subjects
Chapter I:	Introductory-scope, definition etc
Chapter II:	The Drug Technical Advisory Board, The Central Drugs Laboratory & The Drugs Consultative Committee.
Chapter III:	Important of drugs & Cosmetics
Chapter IV:	Manufacture, sale and distribution of Drugs and Cosmetics
Chapter IVA:	Provision Relating to Ayurvedic, Siddha & Unani Drugs
Chapter V:	Miscellaneous Schedules

Administration of the Act and Rules

Under the Drugs and Cosmetics Act, the regulation of manufacture, sale and distribution of Drugs are primarily the concern of the State authorities while the Central authorities are responsible for approval of new drugs, clinical trials in the country, laying down the standards for drugs, control over the quality of imported drugs, coordination of the activities of State Drug Control

Organisations and providing expert advice with a view of bringing about uniformity in the enforcement of the Drugs and Cosmetics Act. In a broader sense the Central Government has responsibilities for Legislation farming, Policy making, Review on monitoring and Maintaining uniformity whereas responsibilities of Implementation rests with State Government. The major aspect of Act is as follows:

(a) Advisory

- Drug Technical Advisory Board (DTAB)
- Drugs Consultative Committee (DCC)

(b) Analytical

- Central Drugs Laboratory (CDL)
- State Drug Testing Laboratories
- Government Analysts

(c) Executives

- Licensing authorities
- Controlling authorities
- Drugs Inspectors

Synopsis of Regulatory Requirements for Ayurvedic, Siddha and Unani Drugs

The regulations of Ayurveda, Siddha and Unani Drugs have been dealt in detail under Chapter I and IV A of the Drugs and cosmetics Act 1940 and also under Part XVI, Part XVI (A), Part XVII, Part XVIII, and Part XIX of the Drugs and Cosmetics Rules, 1945. The synoptic enumeration of different provisions regulating drugs of Ayurvedic, Siddha and Unani are given below in Table 3 & 4.

Table 3 : Drugs and Cosmetics Act, 1940 & Rules, 1945 in respect of Ayurvedic, Siddha and Unani drugs – Quick guide to relevant provisions in respect of Ayurvedic, Siddha and Unani drugs

Subject	Regulations
1. Definitions	
i) Application of Chapter IVA Ayurvedic, Siddha or Unani Drugs	33-B
ii) Ayurvedic, Siddha and Unani (ASU) Classical Drugs	Section 3(a)
iii) Authoritative Books	First Schedule
iv) Patent & Proprietary Medicine	Section 3(h) (i)

Subject	Regulations
2. *Empowerment*	
i) Central Govt. to make rules	u/s 33-N
ii) Licensing Authority, State Govt.	R. 152
iii) Ayurvedic Siddha and Unani Drug Technical Advisory Board (ASUDTAB)	u/s 3(aa) (i), 33-C
iv) Ayurvedic, Siddha and Unani Drugs Consultative Committee (ASUDCC)	u/s 3(aa) (ii), 33-D
v) Power of Central Govt. to prohibit manufacture	u/s 33EED
vi) Power to amend First Schedule	u/s 33-O
vii) Power to give direction	u/s 33-P
3. *Manufacturing*	
i) License Application for grant/renewal	R. 153
ii) Loan License Application for grant/renewal	R. 153-A
iii) Conditions for grant/renewal of License	R. 157
iv) Duration of License	R. 156, 156-A
v) Guideline for issue of Licence	R. 158 (B)
vi) GMP Certification	Schedule T, R155-B
vii) Certificate of Renewal	R. 155, 155-A
4. *Manufacture for sale or for Distribution of Ayurvedic, Siddha and Unani Medicine*	
i) Regulation of manufacture for sale	u/s 33-EEB
ii) Prohibition of manufacture and sale of ASU drugs	u/s 33-EEC
iii) Manufacture on more than one set of Premises	R. 151
iv) Licensing Authorities	R. 152
v) Application for license to manufacture Ayurvedic (including Siddha) or Unani drugs	R. 153
vi) Loan license	R. 153-A
vii) Form of license to manufacture Ayurvedic (including Siddha) or Unani drugs	R. 154, F25-D
viii) Form of loan license to manufacture for sale of Ayurvedic (Including Siddha) or Unani drugs.	R. 154-A, F25-E
ix) Certificate of Renewal	R. 155, F26-D, 26-E
x) Certificate of Renewal of a loan license	R. 155-A, F26-E
xi) Certificate of award of good manufacturing practice Ayurveda, Siddha and Unani drugs	R. 155-B, F 26 E1
xii) Duration of license	R. 156
xiii) Duration of loan license xiv) Condition for the grant or renewal of a license in form 25D	R. 156-A
xv) Maintaining of record of raw materials	R. 157
xvi) Condition of license	R. 157-A
xvii) Condition of loan license	R. 158
xviii) Guidelines for issue of license	R. 158-A
xix) Cancellation and suspension of license	R. 158-B
xx) GMP Certification	R. 159

Subject		Regulations
	xxi) Provision of free sale certificate and non-conviction certificate	Schedule-T, R155-B
	xxii) Identification of raw materials	R. 158-C
	xxiii) Authoritative Books	Rule 160
	xxiv) Standards to be complied with, in manufacture	First Schedule R. 168, u/s 33EEB
5.	*Ingredients*	
	i) Poisonous substance	Schedule-E1
	ii) Extract	R. 158 (B)
	iii) Permitted excipients	R. 169
	iv) Classical formulations	First Schedule : List of Books of Ayurveda, Siddha & Unani
6.	*Packing, labeling & sale of Ayurvedic, Siddha and Unani (ASU) Drugs*	
	i) Labelling, packing and limit of alcohol.	R. 161
	ii) Exemption in labeling and packing provisions for export	R. 161-A
7.	*Shelf life or date of expiry*	R. 161-B
8.	*Quality Control*	
	i) Specifications	Pharmacopoeias & Formularies S -1, R. 160, 168,169
	ii) Misbranded Drugs	u/s 33 E
	iii) Adulterated Drugs	u/s 33 EE
	iv) Spurious Drugs	u/s 33 EEA
	v) Lab Reports	F. 13, F. 50
	vi) Central Drugs Laboratory	R. 163-A, 163-B
	vii) Private Drug Testing Laboratory	R.160-A to160-J
9.	*Penalty*	
	i) Cancellation & Suspension of license	R159
	ii) Prohibition of manufacture and sale	u/s 33EEC
	iii) Prohibition of manufacture and sale (Power of Central Govt.)	u/s 33 EED
	iv) Offences by companies	u/s 34
10.	*Approval of Institutions for carrying out tests on Drugs & raw materials*	
	i) Application for grant of approval for testing drugs	R. 160-A, F 47
	ii) Form in which approval to be granted	R. 160-B, F 48
	iii) Duration of approval	R. 160-C
	iv) Conditions of approval	R. 106-D
	v) Inspection before grant of approval	R. 160-E
	vi) Report of inspection	R. 160-F
	vii) Procedure of approving authority	R. 160-G

Subject	Regulations
viii) Application after rejection ix) Renewal x) Withdrawal and suspension of approvals	R. 160-H R. 160-I, F 49 R. 160-J
11. Standards of Ayurvedic, Siddha and Unani (ASU) Drugs i) Standards of Drugs ii) Permitted excipients	 R. 168 R. 169
12. Drugs Inspectors, State Licensing Authority i) Drugs Inspectors ii) Duties of Inspectors, specially authorized to inspect the Manufacture of drugs iii) Confiscation iv) Disclosure of name of manufacture etc. v) Maintenance of records & furnishing of information vi) Cognizance of offences vii) Qualification for State Drug Licensing Authority viii) Procedure for dispatch of sample to Government Analyst ix) Drug Inspectors, power and procedures x) Qualification of Inspector xi) Recording of condition of seals xii) Report of result of test or analysis xiii) Fees xiv) Signature on certificates xv) Method of test or analysis to be employed	 u/s 3(e), 33-G, 22, 23 R. 162 33-K 33-KA 33-KB 33-M R. 162-A R. 163, 163-C Ch. IV u/s 22,23,24,25 R.167 R. 163-D R. 163-E R. 163-F R.163-G R. 164
13. Government analyst i) Govt. Analyst ii) Qualifications of Government Analyst iii) Duties of Government Analyst	 u/s 3 (c), 33-F, Rule 165-166 R.165, R.166

u/s- under section, R-Rule, Ch-Chapter.

Pharmacopoeia is a book of regulatory standards for drugs manufactured and sold in a political zone. It consist the specifications for identity, purity and strength to ensure quality of drugs. Pharmacopoeia is prepared by recognized authority appointed by the Government of a particular country. Ayurveda, Siddha, Unani, Homoeopathy and modern systems of medicine have independent pharmacopoeia (Table-4). Ayurvedic and Unani Pharmacopoeia have two parts comprising many volumes. Part one consists of standards for single drugs (ingredients) and part two consists standards for classical formulations including their standard operating procedures to manufacture (Anonymous, 1978- 2012; 1981-2008; 1986-2011; 1992-2011; 1998-2009; 2008 & 2011; 2008-2010; 2009 & 2010 and Rai *et al.* 2012)

Table 4 : Pharmacopoeias and Formularies

Ayurvedic System of Medicine	Siddha System of Medicine	Unani System of Medicine
Pharmacopoeia (Single Drugs) Part-I, Eight Volumes (600 monographs)	Pharmacopoeia (Single Drugs) Part-I, Two Volumes (139 monographs)	Pharmacopoeia (Single Drugs) Part-I, Six Volumes (298 monographs)
Pharmacopoeia (Formulations) Part-II, Two Volumes(152 monographs)	Pharmacopoeia (Formulations) Nil	Pharmacopoeia (Formulations) Part-II, Two Volumes (100 monographs)
Formulary Three Parts (986 formulations)	Formulary One Part (399 formulations)	Formulary Six Parts (1231 formulations)

Other Relevant Applicable Regulations

Central Drugs Laboratory – Under Rule 163-B, the functions of the Central Drugs Laboratory in respect of Ayurvedic, Siddha and Unani Drugs shall be carried out at the Pharmacopoeial Laboratory for Ayurvedic, Siddha and Unani medicine, Ghaziabad (Uttar Pradesh) and the functions of the Director in respect of the said drugs shall be exercised by the Director of the said laboratory.

Drugs and Magic Remedies (Objectionable Advisements) Act, 1954 - Ayurvedic, Siddha and Unani medicines are also covered under the purview of the Drugs & Magic Remedies (Objectionable Advertisement) Act 1954.“Magic Remedy” includes a talisman, mantra, kavacha and any other charm or any kind which is alleged to possess miraculous powers for or in the diagnosis cure, mitigation, treatment of prevention of any disease of human being or animals of for the affecting or influencing in any way the structure or any organic function of the body of human beings or animals. Section 3 prohibits advertisement of certain drugs for treatment of certain disease and disorders (Table-5). Section 7 deals with penalty clause, whoever contravenes any of the provision of Drugs and Magic Remedies (Objectionable Advertisement) Act 1954 & Rules 1955 there under shall, on conviction, be punishable in the case of a first conviction, with imprisonment which may extend to six months or with fine or both and in the case of subsequent conviction, with imprisonment which may extend to one year, or with fine, or with both.

Table 5 : Diseases/disorders prohibited under Drugs and Magic Remedies (objectionable advertisement) Act 1954.

1.	Appendicitis	28	Hydrocele
2.	Arteriosclerosis	29	Hysteria
3.	Blindness	30	Infantile Paralysis
4.	Blood poisoning	31	Insanity
5.	Bright's disease	32	Leprosy
6.	Cancer	33	Leucoderma
7.	Cataract	34	Lockjaw
8.	Deafness	35	Locomotor ataxia
9.	Diabetes	36	Lupus
10.	Diseases & disorders of the brain	37	Nervous debility
11.	Diseases & Disorders of the optical system	38	Obesity
12.	Diseases & disorders of the uterus system	39	Paralysis
13.	Disorders of menstrual flow	40	Plague
14.	Disorders of the nervous system	41	Pleurisy
15.	Disorders of the prostatic gland	42	Pneumonia
16.	Dropsy	43	Rheumatism
17.	Epilepsy	44	Ruptures
18.	Female disease (In general)	45	Sexual impotence
19.	Fevers (In general)	46	Small pox
20.	Fits	47	Stature of persons
21.	Form and structure of the female bust	48	Sterility in women
22.	Gallstones, kidney stones and bladder stones	49	Trachoma
23.	Gangreen	50	Tuberculosis
24.	Glaucoma	51	Tumors
25.	Goiter	52	Typhoid fever
26.	Heart disease	53	Ulcers
27.	High or low blood pressure	54	Venereal diseases including Syphilis, Gonorrhoeia, Soft Cancer, Venereal granuloma and Lymphogranuloma.

State Licensing Authorities are responsible to initiate action against manufactures/persons who violate the DMR (OA) Act 1954 and Advertise about the prohibited disease/disorders.

At present, the following other Acts and Rules have impact on the manufacture, export and Clinical research of Drugs and Cosmetics in India:

i. Pharmacy Act, 1948
ii. Narcotic Drugs and Psychotropic Substances (Excise Duties) Act, 1955
iii. Drugs (Prices Control) Order 1955 (under the Essential Commodities Act).
iv. Bio-diversity Act, 2002
v. Wild Life Protection Act 1972
vi. Indian Forest Act, 1927

There are also some other laws which have a bearing on manufacture, distribution, sale and cosmetics drugs in India. The important ones are:

i. Industries (Development and Regulation)Act, 1951
ii. Trade and Merchandise Markets Act, 1958
iii. Indian Patents and Design Act, 1970
iv. Factories Act, 1948
v. Weights and Measures Act, 1976

There are circulars (F.No.K-11020/5/97-DCC (AYUSH) dated 14.10.2005 and 14.12.2005 from Govt. of India, Ministry of Health & Family Welfare, Department of AYUSH regarding heavy metals namely Arsenic, Lead, Mercury and Cadmium which are to be tested in the drugs of Ayurvedic, Siddha and Unani by licensee.

Conclusion

Herbal medicines have, of recent, received renewed attention of scientists in India and abroad with growing acceptability for their medical efficacy in curing a number of diseases and conditions. This has drawn attention of Govt. of India to lay down standards for their safety and quality. It's in this context, various pharmacopoeias of Ayurvedic, Siddha and Unani drugs, and Drugs & Cosmetics Act are now in place to enforce production of genuine medicines. This envisages bringing within its purview various aspects of manufacturing Ayurvedic, Siddha and Unani drugs, their quality control measures, legal provisions and penal actions at one place concerning these drugs. Therefore, various pharmacopoeias related to Ayurvedic, Siddha and Unani drugs and, Drugs & Cosmetics Act, dealing with good manufacturing practices are available to create general awareness among the stakeholders and public at

large. This would ensure enforcing regulatory and recommendatory standards for most of these drugs. The present communication is an endevour in this direction and provides abstracted information compiled from related portions of various Ayurvedic, Siddha & Unani pharmacopoeias of India, and Drugs & Cosmetics Act. For legal purpose or any controversy, the relevant pharmacopoeias and Acts may be referred to.

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