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COMPARISON OF DRUGS AND COSMETICS ACT 1940 AND WITH DRAFT OF NEW DRUGS, MEDICAL DEVICES AND COSMETIC BILL-2022

A. Hemalatha[1]*, R. Neelamegarajan[2], B. Senthilkumar[3] and R. Vijayamirtharaj[4]

[1]PG Scholar, Department of Pharmaceutical Regulatory Affairs, JKKMMRF's Annai JKK Sampoorani Ammal College of Pharmacy, Komarapalayam.

[2]Associate Professor, Department of Pharmaceutical Regulatory Affairs, JKKMMRF's Annai JKK Sampoorani Ammal College of Pharmacy, Komarapalayam.

[3]HOD and Professor, Department of Pharmaceutical Regulatory Affairs, JKKMMRF's Annai JKK Sampoorani Ammal College of Pharmacy, Komarapalayam.

[4]Principal, Department of Pharmaceutical Regulatory Affairs, JKKMMRF's Annai JKK Sampoorani Ammal College of Pharmacy, Komarapalayam.

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***Corresponding Author**
A. Hemalatha
PG Scholar, Department of Pharmaceutical Regulatory Affairs, JKKMMRF's Annai JKK Sampoorani Ammal College of Pharmacy, Komarapalayam.

ABSTRACT

The Drugs, Medical Devices and Cosmetics Bill of 2022 proposes a significant overhaul of India's regulatory framework for these critical products. This bill aims to consolidate existing laws and introduce modern regulations to ensure the quality, safety, and efficacy of drugs, medical devices, and cosmetics. Streamlining regulations for import, manufacture, distribution, and sale. Establishing robust protocols for clinical trials of new drugs and medical devices. Upholding international quality standards for all regulated products. Fostering advancements in medical technology and domestic production of medical devices. Safeguarding the rights, safety, and well-being of individuals participating in clinical trials. Ultimately, promoting the health and well-being of the Indian populace. This comprehensive legislation promises to create a more robust and efficient system, fostering innovation while prioritizing public health. Currently the comparison of this study is to know about the clinical trial which may include in the new draft bill. The draft Bill prohibits all the clinical trials or clinical investigations of drugs and medical devices without permission from the central licensing

authority.

KEYWORDS: The Drugs, Medical Devices and Cosmetics Bill of 2022, drugs and cosmetic act 1940, Draft of new drugs, clinical trials.

INTRODUCTION

DRUGS, MEDICAL DEVICES, COSMECTIC BILL-2022

- The Central Legislative Assembly passed the Drugs and Cosmetics Act of 1940 prior to independence. In order to account for evolving needs and technological advancement, out dated laws are continually reviewed and updated. The Government has often underlined the necessity of reviewing out dated laws, as well as of regularly repealing and amending legislation, for which Bills are now being introduced into Parliament. From the year 2016, the task of reviewing and amending the Drugs and Cosmetics Rules, 1945, was intensively pursue.
- A committee was formed to draught the New Drugs, Cosmetics and Medical Devices Bill in response to proposals made by the Central Government and the perceived need for comprehensive regulation. Ministry of Family Welfare and Health In order to stay up with changing requirements, circumstances, and technological advancements, the Government of India has proposed a draught New Drugs, Medical Devices, and Cosmetics Bill, 2022. A draught bill has been created in this respect, a copy of which is included.
- It has been decided to ask the public and other stakeholders for ideas, comments, and objections to the aforementioned draught Bill. Within 45 days after the date this notice was issued, recommendations, comments, or objections may be sent through email to drugs divmohfw@gov.in or by mail to the Ministry of Health and Family Welfare's Under Secretary (Drugs Regulation), Room No. 434, C Wing, Nirman Bhawan, New Delhi. The ideas, comments, and objections sent via the aforementioned email or address within 45 days of the Notice's issuance date will be taken into account when the notice is finalise.
- The Ministry of Health and Family Welfare published a draught of the Drugs, Medical Devices, and Cosmetics Bill, 2022 ("THE BILL") in July 2022 with the intention of reviewing, replacing, and modernising the out dated Drugs and Cosmetics Act, 1940. The ministry has been consistently reviewing and streamlining the regulations to further accommodate the changes and to adopt new technology. The Drug Controller General of

India, Mr. V.G. Somani, led an eight- member committee established by the Ministry of Health and Family Welfare to draught the draught bill, which has since been posted on the ministry's website for comments and suggestions from stakeholders and the general public.

- Since the Ministry of Health and Family Welfare has not yet issued new regulations to match the modernized Bill's requirements. The bill now includes a temporary provision that 9th Schedule, which includes the Drugs Rules of 1945, Medical Devices Rules of 2017, New Drugs and Clinical Trials Rules of 2019, and Cosmetics Rules of 2020, shall remain in force until new standards are established. Since the Ministry of Health and Family Welfare has not yet issued new regulations to match the modernised Bill's requirements.
- The bill now includes a temporary provision that states that the laws listed in the 9th Schedule, which includes the Drugs Rules of 1945, Medical Devices Rules of 2017, New Drugs and Clinical Trials Rules of 2019, and Cosmetics Rules of 2020, shall remain in force until new standards are established.
- This Bill which is an exaltation of the Principal Act, 1940 introduces provisions for clinical trials and regulation of medical devices. This has been welcomed by the industry as it effectively addresses the problems plaguing the healthcare industry in India and is an improvement on the current regulations, which is imprecise and has done more harm than good.
- The key definitions introduced under the bill are given as
- **Clinical Trial** means any systematic investigation of a new drug, an investigational new drug, or a bioavailability or bioequivalence study of a new drug in humans with the aim of determining the drug's safety, efficacy, or tolerance. This data is used to discover or confirm the drug's clinical, pharmacological, including pharmacodynamics and pharmacokinetic, or adverse effects.
- **Over-the-counter Drugs** meaning medications that, under the conditions and in the manner they may be prescribed, can be sold to a customer by way of retail without a prescription from a licenced doctor.
- **Investigational New Drug** new chemical or biological entity or substance which is under investigation in a clinical trial regarding its safety, tolerance and efficacy.
- **Proprietary Medicine** means a drug which is a remedy or prescription presented in a form ready for internal or external administration on human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being in force or

any other Pharmacopoeia authorized in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board.

- **Ayurveda, Siddha, Sowa Rigpa or Unani or Drug** means 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 Ayurveda, Siddha, Sowa Rigpa and Unani TIBB systems of medicine.

Salient features of Draft New Drugs, Medical Devices and Cosmetics Bill, 2022

- The said draft bill has been published on 08-07-2022 by the Union Health Minister for suggestions, comments and objections from Public and stakeholders within 45 days from the date of publicat.
- It is a comprehensive legislation for New Drugs, Medical Devices, clinical trials and Cosmetics under one statute.
- The regulation to conduct clinical trials, new drugs, Cosmetics and Medical Devices have been brought under the Draft under title as Drugs Medical Devices and Cosmetics Act, 2022
- The said Draft bill included a separate CHAPTER FOR Ayush Drugs, which proposes to regulate SOWA-Rigpa and Homoeopathy.
- The new bill for the first time regulate e-Pharmacy and Medical devices by mentioning the words of License and permission and also provides penalties under Sec. 41
- Penalties for offences related to Import of drugs and Cosmetics have been enhanced.
- Under chapter 1 (Sec.1 to 4) various new definitions are introduced including for Bioavailability, Bio equivalence, Drugs Control Officer, Medical Device officer, Over the Counter Drugs, Indian Pharmacopoeia as book of reference and State licensing Authority.
- Under Chapter 11(Sec.5 to 13) Technical Advisory Boards, Drugs Laboratories, Medical Devices testing centre and Consultative Committee, introduced procedure of Board, state Government has been given powers to notify Labs including testing for Medical Devices, Including DTAB and MDTAB Consultative Committee instead of DCC.
- Chapter 111 (Sec.14 to 32) deals on Import of Dugs and Cosmetic
- Under Chapter 1V (Sec.33 to84) Manufacture, sale and Distribution of Drugs and Cosmetics and clinical Trials of Drugs.

METHODOLOGY

Framing the research area and title

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Literature review

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Development of titles, aims and objectives

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Data collection

↓

Literature based on the statistical analysis

↓

Study discussion

↓

Conclusion

↓

Thesis writing

COMPARISION OF DRUGS AND COSMETIC ACT 1940 VS THE DRAFT BILL – 2022

DRUGS AND COSMETIC ACT 1940	NEW DRUGS, MEDICAL DEVICES AND COSMETIC BILL 2022
I. Introductory	I. Bill
II. DTAB, DCC, CDL	II. Technical Advisory Board, Drug Laboratories, Medical Device Testing Centers, And Consultative Committee.
III. Import Of Drugs And Cosmetics	III. Import of drugs and cosmetics
IV. Manufacture Sales And Distribution Of Drugs & Cosmetics Act	IV. Manufacture Sales And Distribution of Drugs & Cosmetics Act and Clinical Trial of drugs.
IV-A Provisions Relating To Ayurveda, Siddha, Unani and Homoeopathic Drugs	V. Provisions Relating t o Ayurveda, Siddha, Sowa Rigpa, Unani And Homoeopathic Drugs
V. Miscellaneous	VI. Import, Manufacture Sales And Distribution And Clinical Investigation Of Medical Devices
	VII. Miscellaneous

CHAPTER- I

CHANGES IN INTRODUTION

BILL: relating to import, manufacture, sales and distribution of drugs, medical devices, cosmetics to ensure Safety, Efficacy and Quality performance and clinical trial of new drug and clinical investigation of investigational Medical Devices came into the act 8th July 2022. It extends to whole India.

Reason to adapt this draft bill

The main reason for the change of draft bill is to adopt the modern technologies, with the needs to review laws and amend the laws.

The bill proposes new definitions for

- Clinical trials,
- Over-the-counter drugs,
- Manufacturers,
- Cosmetics,
- Medical devices,
- New drugs,
- Bioavailability studies,
- Bioequivalence studies,
- Investigational new drugs,
- Proprietary medicine,
- Imported spurious drugs.

BOARD

- **Central drug laboratory:** sub section[1] of section.[10]
- **State drug laboratory:** sub section[2] of section.[10]
- **Central licensing approving authority:** DCGI appointed by central Gov. Under sub section[2] sub sec.[161]
- **Controlling authority:** responsible for overall control activity as provided in the act or rules.

CHAPTER- II

NEW DRUGS, MEDICAL DEVICES AND COSMETIC BILL-2022

Constitution of Drug Technical Advisory Board

- In the New drugs, Medical devices, and Cosmetics bill the members of the constitution are same as compared to the Drugs and Cosmetics Act 1940 but some constitutional members are added newly in the new draft bill. The additional members included in the bill are:
- One person to be nominated by the department of Animal Husbandry, Dairying and, Fisheries
- Three person to be nominated by the central government from among persons who are in charge of drugs control in States:
- Three person to be nominated by the central government, one each from amongst Pharmaceutical Industry, Bio- pharmaceutical industry and cosmetic industry;
- One person nominated by the Department of Health Research from among pharmacologists;
- One person nominated by the Department of Bio-technology, Government of India;
- One person nominated by the Indian Pharmacopeia Commission
- One person nominated by the National Institute of Biological.

Constitution of Medical Devices Technical Advisory Board

The board consist of following members;

- Director General of Health Services, Chairperson, ex officio,
- Drugs Controller General, Member Secretary, ex officio,
- One person from the Department of Atomic Energy,
- One person from the Department of Science and Technology, Ministry of Science and Technology,
- One person from the Ministry of Electronics and Information Technology,
- One person from the Bureau of Indian Standards established under section 3
- One person from the Defence Research and Development Organisation,
- One person, to be nominated by rotation by the Central Government, who are in charge of Central medical devices testing centres,
- Drug controller general: sec: 161
- Drug control officers: appointed by central and state Gov. Sec.[46]
- Indian pharmacopoeia, IMD – which does not have predicate device or substantially equivalent devices,
- Licensing authority:

- Central government appointed under section 161.
- State government appointed under section 162.

CHANGES IN DRUGS

- **Ethics committee:** previously constituted under rule 17 of D & C rule 1945 and registered in Rule 8 Now it is constituted under section 74
- **Government analyst:** previous section[20] changed to section.[45]
- **State licensing authority:** under section.[161] Pervious the qualification – rule 49A of drugs and cosmetic rules 1945.
- **IND –** new chemical or biological entity or substance is under investigation in clinical trial for safety efficacy and tolerance**. Previously** the drug was not approved for marketing in any country.

MEDICAL DEVICES

- **Medical device officer:** sub rule[2] of rule[18] - sub section[1] of section 133.
- **Medical devices testing officer:** sub rule[1] of rule[18] – section 131.

COSMETICS

- It means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes new cosmetic or any article intended for use as a component of cosmetic.

New cosmetic

- It means any cosmetic containing ingredients which have not been established as safe for human use.

Over The Counter Drugs

- It means drugs that can be sold by way of retail to a consumer without prescription from a registered medical practitioner as per the conditions and in such manner as may be prescribed.

Consultative Committee

Drugs and Cosmetics Act 1940	New Drugs, Medical Devices, and Cosmetics Bill-2022
❑ The committee may call as the Drug Consultative Committee. ❑ No chair person is involved in Drugs and Cosmetics act. ❑ No meeting was conducted in this committee. ❑ Here section 5 & 7 may not apply to the Ayurveda, siddha, Unani Drugs	❑ The committee may call as the Drugs, medical Devices and Cosmetics Consultative Committee. ❑ The DCGI will be chairperson for this committee. ❑ Meeting conducted for at least once in six months. ❑ Here section 5 & 11 may not apply to Ayurveda, BSowa-Rigpa, Siddha, Unani or Homoeopathic Drugs.

CHAPTER: III

COMPARSION OF PENALTIES

PENALTY IN THE DRUGS AND COSMETICS ACT 1940

❖ Only **manufacturer** were responsible for all the confiscation. Here the manufacturer will the punishable person and he is responsible for all sort of penalties

Draft Bill act 2022

❖ Here both the **manufacture and the marketer** are responsible for all the confiscations. The marketer will also be the punishable person and he is also responsible for all of penalties.

Penalty Import of cosmetics

Previous penalty	**New penalty**
✓ Adulterated drug comes under the section 9A ✓ Spurious drug-9B ✓ Spurious cosmetics- 9D ✓ Clause section -10	✓ Adulterated drug comes under the section 17 ✓ Spurious drug-18 ✓ Clause section -22

Previous penalty in import of drugs and cosmetics

❖ Adulterated drug comes under the section 9A

❖ Spurious drug-9B

❖ Spurious cosmetics- 9D

Clause section-10 or a cosmetic nature referred in clause [ee] will be punishable with imprisonment for 3 years and fine may **extend up to 5000 Rupees**.

Import prohibited under section[10]

- Up to 6months imprisonment and fine up to 500 rupees
- 1year imprisonment and fine up to **1000 Rupees** for repeated conflict.

Prohibited under public interest

- 3years imprisonment and 5,000 rupees fine for first conflict.
- 5years imprisonment and 10,000 Rupees fine for second conflict

New penalty for import of drugs and cosmetics

- Adulterated drug: section17
- Spurious drug: section 38
- Imprisonment will not be less than 10 years and may extend for life.
- Fine: not less than **10 lakh** Rupees.

CHAPTER – IV

- Under clause [e] of section [56] imprisonment will not be less than 1yrs and extended up to 2 years and fine will not be less than 7 Lakh Rupees.
- The penalty comes under the sub section[1] of section 72, here the penalty is liable and the fine which is not less than **3 lakhs** and may extended up to **5 lakh** Rupees.

Penalty for violation of conditions of permissions

- If the permission is violated if the permission is granted under these section 72.
- They may issue a warning letter with the detail of deficiency found during the inspection, which may affect the wellbeing of clinical trial.
- Study may be discontinued or may reject.
- They may suspend or cancel the clinical trial permission.

Penalty for failure to provide compensation

- If a person may fails to provide the compensation under section 73 he shall be punished with imprisonment may extend up to **one year**and fine will not be less than twice the amount of compensation.

NEWLY ADDED PENALTY

- Under clause [e] of section[56] imprisonment will not be less than **1yrs** and extended up to **2 years** and fine will not be less than 7 **Lakh** Rupees.

Previous penalty	New penalty
✓ Whoever convicted an offence section 27A Imprisonment may extend up to **2 years** Fine: may extended about **20,000** rupees	✓ Whoever convicted an offence under clause [a] section 57 Imprisonment may extend up to **3 years** Fine: may extended about not less than **5 Lakh** Rupees ✓ Whoever convicted an offence under clause [b] section 57 Imprisonment may extend up to **1 years** Fine: may extended about not less than **3 Lakh Rupees** ✓ Whoever convicted an offence under section 60 or 61 Imprisonment may extend and not less than **3 years** but may extend up to **5 years** Fine: may extended about not less than **5 Lakh** Rupees ✓ Whoever convicted an offence under section 62 shall be punishable with fine and not less than **5 Lakh** Rupees.

COMPARISON OF CHAPTER IV-A AND NEW CHAPTER- V

COMPARSION OF PENALTIES

Chapter –IV –A[provisions relating to Ayurveda, siddha, and unani drugs	Chapter–V provisions relating to Ayurveda. Siddha, sowa rigpa, unani, and homoeopathic drugs.
a) Misbranded drug comes under section 33E Adulterer drug section-33EE	Misbranded drug under section -95 ✓ Misbranded drug which may include 8th schedule then the fine is not less than **50,000Rupees**. ✓ Misbranded drug which include expect the categories involved in 8th schedule where the fine is not less than **1 Lakh** Rupees. ✓ Adulterated drug section-97. Not a standard quality of drug section - 94

Chapter –IV –A [provisions relating to Ayurveda, siddha, and unani drugs.	Chapter–V provisions relating to Ayurveda. siddha, sowa rigpa, unani, and homoeopathic drugs.
Under clause [b] of sub section [1] of section 33-1 The person may be punishable and again convicted with the imprisonment that will be not less than **2 years** but may be extend up to **6 years.** Fine: will not be less than **1 Lakh** rupees or 3 times the value of drug confiscated. **Court applied for special reasons: Imprisonment** will be less than **1year** Fine: will not be less than **1lakh** or 3 times the value of drug confiscated.	**Under clause [b] of sub section [1] of section 108** The person may be punishable and again convicted with the imprisonment that will be not less than **2 years**. Fine: will not be less than **3 Lakh** rupees or 3 times the value of drug confiscated.

CHAPTER -VI

IMPORT, MANUFACTURE, SALE, DISTRIBUTION AND INVESTIGATION OF MEDICAL DEVICE

PENALTY FOR CLINICAL INVESTIGATION OF MEDICAL DEVICES

Penalty for conducting clinical investigation of investigational medical device without permission

- Under sub section[1] of section 139 the person may liable to a penalty fine: which will be not less than **2 lakh** rupees but may extend up to **6 Lakh** rupees.

Penalty for violation of conditions of permission

Under sub section[1] of section 139 it may be in writing statement the reasons such as:

- They may issue a warning letter with the detail of deficiency found during the inspection, which may affect the wellbeing of clinical investigation.
- Study may be discontinued or may reject.
- They may suspend or cancel the clinical investigational permission.

Comparison of Chapter- V in D & C Act 1940 & Chapter- VII in Draft Bill 2022

MISCELLANEOUS

Penalty for submission for misleading or wrong information

Whoever it may be himself or by a any other person on behalf of import, manufacture, stock, sells, or intends to do, drugs and cosmetics notified category of medical devices and submit misleading files or information he may be punishable with the Imprisonment which may be not less than **2 years** and the fine which shall be not less than **1 lakh** Rupees.

Previous penalty	**New Penalty**
Commits only **inspectors** to the injury of the person without any reason to believe that such act is required for the execution of this duty **FINE:** It may extend up-to **1000 rupees**.	Commits such as **Drug Controller Officer or Medical Device Officer** to the injury of the person without any reason to believe that such act is required for the execution of this duty **FINE:** It may extend up-to **30,000 Rupees**.
	Provided any false cases by the **Drug Controller Officer or Medical Device Officer** it may be punishable that may be not less than **50,000 Rupees**.

OVER ALL COMPARATIVE VIEW

Particulars	The Drugs and Cosmetics Act 1940	The Drugs, Medical devices, and Cosmetics Bill 2022
Constitution of technical advisory Board State drugs laboratories and State	Single Drugs Technical Advisory Board is constituted Provisions for states to establish drug	Advisory Boards for Drugs and Medical Devices are to be constituted eparately State Drug Laboratories and Medical
Testing centres	Laboratories for testing not covered under the 1940 Act or 1945 Rules	Devices Testing Centres are to be constituted.
Prohibition of import of certain cosmetics	No such provision for prohibition of import of adulterated Cosmetics prescribed in the Act	Prohibits import of cosmetics which is not of standard quality,or is misbranded, adulterated orSpurious
Prohibition of online sale of Drugs and Cosmetics.	The Act does not regulate online sale of drugs and cosmetics.	Prohibits import of cosmetics which is not of standard quality, or is misbranded, adulterated or Spurious
Prohibition of manufacturing of New Drug	No such restriction prescribed in the 1940 Act.	Prohibition on manufacturing of an obtaining license
Police to assist Drugs Control Officer	No equivalent provision under 1940 Act.	Police officer to assist Drugs Control Officer demanding his assistance in the investigation and preventing the escape of suspected Offenders
Scientific Research Board	No Such Research board has been established under the Act	Scientific Research Board to be established to support the regulatory authority on the scientific advances used for developing, innovative Drug of Ayurveda, Siddha, Sowa- Rigpa, Unani and Homoeopathy

CONCLUSION

- The Drugs, medical devices and cosmetic bill of 2022 proposals compared with the drugs and cosmetic act 1940 with this comparsion. I have outlined the importance of the proposed bill 2022 with the safeguarding of drugs, medical products. I have compared the penalties a lived under the act 1940 and the amendments with new draft of new drugs, medical devices, cosmetics bill 2022.
- In this research, studied the guidelines proposed drug and cosmetics 1940 newly added penalties for spurious drugs, cosmetics conducting clinical trial without permission misbranded drugs, adulterated drugs, cosmetics and medical devices so, this research further studied comparison import, manufacture, sale, distribution, violation, penalties and their contravenes. Hence, above mention paragraph I have summarized my research.
- Several new firms have entered the pharmaceutical market in recent years, hoping to

profit from the growing health sector. Thus, it's crucial to watch out that they don't profit by endangering people's health. The Pharmaceuticals and Cosmetics Act of 1940 is a comprehensive piece of law that guarantees effective pharmaceutical sector regulation in India. The Act has very few gaps within it and has properly matured and evolved to accept changes as the times have changed. The Act's definitions are quite specific and leave little room for interpretation, which is a good thing because any room for legal misuse in this area might significantly affect the health and safety of the public.

- The overhaul of the Pharmaceuticals and Cosmetics Act is a much-needed and welcome step in the direction of improving India's present system of drug and cosmetic regulation. Despite the repetition of the old law, the Bill's insertions, omissions, and objective are expected to raise expectations for stakeholders, consumers, and quality in the healthcare sector as there was a need for comprehensive legislation to accommodate and adapt to new requirements of modern technology. The main focus of the Draft Bill is the regulation of medical devices as a separate category
- Moreover, it recognises the importance of autonomous governing bodies with expertise in medical devices. The Draft Bill is perfect for the sector in this respect since it would regulate e-pharmacies, clinical trials, and investigations, along with imposing harsh penalties, to close any current legal and regulatory gaps in the healthcare sector.

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