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Review Article

DRUGS AND COSMETICS ACT, 1940 AND INTERPRETATION OF DEFINITIONS

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ABSTRACT

The review aims to write on drugs and cosmetics act, 1940 and interpretation of definitions. Drugs and Cosmetics Act, 1940 (Act 23 of 1940) is a pre-independence Act passed by British Legislature under the Government of India Act, 1935 as the Drugs Act, 1940. The Drug Act, 1940 was passed by the Central Legislature, when the drug was covered by the list 2 of the 7th Schedules of the Government of India Act, 1935. Stringent penal actions are recommended against the person(s) involves in manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale of spurious drugs and adulterated drugs.

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INTRODUCTION

Drugs and Cosmetics Act, 1940 (Act 23 of 1940) is a pre-independence Act passed by British Legislature under the Government of India Act, 1935 as the Drugs Act, 1940. Britishers were very much reluctant to accept the major demand of Indians. Major Act made by the Britishers are i) Indian Council Act, 1909 ii) the Government of India Act, 1919 iii) the Government of India Act, 1935 and iv) Indian Independence Act, 1947 [1]. There were there lists under the Government of India Act, 1935 were made under 7th Schedule of the said Act to be regulated, which were the federal lists, the provinces lists and the concurrent lists. The

Drug Act, 1940 was passed by the Central Legislature, when the drug was covered by the list 2 of the 7th Schedules of the Government of India Act, 1935. All legislatures of provinces passed a resolution, wherein Central Legislature was authorised to legislate for regulating the import, manufacture, distribution and sale of drugs, that was resulted the Drug Act, 1940. After independence, the Articles 246 to 256 of Constitution of India regulates the distribution of legislative power of the Centre (Union) and the State. The Article 246 of the Constitution of India gives law making powers upon some specific subjects to the Parliament and State legislatures of our Country. The Seventh Schedule to the Constitution provides Central list, State list and Concurrent list. For any subject on the Central list only Central Government can legislate. For any subject on the State list only State Government can legislate. For any subject on the Concurrent list both the Central Government as well as the State Government can legislate. But, Drugs are enlisted on serial 19th of the concurrent list, hence both the Central Government as well as the State Government can legislate. Hence, both the Central Government as well as the State Government can amend the said Act. Some of the State like Maharashtra, West Bengal and others have own state amendment under said the Act.

India was mainly dependent on import of modern medicines until after First World War. In 1927, "Quinine Fraud" had brought a thought to take immediate measures to legislate for the standardisation of the preparations and for sale of such drugs.

In 'August 1930 ' the Government of India appointed a Drug Enquiry Committee under Chairmanship of Colonel R.N. Chopra, to get into the question of adulterated and substandard drugs sold in country and to recommend mechanism by which this menace could be controlled. The committee, in its report submitted in 1931, recommended for enactment of comprehensive all India legislation for the control of drugs and pharmacy either as a combined Act or a separate Drugs Act and Pharmacy Act. On basis of report, Drugs Act received assent of the Governor General in Council, on 10th April, Act 23 of 1940. Thereafter, subsequently amended during the year, 1955 (Import Chapter, Patent and Proprietary) and 1960 (Power of Drugs Inspector).

In the year 1962, word "Cosmetics" has also been inserted in the Drugs Act, 1940 and

thereafter the Act renamed as Drugs and Cosmetics Act, 1940.

Again, in year 1964 (Amendments to DTAB and Second Schedule), 1972 (Applicable to Jammu and Kashmir), 1982 (Definitions Spurious Drugs and Cosmetics) and 2008 (Stringent Penal provision such life imprisonment and fine not less than 10 lakhs).

All provisions under this Act are placed suitably in five Chapters for better understanding and enforcement by the regulators. Provisions under this Act are clearly described in a particular sections and sub-sections in a chapter such as Section 1 of the Chapter I describes "Short title, extend and commencement". Similarly, definitions of Drugs and others are described under Section 3 of the Chapter I of Drugs and Cosmetics Act, 1940. The Chapter II of the said Act describes details about The Drugs Technical Advisory Board (DTAB) and other committees. Similarly, The Chapter III of the said Act describes details about Import of the Drugs and Cosmetics. The Chapter IV of the said Act describes details about manufacture, Sale, and distribution of the Drugs and Cosmetics where as Chapter IV-A of the said Act describes details of the provisions relating to Ayurvedic, Siddha and Unani Drugs Further, the Chapter V of the said Act related to power to give directions and miscellaneous provisions. Chapter IV shall take effect in a particular State only from such notification as given by the State Government. Similarly Chapter III shall come into as date of notification by the Central Government.

Rules under the Drugs and Cosmetics Act, 1940 (23 of 1940): In excise of the powers conferred by Sections 12,33 and 33N of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government has made following Rules and necessary amendments therein from time to time in interest of public for total quality management of drugs. Necessary schedules are also made to these Rules.

1) The Drugs and Cosmetics Rules, 1945 (Amendments),
2) The Medical Devices Rules, 2017 (Amendments) and
3) The New Drugs and Clinical Trials Rules, 2019.

1) **The Drugs and Cosmetics Rules, 1945 (Amendments):** Drugs and Cosmetics Rules, 1945has come in force vide Notification No.F.28-10/45 (H) (1), the 21st December, 1945, Department of

Health, Government of India, New Delhi. Drugs and Cosmetics Rules, 1945 has been divided into different Parts with suitable Rules for better understanding and enforcement. Part I (Rule 1 to Rule 2) of the said Rules describes "Short title, extend and commencement". Similarly, definitions of Homoeopathic Medicines (dd), Registered Homoeopathic Medical Practitioner (ea), and Registered Medical Practitioner (ee), **Biopharmaceutical Classification System (BCS)** (aa) and other definitions are also given under Rule 1 and Rule 2 of said Rules. Part II (Rule 3 to Rule 8) of the said Rules describes all about the Central Drugs Laboratory. Similarly in Part IV (Rule 21 to Rule 43- B) of the said Rules describes about procedure of Import and registration of Drugs. Part V (Rule 44 to Rule 58-A) of the said Rules describes all about the Government Analyst, Inspectors, Licensing Authorities and Controlling Authorities. In Part VI (Rule 59 to Rule 66-A) descriptions about licensing requirements for sale of drugs other than Homoeopathic Medicine whereas in Part VI-A (Rule 67-A to Rule 67-H) for Homoeopathic Medicines. Part VII (Rule 68 to Rule 85) of the said Rules describes about manufacture for sale or distribution of drugs other than the homoeopathic medicines but in Part VII-A (Rule 85-A to Rule 85-I) for homoeopathic medicines. Part VIII (Rule 86 to Rule 93) of the said Rules describes about manufacture for examination, test or analysis. The labelling and packing of drugs other than homoeopathic medicines are given in Part IX (Rule 94 to Rule 106) but in Part IX-A (Rule 106-A to Rule 106-B) for homoeopathic medicines. Part X (Rule 107 to Rule 122) of the said Rules describes special provision relating to biological and other special product and in part X-A (Rule 122-A to Rule 122-E) for import or manufacture of new drug for clinical trial or marketing. Part X-B (Rule 122-EA to Rule 122-P) of the said Rules describes requirement for the collection, storage, processing and distribution of whole human blood, human blood component by blood bank. Exemption to extend is given in Part XI (Rule 123). Accepted standards of allopathic drugs, veterinary drugs, homoeopathic medicines and others are given in Part XII (Rule 124 to Rule 128). In part XIII (Rule 129 to Rule 136), part XIV (Rule 137 to Rule 145-D) and part

XV (Rule 146 to Rule 150-A) statutory requirements all about of import, manufacture of cosmetics for sale or distribution, labelling, packing and standards of cosmetics are given. Part XV(A) (Rule 150-B to Rule 150-K) of the said Rules describes approval of institution for carrying out test on drugs, cosmetic and raw materials used for manufacturer. Part XVI to XIX related to manufacture of ayurvedic or unani drugs (Rule 151 to Rule 169).

Recent Amendments to the Drugs & Cosmetics Rules, 1945: Recently vital amendments to these Rules have been made in interest of public. Introduction of Schedule-H1 to D & C Rules vide Gazette Notification No. GSR 588(E) dated 30.08.2013 acts as check to the Multi Drug resistant T.B, rampant use of antibiotics prone to resistance and habit forming drugs. Sale of such drugs enlisted under Schedule-H1are to be recorded in separate register as per Rule 65(3) (1) (h) [2]. To improve the standard for sale of Homoeopathic medicines, educational qualification and period of experience for competent person have been amended vide Gazette Notification No. GSR 1380(E) dated 10.11.2017 [3].

New definition has been introduced as a clause (aa) under Rule 2 of the D & C Rules, 1945 for "Biopharmaceutical Classification System" (BCS) to classify drugs on the basis of solubility and permeability in four different categories.

Provision for issuance of Certificate of Renewal of licences meant for manufacture and sell of drugs other than Homoeopathic medicines have been omitted and several other amendments have been made vide Gazette Notification No. GSR 1337(E) dated 27.10.2017 [4].

These include inspection and action needed as per risk based approach, introduction of perpetual validity of licences on compliance with the condition of licences and the provision of the D & C Act and Rules. Labelling provisions under Rule 96 and 97 have been amended vide Gazette Notification No. GSR 408(E) dated 26.04.2018 for drugs categorised under Schedule G, H, H1and X for labelling of caution or warning for the professional as well as the users [5].

Table 01: Description of Rules under different Part

Serial No.	Name of the Part and Rules thereunder	Descriptions under Part and Rules
1	Part I (Rule 1to Rule 2)	"Short title, extend and commencement", definitions of Homoeopathic Medicines and others
2	Part II (Rule 3 to Rule 8)	Functions of the different Central Drugs Laboratory
3	Part IV (Rule 21 to Rule 43- B)	Procedure of Import and registration of Drugs
4	Part V (Rule 44 to Rule 58-A)	Government Analyst, Inspectors, Licensing Authorities and Controlling Authorities
5	Part VI (Rule 59 to Rule 66-A)	Sale of drugs other than Homoeopathic Medicines
6	Part VI-A (Rule 67-A to Rule 67-H)	Sale of Homoeopathic Medicines
7	Part VII (Rule 68 to Rule 85)	Manufacture for sale or distribution of drugs other than the homoeopathic medicines
8	Part VII-A (Rule 85-A to Rule 85-I)	Manufacturer for sale or distribution of drugs homoeopathic medicines
9	Part VIII (Rule 86 to Rule 93)	Manufacture for examination, test or analysis
10	Part IX (Rule 94 to Rule 106)	Labelling and packing of drug other than homoeopathic medicines
11	Part IX-A (Rule 106-A to Rule 106-B)	Labelling and packing of homoeopathic medicines
12	Part X (Rule 107 to Rule 122)	Special provision relating to biological and other special product
13	Part X-A (Rule 122-A to Rule 122-E)	Import or manufacture of new drug for clinical trial or marketing
14	Part X-B(Rule 122-EA to Rule122-P)	Requirement for the collection, storage, processing and distribution of whole human blood, human blood component by blood bank
15	Part XI (Rule 123)	Exemption to drug specified in Schedule-K
16	Part XII (Rule 124 to Rule 128)	Standards of allopathic drugs, veterinary drugs, homoeopathic medicines and others
17	Part XIII (Rule 129 to Rule 136)	Import of cosmetics
18	Part XIV (Rule 137 to Rule 145-D)	Manufacture of cosmetics for sale or distribution
19	Part XV (Rule 146 to Rule 150-A)	Labelling, packing and standards of cosmetics
20	Part XV(A)(Rule150-B to Rule150-K)	Institution for carrying out test on drugs, cosmetic and raw materials used for manufacturer
21	Part XV Ito XIX (Rule 151 to Rule 169).	Manufacture of ayurvedic or unani drugs

To prevent the misuse of oxytocin in dairy farming as well as in vegetables, restrictions have been imposed by the Government by placing oxytocin under Schedule H1 vide Gazette Notification No. GSR 795(E) dated 21.08.2018[6]. Draft Rules have been published under D & C Act introduction of Sale of Drugs by E- Pharmacy vide Gazette Notification No. GSR.817 (E) dated:-28.08.2018 [7].

The Medical Devices Rules, 2017 (Amendments):- New Rules have been introduced under the D & C Act, 1940 apart from D & C Rules, 1945 as " The Medical Devices Rules, 2017" for better quality management of medical devices vide Gazette Notification No. GSR 78(E) dated 31.01.2017 [8].

The New Drugs and Clinical trials Rules, 2019:- New Rules have been introduced under the D & C Act, 1940 such as the New Drugs and Clinical trials Rules, 2019 apart from the Drugs & Cosmetics Rules, 1945 and the Medical Devices Rules, 2017 for better management of clinical trials, bioequivalence studies, investigational new drugs for human use and ethics committee vide Gazette Notification No. GSR.227 (E) dated:-19.03.2019[9].

Definitions of Drugs:

Definitions of Drugs as per Section 3 of the Drugs and Cosmetics act, 1940 in Chapter I are as:

Ayurvedic, Siddha or Unani drug:

Sub section (a) of section 3 of D & C Act defines as "includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of [disease or disorder in human beings or

animals, and manufactured] exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani (Tibb) systems of medicine, specified in the First Schedule".

Allopathic Drugs: Under section 3(b) defines as (i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes; ***Intended to be used"*** are the critical words in the definition. Diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals such as Bulk drugs, bandages etc.

(ii) Such substances (other than food) intended to affect the structureor any function of human body. **Contraceptives** are included as drugs but **pregnancy kit** is not included as Drugs as pregnancy is a normal physiological phenomena.

Or such substances intended to be used for the destruction of (vermin) or insects which cause disease in human beings or animals, such as: **Disinfectant** or as may be specified from time to time by the Central Government by notification in the Official Gazette.

(iii) All substances intended for use as components of a drug including empty gelatin capsules; and

(iv) Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board. It includes Cardiac Stents, Drugs Eluting Stents, Catheters, Intra Ocular Lenses, I.V. Cannulae, Bone Cements, Heart Valves, scalp vein set, orthopaedic Implants, Internal Prosthetics Replacement and Ablation devices as Government of India gazette notification from time to time.

Public Notice has been floated with proposal for introduction of several medical devices including all implantable devices, CT Scan Equipment, MRI Equipment, Defibrillators, Dialysis Machine, PET Equipment, X-Ray Machine, Bone Marrow Cell Separator as drugs under Section 3(b)(iv) of the D & C Act.

Homoeopathic Medicines: Under Rule 2(dd) defines as: it 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.

Conclusions:

Stringent penal actions are recommended against the person(s) involves in manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale of spurious drugs and adulterated drugs.

The above are few examples of recent amendments made by the Government for availability of standard quality drugs and to impose restriction on misuse of certain drugs in public interest. Professional in pharmaceutical sector as well as general public must be aware of prevailing law including up to date amendments. Indian pharmaceutical sector is globally accepted for manufacturing of standard quality drugs. However, to be a benchmark in this sector, we all have to follow the legal aspects, guidelines, and vigilant on activities of miscreants.

References:

1. Sri S.W. Deshpande and Sri Nilesh Gandhi., A Commentary on The Drugs and Cosmetics Act, 1940 and Rules, 1945, Susmit Publishers., Mumbai-400051., page LVII-LX.
2. Gazette Notification No. GSR 588(E) dated 30.08.2013 of https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications.
3. Gazette Notification No. GSR 1380(E) dated 10.11.2017 of https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications.
4. Gazette Notification No. GSR 1337(E) dated 27.10.2017 of https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications.
5. Gazette Notification No. GSR 408(E) dated 26.04.2018 of https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications.
6. Gazette Notification No. GSR 795(E) dated 21.08.2018 of https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications.
7. Gazette Notification No. GSR.817 (E) dated:-28.08.2018 of https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications.

8. Gazette Notification No. GSR 78(E) dated 31.01.2017 of https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications.

9. Gazette Notification No. GSR.227 (E) dated:-19.03.2019 of https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications.