INTERNATIONAL JOURNAL FOR LEGAL RESEARCH AND ANALYSIS

Open Access, Refereed JournalMulti Disciplinary
Peer Reviewed Edition :

www.ijlra.com

 ISSN: 2582-6433

DISCLAIMER

ISSN: 2582-6433

EDITORIAL TEAM

EDITORS

Megha Middha

Megha Middha, Assistant Professor of Law in Mody University of Science and Technology, Lakshmangarh, Sikar

Megha Middha, is working as an Assistant Professor of Law in Mody University of Science and Technology, Lakshmangarh, Sikar (Rajasthan). She has an experience in the teaching of almost 3 years. She has completed her graduation in BBA LL.B (H) from Amity University, Rajasthan (Gold Medalist) and did her post-graduation (LL.M in Business Laws) from NLSIU, Bengaluru. Currently, she is enrolled in a Ph.D. course in the Department of Law at Mohanlal Sukhadia University, Udaipur (Rajasthan). She wishes to excel in academics and research and contribute as much as she can to society. Through her interactions with the students, she tries to inculcate a sense of deep thinking power in her students and enlighten and guide them to the fact how they can bring a change to the society

Dr. Samrat Datta

Dr. Samrat Datta Seedling School of Law and Governance, Jaipur National University, Jaipur. Dr. Samrat Datta is currently associated with Seedling School of Law and Governance, Jaipur National University, Jaipur. Dr. Datta has completed his graduation i.e., B.A.LL.B. from Law College Dehradun, Hemvati Nandan Bahuguna Garhwal University, Srinagar, Uttarakhand. He is an alumnus of KIIT University, Bhubaneswar where he pursued his post-graduation (LL.M.) in Criminal Law and subsequently completed his Ph.D. in Police Law and Information Technology from the Pacific Academy of Higher Education and Research University, Udaipur in 2020. His area of interest and research is Criminal and Police Law. Dr. Datta has a teaching experience of 7 years in various law schools across North India and has held administrative positions like Academic Coordinator, Centre Superintendent for Examinations, Deputy Controller of Examinations, Member of the Proctorial Board

ISSN: 2582-6433

Dr. Namita Jain

Head & Associate Professor

School of Law, JECRC University, Jaipur Ph.D. (Commercial Law) LL.M., UGC -NET Post Graduation Diploma in Taxation law and Practice, Bachelor of Commerce.

Teaching Experience: 12 years, AWARDS AND RECOGNITION of Dr. Namita Jain are - ICF Global Excellence Award 2020 in the category of educationalist by I Can Foundation, India.India Women Empowerment Award in the category of "Emerging Excellence in Academics by Prime Time & Utkrisht Bharat Foundation, New Delhi.(2020). Conferred in FL Book of Top 21 Record Holders in the category of education by Fashion Lifestyle Magazine, New Delhi. (2020).Certificate of Appreciation for organizing and managing the Professional Development Training Program on IPR in Collaboration with Trade Innovations Services, Jaipur on March 14th, 2019

Mrs.S.Kalpana

Assistant professor of Law

Mrs.S.Kalpana, presently Assistant professor of Law, VelTech Rangarajan Dr. Sagunthala R & D Institute of Science and Technology, Avadi.Formerly Assistant professor of Law,Vels University in the year 2019 to 2020, Worked as Guest Faculty, Chennai Dr.Ambedkar Law College, Pudupakkam. Published one book. Published 8Articles in various reputed Law Journals. Conducted 1Moot court competition and participated in nearly 80 National and International seminars and webinars conducted on various subjects of Law. Did ML in Criminal Law and Criminal Justice Administration.10 paper presentations in various National and International seminars. Attended more than 10 FDP programs. Ph.D. in Law pursuing.

Avinash Kumar

Avinash Kumar has completed his Ph.D. in International Investment Law from the Dept. of Law & Governance, Central University of South Bihar. His research work is on "International Investment Agreement and State's right to regulate Foreign Investment." He qualified UGC-NET and has been selected for the prestigious ICSSR Doctoral Fellowship.He is an alumnus of the Faculty of Law, University of Delhi. Formerly he has been elected as Students Union President of Law Centre-1, University of Delhi.Moreover, he completed his LL.M. from the University of Delhi (2014-16), dissertation on "Cross-border Merger & Acquisition"; LL.B. from the University of Delhi (2011-14), and B.A. (Hons.) from Maharaja Agrasen College, University of Delhi. He has also obtained P.G. Diploma in IPR from the Indian Society of International Law, New Delhi.He has qualified UGC – NET examination and has been awarded ICSSR – Doctoral Fellowship. He has published six-plus articles and presented 9 plus papers in national and international seminars/conferences. He participated in several workshops on research methodology and teaching and learning.

ISSN: 2582-6433

ABOUT US

INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANLAYSIS ISSN 2582-6433 is an Online Journal is Monthly, Peer Review, Academic Journal, Published online, that seeks to provide an interactive platform for the publication of Short Articles, Long Articles, Book Review, Case Comments, Research Papers, Essay in the field of Law & Multidisciplinary issue. Our aim is to upgrade the level of interaction and discourse about contemporary issues of law. We are eager to become a highly cited academic publication, through quality contributions from students, academics, professionals from the industry, the bar and the bench. INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANALYSIS ISSN 2582-6433 welcomes contributions from all legal branches, as long as the work is original, unpublished and is in consonance with the submission guidelines.

www.ijlra.com
Volume 2 Issue 7 | July 2023
ISSN: 2582-6433

LEGISLATIVE ANALYSIS OF THE DRUGS AND COSMETICS ACT, 1940

AUTHORED BY - TANYA KUKADE 1 & DR. VIVEK NEMANE 2

1. LLM Candidate, Symbiosis Law School, Pune, Symbiosis International (Deemed) University, Pune, India.

2. Assistant Professor, Symbiosis Law School, Pune, Symbiosis International (Deemed) University, Pune, India.

Introduction

The healthcare industry has seen tremendous change in the past decade especially with the dawn of the pandemic over the world. Not only the healthcare industry but the society as a whole has also come to realize the importance of increasing the efficiency and improving the effectiveness of drugs and medical devices in the healthcare sector.

With increased research and innovation in the healthcare industry there is a greater need felt to ensure that the quality of the drugs being manufactured domestically as well as drugs being imported into the country meet certain basic requirements. This is ensured through thelegislations and guidelines introduced by the authorities in the country. Although, withinnovations seeping into the healthcare industry there is a constant need for the updating of theexisting legislations.

In India drugs and cosmetics are primarily regulated under the Drugs and Cosmetics Act, 1940 ("**D&C Act**")[1] and the Drugs and Cosmetics Rules, 1945 ("**D&C Rules**") framed thereunder.The D&C Act also applies to Ayurvedic, Siddha and Unani drugs ("**AYUSH drugs**"). The D&C Act is implemented by the Central Drugs Standard Control Organization ("**CDSCO**"), headed by the Drug Controller General of India ("**DCGI**"). The D&C Act and the D&C Rules govern the manufacture, import, labelling, distribution as well as the sale of drugs in the country.

[1] Drugs and Cosmetics Act, 1940, Section 3(b).

ISSN: 2582-6433

Summary of Legislation

The D&C Act aims to regulate various processes associated with the manufacturing and importand distribution of drugs and cosmetics in the country. It is a positive step taken in the directionof ensuring health and safety of consumers in the country. The D&C Act has various objectives including the maintenance of the quality of drugs and to prevent the adulteration of drugs and cosmetics. It also provides for the definitions of what constitutes drugs and cosmetics in orderto provide the ambit of regulation of various substances in addition to the licenses required to be taken by individuals in order to import, distribute or sell drugs and cosmetics in the country.The D&C seeks to ensure that drugs and cosmetics of sub-par quality are prevented from entering the market to ensure the quality of drugs is maintained.[2]

The definition of drug encompassed under the D&C Act is of a wide import and primarily includes pharmaceutical drugs, medical devices and biologics. The D&C Act has established various specialized wings to cater to the needs of the pharmaceutical and healthcare industry including specialized courts for the trial of offences covered by the act. Certain acts are made cognizable and non-bailable under the D&C Act and certain officers are given the authority to initiate prosecution for the violation of the D&C Act. The D&C Act further provides the powersof licensing authorities to inspect drug selling and storage establishments prior to the grant of licenses and to ensure that the conditions of the license are satisfied to continue the validity ofthe license. The penalties for the violation of any provision under the D&C Act have been prescribed and may include fines or imprisonment.

D&C Rules are further made under the D&C Act to cater to the specific regulatory needs of the categories. The D&C Rules require a person to obtain the relevant licenses under the D&CAct to undertake various activities including manufacturing, import, distribution, etc. prior to undertaking such activities to be in compliance with the applicable law. The D&C Rules also categorize drugs into schedules based on various factors and subsequently, additional compliances are placed on the persons undertaking any of the mentioned activities with respectto such scheduled drugs in the country.

[2] Anindita Deb, *Drugs and Cosmetics Act, 1940,* iPleaders (Sept. 07, 2022), https://blog.ipleaders.in/drugs-and-cosmetics-act-1940/.

ISSN: 2582-6433

Analysis

The D&C Act is the central legislation regulating drugs and cosmetics in India at present alongwith the D&C Rules drafted thereunder. It caters to the compliances as well as conditions for undertaking manufacturing, distribution and sale of drugs and cosmetics in the country and is a comprehensive legislation for ensuring their quality is maintained. The D&C Act caters to the importance of health and safety of consumers and prescribes penalties for violation of any of its provisions on any person dealing with drugs or cosmetics in the country. Further, the D&C Act is the parent legislation under which various legislations have been introduced including the D&C Rules, Medical Devices Rules, 2017[3] ("**MDR**") and the Clinical Trial Rules, 2019[4] which seek to regulate drugs, medical devices and clinical trials, respectively.

The D&C Act ensures the enforcement of its provision and maintaining the quality of drugs and cosmetics by imposing liability on all stakeholders undertaking manufacturing, import, distribution and sale of drugs and cosmetics. While the D&C Act imposed liability on the manufacturers, importers and distributors of drugs and cosmetics, a recent notification by the Ministry of Health and Family Welfare ("**MoHFW**") to amend the D&C Act have imposed liability on the marketers for ensuring quality and compliances of the drug being marketed in the country.[5] Thus, the D&C Act makes each stakeholder liable for the drugs being circulatedin the market and ensure shared liability.

While the D&C Act is a comprehensive legislation for the regulation of drugs and cosmetics, medical devices are regulated under the MDR introduced under the parent legislation i.e. D&CAct without a special definition for the same. The MDR provides elaborate provisions on maintaining the quality, licensing, classifications, labelling, etc. for medical devices. Thus, under the D&C Act only medical devices notified by the Central Government were regulated as 'drugs'. Although, the amendment brought about to the definition of drugs in 2020 has brought within its ambit all medical devices.[6]

[3] Medical Devices Rules, 2017
[4] Clinical Trial Rules, 2019
[5] Drugs and Cosmetics (Amendment) Rules, 2020
[6] Ministry of Health and Family Welfare published two notifications (Apr. 1, 2020), https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OA== ; https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OQ==

ISSN: 2582-6433

The D&C Act and the D&C Rules cater to provisions for licensing of establishments and individuals for the sale and distribution of drugs and cosmetics. The license for sale or distribution of drugs under the D&C Act is issued to the brick and mortar establishment and not to a brand or individual. Thus, the pharmaceutical industry is clouded with the confusion surrounding the running of online pharmacies. The online sale of drugs is facing various hurdles in terms of recognition of scans of prescriptions, obligations of the pharmacists, licensing of online pharmacies, storage and delivery of medicines over long distances, etc.

Courts in different states have taken differing views regarding the same[7] and there is no provision under the D&C Act which provides for licensing of online pharmacies in India. In 2018 the Madras High Court[8] stayed its view on banning online sale of drugs and allowed suchsale under licenses issued to regular brick and mortar pharmacies. Although, the Delhi High Court in the case of *Zaheer Ahmed*[9] banned all online sale of drugs in the state of Delhi until further clarification is issued by the Central Government on such sale. The absence ofprovisions pertaining to online pharmacies may hamper the sale and distribution of drugs as noaccountability may be ensured without specific regulations.

The D&C Act recognized drugs, cosmetics and AYUSH drugs as specified above, although itfails to recognize AYUSH cosmetics and medical devices as separate products but continues to apply the provisions to all AYUSH products as one class of products. There is a need for separate regulation of AYUSH cosmetics as well as medical devices given the difference in use and application of the products. There is a need for the introduction of specific rules or guidelines for regulation of AYUSH products to ensure quality and safety for the consumers.

Further, technological developments in the pharmaceutical and healthcare sector have led to the application of nanomaterials to increase the effectiveness and efficiency of existing drugs. Engineers and scientists around the world are focusing on research and manipulating particles ranging between the size of 0-100 nanometers or nanoparticles for exploiting the characteristicsthat each particle inhibits. At the root of innovation with nanotechnology is its application to medicine.

[7] Soibam Singh, *Two High Courts, two different views on online drugs sale*, THE HINDU (Jan. 21, 2019), https://www.thehindu.com/news/cities/Delhi/two-high-courts-two-different-views-on-online-drugs-sale/article26045505.ece
[8] The Tamil Nadu Chemists and Druggists Association v. Union of India and Ors., W.P. No. 28716 of 2018.
[9] Zaheer Ahmed v. Union of India W.P.(C) 11711/2018

ISSN: 2582-6433

The application of nanotechnology to medicine has gathered much attention in the recent years. Adam Keiper[10] recognizes the revolution that nanotechnology is bound to bring about in our understanding of the medicine and drug delivery mechanisms in the healthcare sector.

Although, the regulation of nanomedicine under the current drug regulatory regime is a cause for concern. There is an absence of a universally agreed definition for nanomedicine, given itsdynamic nature, and various attempts made by researchers around the world to define the technology, there may be inherent gaps in the legal recognition and regulation of the technology around the world until specific guidelines are provided or recognition is taken of the technologyunder existing laws. Robert Freitas Jr. has also recognized that there are certain foreseeable limitations to the application of nanotechnology to medicine.[11]

Various authors have undertaken to analyze the consequences that the application of nanotechnology in the Indian scenario would have and further analyze the preparedness of the regulatory bodies in addressing concerns arising out of such applications.[12]

Nanomedicine applications may range from drugs to medical devices and may also perform complementary functions in which case they fall within the ambit of regulation as both a drugand a medical device. In such instances, regulation and compliance becomes a cause for concern. For instance, smart pills meant for ingesting which involve imaging as well as drug delivery followed by dissolution are said to be a hybrid of a medical device and a drug. The D&C Act fails to recognize nanomedicines as a combination product under any schedule to theD&C Rules or to the D&C Act respectively. In the absence of a categorization attached to suchnanomedicine products in India under any regulation, such products which fulfil the criteria ofperforming functions falling within the ambit of both – a drug and a medical device - should be categorized as a ‘combination product’.

The MoHFW recognized the lacunae arising out implementation of the existing legislation in light of the advancements and developments taking place in the pharmaceutical and healthcareindustry. Thus, a need is felt for refurbishing the drug regulatory law for governing modern medicine, to

[10] Supra at 2.
[11] Supra at 2
[12] A.P. Jayanthi, Koen Beumer, Madhulika Bhati, Sujit Bhattacharya, *Nanotechnology: ‘Risk Governance’ in India*, Economic and Political Weekly, 2012, Vol. 47, No. 4 (Jan. 28, 2012), pp. 34-40, https://www.jstor.org/stable/41419763.

ISSN: 2582-6433

keep a check on the quality of the medicines being imported and distributed as well as bring within a common umbrella all legislation regulating drugs, medical devices and clinical trials to ensure harmonious regulation of the same.

Current Developments

Recently in 2022, the MoHFW introduced the Drugs, Medical Devices and Cosmetics Bill, 2022 ("**Bill**")[13] to supplement the D&C Act to cater to the dynamic developments in the healthcare and pharmaceutical sector in India. A committee was constituted by the Central Government to consider the potential amendments to the existing drug laws to cater to the changing demands of the sector and inflow of technology. The primary objective of the Bill is to regulate drugs, cosmetics, medical devices, clinical trials as well as online or e-pharmacies in the country.[14]

The Bill proposes amended definitions of medical devices, new drugs, clinical trials, investigational new drugs, clinical trials, bioavailable and bioequivalence studies, etc.

The Bill seeks to regulate medical devices independent from regulation of drugs as is practice under the current legislation and brings within its ambit the entire legislation on medical devices. The Bill also proposes to establish an independent authority for the regulation of medical devices and to constitute the Medical Devices Technical Advisory Board and appointment of medical devices officers for the implementation of the provisions pertaining tothe same under the proposed Bill.

The Bill also seeks to fill the gap in the current legislation regarding the regulation of online pharmacies. The Bill proposes to mandate online pharmacies to obtain relevant licenses as provided under the Bill for the sale of drugs and medical devices through the online mode. Although, the Bill too lacks specific compliances for the online pharmacies which may be introduced in the future.

Regarding AYUSH products in India, the Bill proposes to regulate traditional medicines in addition to the AYUSH drugs, medical devices and cosmetics. The Bill also proposes the setting

[13] Draft of the Drugs, Medical Devices and Cosmetics Bill, 2022, https://main.mohfw.gov.in/newshighlights-97

[14] Varsha Rajesh, Darren Punnen, Milind Antani, *Draft Drugs, Medical Devices and Cosmetics Bill, 2022: Dawnof a New Era*, NDA (Aug. 18, 2022), https://www.nishithdesai.com/SectionCategory/33/Pharma-Healthcare-Update/12/67/PharmaHealthcareUpdate/6264/1.html

ISSN: 2582-6433

up of a separate body for the regulation of AYUSH products and a separate scientific research board for AYUSH products.

The Bill contains provisions which have been overlooked in the past and many provisions to fill the existing gaps in the D&C Act, which is being looked at from a positive light by the industry players in India. Issues such as regulation of all medical devices separate from the definition of drugs, registration of medical devices, regulation of software as medical device, compensatory provisions, etc. require further deliberation as the Bill is silent on such provisions.

While the Bill contains welcome provisions for the regulation of drugs, medical devices, cosmetics, clinical trials, etc. it remains to be in the draft form and is under the refurbishing process. It may be introduced in the Parliament and upon deliberation may see the light of dayas a law, thereby suppressing the D&C Act. Although, the timelines for the Bill to become a law are cloudy and have not been discussed at present.

Conclusion

The pandemic has led to a rise in the number of players entering the pharmaceutical and healthcare market with an aim of generating profits while ensuring low cost to the company. This race to the top of the profit generating chain has led to the degradation of the quality of drugs and cosmetics around the world. The D&C Act in its present form ensures that such threats to the health of the consumers are kept at bay as it monitors the drugs being circulated in the market and imposes liability on each stakeholder involved in the process from the manufacturer to the marketer. The D&C Act through its implementing agencies ensures that the quality of drugs is maintained and that licenses are obtained by the individuals prior to undertaking the manufacturing, distribution or sale of drugs or cosmetics in India.

While the D&C Act is comprehensive, there is a need for certain changes to be brought aboutto ensure that the legislation caters to the dynamic technology entering into the pharmaceuticaland healthcare sector. This may be ensured by consolidating the various legislations governingdrugs, cosmetics, medical devices as well as biologics into a single comprehensive legislationto prevent confusion and chaos in the industry and to cater to the dynamic needs being generated.

ISSN: 2582-6433

References

Statutes

- Drugs and Cosmetics Act, 1940
- Drugs and Cosmetics Rules, 1945
- Medical Devices Rules, 2017
- Clinical Trial Rules, 2019
- Drugs and Cosmetics (Amendment) Rules, 2020

Notifications and Bills

- Ministry of Health and Family Welfare, (Apr. 1, 2020), https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OA== ; https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OQ==
- Draft of the Drugs, Medical Devices and Cosmetics Bill, 2022, https://main.mohfw.gov.in/newshighlights-97

Case Laws

- The Tamil Nadu Chemists and Druggists Association v. Union of India and Ors., W.P. No. 28716 of 2018.
- Zaheer Ahmed v. Union of India W.P.(C) 11711/2018

Internet Sources

- Anindita Deb, *Drugs and Cosmetics Act, 1940*, iPleaders (Sept. 07, 2022), https://blog.ipleaders.in/drugs-and-cosmetics-act-1940/.
- Soibam Singh, *Two High Courts, two different views on online drugs sale*, THE HINDU (Jan.21, 2019), https://www.thehindu.com/news/cities/Delhi/two-high-courts-two-different-views- on-online-drugs-sale/article26045505.ece
- A.P. Jayanthi, Koen Beumer, Madhulika Bhati, Sujit Bhattacharya, *Nanotechnology: 'Risk Governance' in India*, Economic and Political Weekly, 2012, Vol. 47, No. 4 (Jan. 28, 2012), pp. 34-40, https://www.jstor.org/stable/41419763.
- Varsha Rajesh, Darren Punnen, Milind Antani, *Draft Drugs, Medical Devices and Cosmetics Bill, 2022: Dawn of a New Era*, NDA (Aug. 18, 2022), https://www.nishithdesai.com/SectionCategory/33/Pharma-Healthcare-Update/12/67/PharmaHealthcareUpdate/6264/1.html