Regulatory Framework of Indian System of Medicines

Presentation by

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Regulation thru

a) Self Regulation by Industry

b) Statutory Framework

Regulation thru

Self Regulation by Industry

Before the act became applicable to the ISM Industry, the firms existing then were ensuring self regulation thru their own in-house standards, these standards have, in many cases, come to be accepted as Regulatory Standards

Regulation thru

Self Regulation by Industry

....contd

Some of these Companies who help established these standards are over 100 years old.

Regulation thru

Statutory Framework

The Purpose

- To Ensure Quality, safety of Indian System Medicines
- To Ensure that drugs are promoted/marketed on the basis of factual information

Statutory Basis

- Drugs and Cosmetics Act,1940 and Rules, 1945 - To regulate import, manufacture and sale of drugs including Ayurvedic, Siddha and Unani medicines.

- Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules, 1955

  To control and prohibit misleading and exaggerated advertisements

Responsibilities of Central Government

- Legislation Framing
- Policy Making
- Review and Monitoring
- Maintaining uniformity

Central Government acts through

- Secretary, Department of AYUSH, Ministry of Health and Family Welfare
- Ayurvedic, Siddha, Unani Drugs Technical Advisory Board- Section 33-C
- Ayurvedic, Siddha, Unani Drugs Consultative Committee- Section 33-D

Responsibilities of State Government

- Implementation of the Act and Rules

  i.e. Drug and Cosmetics Act, 1940 and Rules, 1945 Drug and Magic Remedies (objectionable Advertisements) Act 1954 and Rules, 1955.

- Functions of State Government are performed through State Licensing Authorities and Drugs Inspectors appointed by the State Government

Legislative Scheme (Central Government)

- Chapter IV A- Provisions relating to Ayurvedic, Siddha and Unani drugs
- Part XVI - Licensing provisions
- Part XVII -Labeling, packing and limit of alcohol
- Part XIX - Standards and permitted excipients

Legislative Scheme (State Government)

- Part XVIII - Government Analyst and Inspectors
- Part XVI (A)- Approval of Public Testing Laboratory
- Schedule T - Good Manufacturing Practices

Scheme of the Act

- Emphasis on self regulation
- Selective approach specific to category of drugs
- Definitions
- Prohibitions
- Prescriptions
- Penalty

Definitions

- Section 3(a)- Ayurvedic, Siddha and Unani drugs (commonly known as classical drugs)

- Section 3(h)(ii), Patent or Proprietary Medicines - Formulations containing ingredients mentioned in the formulae described in authoritative text books - Does not include Injectables

Definitions ....contd

- Section 33-E - Misbranded drugs
- Section 33-EE - Adulterated drugs
- Section 33-EEA - Spurious drugs

Ensuring Safety

- Safety inbuilt in the definition - Drugs required to be manufactured strictly in accordance with the formulae and methods specified in the authoritative books

- Patent or proprietary medicines required to contain ingredients mentioned in the formulae described in authoritative books

Ensuring Safety ....contd

- Central Government empowered to prohibit manufacture, sale and distribution of irrational or unsafe drugs - Section 33EED
- Directives issued by the Central Government to ensure that the products do not contain heavy metals like lead, cadmium, arsenic and mercury beyond permissible limits as per WHO norms - manufacturer to ensure this by following GMP and proper testing
- Preparations containing ingredients specified in schedule E(1) required to be labeled with caution “To be under medical supervision”

Quality Monitoring
Legislative Mechanism

- Through licensing
- Ensuring compliance of standards
- Periodic inspections

Quality Monitoring
Licensing

- Through prohibitions and prescriptions under section 33EEC it is ensured that drugs are manufactured under a valid license and strictly in accordance with the conditions of licenses including compliance of **Good Manufacturing Practices (GMP)**

Codification of concept of GMP

Schedule T specifies:-

- Prerequisites for grant of licenses (Rule 157)
- **Compliance a must**- during validity of licenses (Rule 157 & 158)

Quality Monitoring thru

Good Manufacturing Practices under Schedule T with emphasis on:-

- Better infrastructure - Elaborate provisions for location, building, water supply, disposal of waste, containers and cleaning and stores
- Area wise requirements specified
- List of machinery for production and quality control recommended

Quality Monitoring thru

Good Manufacturing Practices under Schedule T with emphasis on:-

- Focus on quality of raw material
- Manufacturing and testing to be done by experts in Ayurveda - qualification and experience prescribed under Rule 157 and Para 11 of Schedule T

Quality Monitoring thru

Good Manufacturing Practices under Schedule T with emphasis on:-

- Responsibility of quality control defined
- Testing from approved institution allowed
- Emphasis on documentation
- Distribution of records for effective recall

Quality & Standardisation

To Blend our Rich Heritage with Modern Scientific Testing methodologies, two initiatives of the Government:

- Ayurvedic Formulary of India (**AFI**)
- Ayurvedic Pharmacopoeia Committee (**APC**)

Ayurvedic Formulary of India (AFI)

Is a unique attempt to bridge the gap between the existing Traditional Knowledge, in the Classical Texts and the Modern day requirements of pharmacopoeia standards as per the Drugs & Cosmetics Act.

Ayurvedic Pharmacopoeia Committee (APC)

1. To prepare an official Formulary in 2 parts:-
   a) Single drugs, of whose identity & therapeutic value there is no doubt; &

   b) Compound preparations which are frequently used in Ayurvedic practice throughout the country

2. To provide standards for drug and medicines of therapeutic usefulness or pharmaceutical necessity sufficiently used in the Ayurvedic practice.

Ayurvedic Pharmacopoeia Committee (APC)

3. To lay down tests for identity, quality & purity.

4. To ensure as far as possible uniformity, physical properties and active constituents; and

5. To provide all other information regarding the distinguishing characteristics, methods of preparation, dosage, method of administration with various anupanas or vehicles and their toxicity.

Patent Protection of ISM

The Neem

Haldi-Turmeric

Yoga patenting issues.

To protect India's Rich Heritage of Traditional Knowledge the Government has undertaken a Herculean task of digitalising more than 10 lac pages and making it available to patent offices thru the world.

Traditional Knowledge Digital Library

Promotion / Marketing of medicines on the Basis of factual information

- Restrictions under DMR(OA)Act on advertisement to prevent exaggerated and misleading advertisements
- Prohibitions under section 3, 4 and 5 DMR(OA)Act to impose restrictions on advertisements
- Restrictions are not specific to category of drugs but are specific to disease or disorder

Promotion/ Marketing of Products on the basis of factual information

- Restrictions apply to both direct and indirect advertisements
- Elaborate labeling provisions under Rule 161to ensure that necessary information is conveyed to the consumer
- Drug deemed to be misbranded if label carries misleading statement or claim

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