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Decoding 'Drugs, Medical Devices and Cosmetics Bill, 2022'- Navigating A New Era with Issues and Challenges

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ABSTRACT

Technological advancements in medical devices have drastically transformed the healthcare sector, significantly improving patient outcomes and efficiency. Innovations like wearable monitor's robotic surgery, AI diagnostics, Smart implants, and nanotechnology are enhancing treatment accuracy and patient comfort, making healthcare more effective, accessible, and patient-centered. The rapid growth of the medical device industry is driven by factors such as aging, technological advancements, rise in chronic diseases. The Increasing demand for devices to manage conditions like diabetes and heart disease is shifting focus towards preventive care and early detection. Expanding healthcare access, higher spending capacity, fast regulatory approvals, and evolving reimbursement policies are fueling this growth, with innovations like minimally invasive surgeries, wearable devices, and investments in medical startups further accelerating the sector. These advancements in medical Technology may lead to bring about legal challenges, highlighting the inadequacy of existing laws to address emerging Issues. In India, the only existing law is the Drugs and Cosmetics Act, 1940, which is outdated and unable to address the new challenges posed by the emerging medical devices. To tackle these issues, a Draft of the New Drugs, Medical Devices and Cosmetics bill,2022 has been proposed. This paper tries to critically analyze the new changes introduced in the new drugs, Medical Devices and Cosmetics Bill, 2022, and also discuss the associated Issues and challenges.

Keywords: *Medical devices, Drugs, Clinical trial, Clinical investigation, online pharmacies*

1. INTRODUCTION

Technological advancements in medical devices have greatly transformed healthcare, improving patient's outcomes and procedure efficiency. Innovations like wearable health monitors, robotic-assisted surgery, and AI-driven diagnostic aid real-time health tracking, tailored treatments, and more accurate procedures. 3D printing allows for the development of personalized prosthetics and implants, while telemedicine and remote monitoring ensure accessible healthcare services. The integration of smart implants, nanotechnology, and point of care devices improves treatment precision and patient comfort. These innovations are continuously advancing to enhance the effectiveness, accessibility, and patient-centric nature of modern healthcare. The Medical Device Market was earlier predicted to achieve a staggering revenue of US$ 539.11bn by 2025. The Industry is expected to witness a steady growth rate of 5.57% annually CAGR of 2025-2029, leading to a project market volume of US$ $ 669.74bn by 2029.[iii]The Union Minister of State for health and Family welfare, Smt. Anupriya Patel highlighted the significant growth potential of India's medical device sector, recognizing it as a 'sunrise sector.' She emphasized that this growth is fueled by rising healthcare demands, technological advancements at the 21st Health Summit of the Confederation of Indian Industry, with the theme of the summit being "Transforming healthcare for Viksit Bharat at 2047." The Indian medical device market is currently valued at around $ 14 billion, and is projected to reach $30 billion by 2030. India ranks as the 4th largest medical device market in Asia, after Japan, China, and South Korea, and is among the top 20 global markets in the sector.[iv]

The growth of the medical device market is collectively driven by various factors like ageing, increase in chronic diseases, and other technological advancements like AI diagnostics, robotic surgery, and wearable health monitors. Expanding healthcare access in emerging markets, higher spending capacity in healthcare, rise of telemedicine, favorable reimbursement policies, increased investments in medical startups, and government support with faster regulatory approval are further accelerating the growth of the sector. There is a pressing need for robust legislation to effectively address the emerging challenges and issues posed by continuous technological advancements.

In India, the Drugs and Cosmetics Act, 1940, is the only existing regulation for drugs and cosmetics. However, this act is enacted in 1940, is now considered outdated and it fails to address evolving technologies and emerging challenges. Recognizing the need for reform, the government has consistently stressed the need to update outdated laws to meet evolving demands and technological advancements. As a part of this process, the revision of the Drugs and Cosmetics Rules, 1945 began in 2016. To create more comprehensive legislation, a committee was formed to draft the new drugs, Medical devices, and cosmetics bill. The Ministry of Health and Family Welfare has now introduced the draft New Drugs, Medical Devices, and Cosmetics Bill, 2022, to keep up with modern developments. The present status of the new draft of the Drugs, Medical Devices and Cosmetics Bill, 2022, is still in the draft stage. The draft of the bill has been released but has not been enacted into law. The existing law of the Drugs and Cosmetics Act, 1940, is very old and inadequate to tackle emerging issues and challenges of modern healthcare and technological advancements. The Bill seeks to modernize the regulatory framework to conform to global standards and address new challenges arising in the healthcare industry. The Drugs, Medical Devices, and Cosmetics Bill, 2022, introduced by the Government of India, seeks to replace the old Drug and Cosmetics Act 1940 with updated provisions that reflect the evolving healthcare landscape, including medical devices and online pharmacies. While this is a crucial step towards modernization, the bill raises various issues and challenges that need to be addressed to ensure effective implementation and impact before the bill becomes law.

An increase in growing complexities has created the need for a regulatory framework that ensures safety, efficacy, and quality of drugs, medical devices, and cosmetics while adapting to these changes. Though these laws have been effective for many years, they are now facing issues and challenges due to the rapid pace of innovation. This has highlighted the necessity for comprehensive reforms to address these evolving needs. The government proposed a draft of the new Drugs, Medical Devices and Cosmetics Bill, 2022 to introduce more modern, transparent, and comprehensive regulation. The bill seeks to update and consolidate the existing regulatory framework by remedying loopholes and gaps, issues, and addressing various shortcomings and challenges.

2. CRITICAL ANALYSIS OF THE DRUGS, MEDICAL DEVICES, AND COSMETICS BILL, 2022

1. Introduction of New Definitions

The draft Bill introduces new definitions that were not defined in the Drugs and Cosmetics Act, 1940.The new definitions of terms like drug, new Drugs, New Cosmetics, adulterated Cosmetics, Medical Device, Bioequivalence study, over the counter (OTC) medicines, clinical trials, manufacturer, proprietary medicines, spurious Drugs, Ayurveda, Siddha, Sowa, Rigpa, and Unani. These definitions are introduced in Chapter 1 with an aim of having more clarity and ensuring effective implementation.

2. Medical Devices to be treated as a Separate Chapter

The draft Bill defines Medical Device [5]and proposes to treat medical devices separately from drugs, unlike the existing law, where all medical devices are classified as drugs under the Drugs and Cosmetics Act, 1940, and the Medical Devices Rules, 2020. The Bill seeks to repeal the existing laws and introduce a new definition of medical devices, thereby excluding them from the drug category. Additionally, the draft bill proposes the creation of the Medical Devices Technical Advisory Board (MDTAB)[6] under chapter II, which will be distinct from the Drug Technical Advisory Board (DTAB), which will consist of specialists from various associations to provide technical recommendations on technical matters on medical devices to the central government.

3. Regulation of Online Pharmacies

The bill stipulates and clearly states that no individual or entity will engage in the sale, stocking, exhibition, or distribution of it unless they hold a valid license issued by prescribed regulations, and it empowers the central government to establish rules for the operation of online pharmacies.[7]Today, with the rampant sale of medicines all over the internet in India, at present, there are no direct rules for selling medicines in an online mode. Presently, in the existing Drugs and Cosmetics Act, 1940, there is no provision or rules about online pharmacies. The New draft bill seeks to introduce regulations for online pharmacies and medical devices to address the loopholes in regulation by mandating license requirements for the sale of drugs and medical devices through an online mode. The New draft bill gives the central government the power to regulate online pharmacies [8]and prohibits the sale, stocking, exhibition, or offer for sale of drugs and medicines online without obtaining permission. This regulation of online Pharmacies marks a significant step taken by the government towards controlling the rapidly expanding and largely unregulated online pharmaceutical market. This change will help all patients to maintain price transparency and may lead to the sale of prescription drugs with appropriate checks and balances. In addition to this initiative, a strong regulatory framework is also required to govern the function of online pharmacies.

4. Restriction on Import of certain drugs and Cosmetics

The Bill prohibits the import of drugs and cosmetics that are not of standard quality or are misbranded, adulterated, or spurious, and cosmetics containing any ingredients that may be unsafe or harmful. The bill prohibits to import of any new drug or new cosmetics without permission from the central licensing authority.[9]Currently, the existing Drugs and Cosmetics

Act, 1940, has no such provision about the prohibition of the import of misbranded, adulterated, or spurious drugs and cosmetics. Additionally, proprietary medicines are also required to list their active ingredients and their quantities on the label as prescribed by law.

5. Prohibition of manufacture for sale of drugs and Cosmetics

The draft new bill addresses the prohibition of the manufacture for sale of new drugs[10]without obtaining a license or permission from the Central Licensing Authority.[11]The bill requires individuals who are not manufacturers or authorized distributors to disclose to the Drug Control officer, if requested, the name, address, and details of the source from whom they acquired the drug or cosmetic.[12] But no such prohibition is prescribed in the existing Drugs and Cosmetics Act, 1940.

6. Clinical Trial and Clinical Investigation

The Draft Bill has now introduced a separate chapter on clinical trials and clinical Investigation. At present, only the New Drugs and Clinical Trial Rules, 2019, are the sole regulation dealing with clinical trials. The Draft Bill now has a separate chapter, which has been included in the draft Bill for clinical trials and clinical investigations.

A. Clinical Trial

The new provision of clinical trials is introduced in the current Bill. Presently Drugs and Clinical Trial Rules, 2019 are the sole regulation dealing with clinical trials. The Bill now has a separate chapter that has been included in the draft Bill for clinical trials and clinical investigations. Chapter IV of the draft Bill deals with Clinical Trials of Medical Devices.

i. Compulsory License for Clinical Trials

A Clinical Trial cannot be conducted without prior approval from the central licensing authority, and it is mandatory to obtain compulsory licenses from the central licensing authorities for any clinical trials of medical devices and drugs.[13] The bill has introduced new provisions for consequences of noncompliance, which will make the person conducting a clinical trial liable for a penalty of fine of 3 lakh to 5 lakh rupees.[14] Hence, it's mandatory for investigators to take prior permission from the central licensing authority for the proper regulation of Clinical trials.

ii. Medical management and compensation for Injury or death related to the clinical trial

The Bill makes provisions for compensation to the participants or legal heirs for injury or death suffered on account of their participation in clinical trial for drugs and medical device that is compensation have to be given to the person injured while participating in clinical trials and in case of death, of the participant, the legal heir of the participant should be awarded compensation. The responsibility for providing medical management for any injuries resulting from the clinical trial lies with the investigators conducting the trial.[15] The consequence of failing to provide compensation will be punishable with imprisonment up to one year or with a fine not less than twice the amount of compensation.[16]

B. Clinical Investigation -Chapter VI of the draft deals with Clinical Investigation of Medical Devices.

i. Conduct of Clinical Investigation

Clinical Investigation in respect of investigational medical devices in human participants may not be conducted by any person, sponsor, clinical research organization, any other organization, or investigator without obtaining prior approval from the central licensing authority. The investigation must be carried out in compliance with the prescribed conditions, forms, and procedures established by the central licensing authority. The central licensing authority, in the public interest, may abbreviate, defer, or waive the requirement for clinical Investigation, and such decisions must be based on valid reasons and documented in writing. A medical device that claims substantial equivalence to an already approved device cannot be marked unless the central licensing authority approves the equivalence.[17] The Ethics Committee, as specified in Section 74(1), will be responsible for reviewing and approving all clinical investigations under this regulation.

All the stakeholders must ensure compliance with these requirements to maintain the safety, efficacy, and ethical integrity of clinical investigators for investigational medical devices.

ii. Medical treatment and compensation for injury or death related to the clinical Investigation

If a participant is injured or dies due to their participation in a clinical investigation, in such a situation, the sponsor, clinical research organization, investigator, or any related party must take responsibility. In case of Injury to the participant, they are required to provide necessary medical care to the participant. If an injury is caused by an investigational medical device, then they must also give compensation and if the participant dies as a result of using an investigational medical device during the study, the responsible party must give compensation to the participant's legal heir as prescribed in the regulation.[18] The consequence of non-compliance to obtain necessary permissions under section 139 before conducting the clinical investigation of an investigational medical device, either personally or through another person, will result in the imposition of a fine of 3 lakh rupees up to 6 lakh rupees. Additionally, the responsible person will also be required to give compensation and medical management to the participant.[19] Failure to provide medical management or compensation related to injury or death from a clinical investigation under section 139 will be punishable with imprisonment for one year or a fine that will

amount to double the compensation.[20] The introduction of imprisonment as a penalty is likely to serve as a more effective deterrent and can be seen as a positive change as the previous monetary compensation did not effectively deter companies from conducting clinical trials. However, there is a lack of clarity pertaining to whether academic studies conducted for purposes other than seeking marketing approval are exempted from these regulations.

7. Regulation of AYUSH products: Ayurveda, Siddha, Sowa Rigpa, UNANI, and Homoeopathic drugs

The existing Drugs and cosmetics Act 1940 includes Ayurvedic, Siddha and Unani medicine but the present New Draft of Drugs, Medical Devices and Cosmetics, Bill, 2022 includes AYUSH system such as Ayurveda, Siddha, Sowa-Rigpa and Homeopathy, as well as traditional medicine (indigenous system of medicine legally recognized in their countries of origin, other that Allopathy or western medicine)[21]. The bill includes a separate chapter under which there are various provisions to regulate AYUSH drugs, medical devices.

Chapter V specifically addresses the regulation of AYUSH. The bill proposes to regulate Sowa Rigpa and Homeopathy, in addition to Ayurveda, Siddha, Unani and Yoga, and Naturopathy. The Bill mandates the central government to constitute the Ayurveda, Siddha, Sowa-Rigpa, Unani, and Homeopathy Drugs Technical Advisory Board. This Board was established through a notification in the official gazette and will advise the central and state governments on technical matters related to drugs, medical devices, and cosmetics. [22]The Bill establishes the Ayurveda, Siddha, Sowa-Rigpa, Unani, and Homeopathy Drugs, Medical Devices, and Cosmetics Consultative Committee. This committee will assist the central and state governments and Technical Advisory Board to ensure uniformity in the regulation of AYUSH drugs, cosmetics, and medical devices across India. [23]The draft bill mandates the central government to establish a Scientific Research Board to support the regulatory authority in advancing the development, safety, and efficacy of AYUSH drugs, medical devices, and related matters[24]and to promote the use of modern science and technology for developing innovative drugs and devices in Ayurveda, Siddha, Sowa-Rigpa, and Unani.

3. ISSUES AND CHALLENGES

1. Ambiguity and vagueness in Definitions

The definition of clinical trials[25] provided in the bill lacks clarity and significantly diverges from the established definition set by the World Health Organization (WHO). This discrepancy may lead to confusion and inconsistencies in its application and interpretation. According to the World Health Organization, a clinical trial refers to any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. This definition encompasses both interventional trials and trials from Phase I to Phase IV.[26]

2. Centralization of regulatory Authority

The power to regulate medical devices and cosmetics is centralized in the central government by the bill. [27] This can lead to inadequacies due to the concentration regulatory authority. The role of state-level authorities in effectively regulating public health may be undermined by this centralization.

3. Post-marketing Surveillance

Post-marketing surveillance for drugs and medical devices is not explicitly addressed in the Drugs, Medical Devices and Cosmetics Bill, 2022. The bill outlines provisions for clinical trials and clinical investigations, but does not provide clear guidelines on post-marketing monitoring or the recall of drugs or devices. This oversight creates a significant glitch, particularly for medical devices like implants, which can have long term effects on patient's as the implants can remain in the patient's body for years. Additionally identifying unforeseen side effects, adverse events, or quality issues that may not have been detected during pre-marketing trials is made possible through post –marketing surveillance. Hence, there is a need for inclusion of a provision for recall of medicines or devices in case any issues are identified, and a provision for post-marketing surveillance has to be included in the Bill.

4. No appropriate guidelines for the operation of online pharmacies

The Bill simply suggests that the government create regulations for the operation of online pharmacies, but no clear guidelines are provided for the implementation. Many times, the existing regulation on online pharmacies is violated as many online pharmacies operate without adhering to the law, holding licenses for physical stores or storage units while delivering medicines without prescriptions. Practically, when any violation occurs, the existing regulatory authorities are uncertain about which legal provision to use when filing a suit against these companies. Additionally, it's seen that few companies hold licenses from one state but operate in another state, further complicating enforcement.

5. Need for a Holistic Approach

The Bill primarily focuses on medical devices and fails to adequately address the issues and challenges faced by drugs and cosmetics. The bill prioritizes medical devices, with drug–related issues considered secondary, while cosmetics are largely unnoticed. Although the bill introduces a new definition for cosmetics and covers the import, export, and manufacture of cosmetics. The bill needs to have a holistic approach as it is crucial to address the issues related to drugs, medical devices,

and cosmetics, however, the lawmakers should consider this as the bill aims to replace the old law of 1940 with a more comprehensive and balanced framework.

6. Good Manufacturing Practice

The inclusion of Good Manufacturing Practices (GMPs), which are recognized as standard and essential criteria, has not been addressed in the new draft bill. The issues relating to good manufacturing practices in the Pharmaceutical industry have not only been neglected by the government but also failed to be mentioned anywhere in the bill.

4. CONCLUSION

The Draft of New Drugs, Medical Devices and Cosmetics Bill, 2022 can be seen as a welcome step for improving and reforming India's existing legislation of the Drugs and Cosmetics Act 1940. The Bill prioritizes medical devices, with drug-related issues secondary, while issues about cosmetics are largely overlooked. Although the bill introduces a new definition and covers the import, export, and manufacture of cosmetics, it still fails to address the issues relating to cosmetics holistically. The prerequisite to have comprehensive legislation for adapting to new requirements of modern technology in the healthcare sector, despite the recurrence of the old law, the new draft Bills insertions, omissions, and aims are to improve quality, consumer confidence, and expectations of stakeholders. There has been growing pressure from the medical professionals as well as from policymakers for appropriate legislation that will address the present loopholes and technological advancements by filling the gaps in the law. The bill has extensively focused on Medical Devices as a distinct category. The Bill has proposed several prominent good provisions, but it also contains significant loopholes and gaps that require utmost attention. The Drugs, Medical Devices and Cosmetics Bill, 2022, at present, is vague and needs clarification. It is crucial to have a strong regulatory framework that will address the existing loopholes and gaps, which will improve India's standing in the global pharmaceutical industry. Hence, for the bill to be implemented effectively, it is essential to address and resolve the existing ambiguities, loopholes, and gaps in the bill, thereby enhancing its quality and fostering growth in India's medical industry. Before passing the Bill into law, the government should prioritize addressing the existing loopholes and gaps to make the law more holistic and comprehensive.

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