

INTERNATIONAL JOURNAL FOR LEGAL RESEARCH AND ANALYSIS



Open Access, Refereed Journal Multi Disciplinary
Peer Reviewed

www.ijlra.com

DISCLAIMER

No part of this publication may be reproduced or copied in any form by any means without prior written permission of Managing Editor of IJLRA. The views expressed in this publication are purely personal opinions of the authors and do not reflect the views of the Editorial Team of IJLRA.

Though every effort has been made to ensure that the information in Volume II Issue 7 is accurate and appropriately cited/referenced, neither the Editorial Board nor IJLRA shall be held liable or responsible in any manner whatsoever for any consequences for any action taken by anyone on the basis of information in the Journal.

Copyright © International Journal for Legal Research & Analysis

EDITORIALTEAM

EDITORS

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



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.

ABOUT US

INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANALYSIS
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.

REGULATING ONLINE SALE OF MEDICINES

AUTHORED BY - ANU MARIA

Abstract

By making pharmaceuticals more accessible and convenient for customers, the swift growth of e-pharmacies has completely transformed the pharmaceutical sector. Significant ethical and legal issues have been brought about by this change, nevertheless, including worries about patient safety, hazards to data privacy, and the possibility of abuse of online medication sales. This paper looks at India's internet pharmacy laws, pointing out areas where they are not strictly enforced. It also looks at the risks associated with the selling of illegal and counterfeit drugs, the effect of uncontrolled e-pharmacies on patient confidentiality, and unlawful data collecting. The study highlights the need for strong regulatory frameworks to guarantee adherence and protect the public's health.

Keywords: E-Pharmacy, Data Privacy, Patient Safety, Online Drug Sales, Regulatory Framework, Digital Personal Data Protection Act.

Introduction

The advantages of these online pharmacies are followed by a growing concern among clients about their safety. In particular, the most common issues raised by these online pharmacies are the quality of the drugs they provide, inconsistent dispensing, and lack of proper regulatory checks. While this trend has only recently gained popularity in India, it is very much in vogue in Western nations when properly regulated.

Statement of Problem

It is contended that the rise of E-Pharmacies though increasing the convenience and accessibility to consumers has raised ethical, regulatory Issues of breach of information such as patient safety, privacy and potential misuse of online drug sales.

Issues

1. How has the increasing number of e-pharmacies raised ethical and regulatory concerns regarding patient safety, privacy, and the potential misuse of online drug sales?

2. Whether illegal e-Pharmacies create their own health data on their portal violating the Right to privacy of health care records?

Research Objective

1. To analyse and evaluate the ethical and regulatory issues with the increasing sales of medicines online
2. To analyze whether illegal e-pharmacies create their own health data on their portals, violating the right to privacy of healthcare records.

Issue 1: Whether the increasing number of E-Pharmacies have raised Ethical and Regulatory concerns regarding patient safety, privacy and the potential misuse of online drug sales?

Firstly Issue No.1 should be addressed by breaking down into sub-issues of whether there has been an increase of online sale of medicines and in case the first question is affirmative then the second sub question will address whether the registration of E-pharmacies have raised the concerns regarding patient safety of privacy breaches and potential misuse of online drug sales.

India's Pharmaceutical Industry is valued at USD 50 Billion with domestic consumption valued at USD 23.5 Billion and export valued at USD 26.5 Billion for the financial year 2023-24.¹ Additionally world's third largest pharmaceutical industry by volume and 14th in terms of value of production.² The driving factors for E-Pharmacy has the foundation being internet penetration with Digital India supported by the Government. The changing lifestyle and disease progression and the booming of the Indian Economy with the increase in domestic demand and finally the Covid pandemic outbreak which revolutionized online workforce and home delivery.

A web based pharmacy is an online system that provides a platform for customers to purchase medicinal drugs and E-services online allowing the customer to receive medicines/services in the comfort of their homes within a short time.³ The Government of India and the Ministry of Health and Family Welfare with promoting Digital India accessing Health care facilities have implemented the national health portal and schemes for providing medicines and treatment at

¹ Ministry of Chemicals and Fertilizers (<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2085345>)

² Ministry of Chemicals and Fertilizers (<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2085345>)

³ Desai, C. (2016). Online pharmacies: a boon or bane?. Indian Journal of Pharmacology, 48(6), 615. <https://doi.org/10.4103/0253-7613.194865>

subsidised rates. At a time when the world was put on hold and no human contact was prohibited, the role of online pharmacy developed through customised healthcare solutions with personalised health plans, telemedicine, and testing of blood samples. It has also enabled Doctors to send the prescription directly to the pharmacy electronically reducing errors and waiting periods. The Supply chain management in the pharma industry have also picked pace ensuring timely delivery of medicines. The online pharma Industry is not just limited to supply of medicines but also as an ancillary services of medication therapy management, patient counselling and prescription verification. There is continuous professional development offering ongoing education and training for pharmacy professionals to stay updated with the latest knowledge and skills. The online platform also facilitates knowledge sharing and networking among professionals globally. In earlier times, there existed only a direct link between patients/customers and the doctor who prescribed the medicine. Whereas now, the pharmaceutical industry has transitioned from brick and mortar to e-commerce platforms with regulatory bodies to ensure compliance. There is increased convenience with improved accessibility of medicines and medical services to customers.

While there is an increase in online sales of medicines and medical health services, in certain applications developed by pharma companies require the registration of the customer which includes the name, age, gender, pincode for home delivery and the purasance of medicines at discounted rates when registered. As soon as the registration begins, for ordering the medicines, some essential information such as the prescription is required. The feeding of prescription stores the health information of the online customer. While internet usage with a positive approach could be efficiently tracked with details of the medicines such as the batch number, the dispensing pharmacy, prescribing doctor and the data stored in these applications could be analysed for planning health care policies. The online sale of medicines without a regulatory framework risks the interstate sale of drugs, patient identity, opposition from offline medical companies. Disease and treatment are the private information of the patients, which cannot be made available for data mining and for commercial use by on-line pharmacists.⁴ The Potential concerns of online pharmacy includes the rise of fake e pharmacies, sale of sensitive drugs, addressing medication errors, counterfeit medicines. Additionally online pharmacies are accused of predatory pricing.

⁴ Para 5, The Tamil Nadu Chemists and Druggists Association v Union of India, 2018 SCC OnLine Mad 3515 : (2019) 1 CTC 548

The Drugs and Cosmetics Act, 1940 read with Drugs and Cosmetics Rules 1945 and the Pharmacy Act 1948 governs the manufacture, sale and distribution of Drugs and Cosmetics in India. While the existing Statute do not cater for regulating online sale of medicines, the Ministry of Health and Family welfare (Department of Health and Family Welfare) through a notification dated 28th August 2018, the Central Government proposing to amend the Drugs and Cosmetics Act 1940 vide powers conferred by Section 12⁵ and Section 33 of the D & G⁶ published draft rules inviting public objections and suggestions. The draft rules are still yet to be notified by the Government.

One of the notable cases on sale of medicines online is the *The Tamil Nadu Chemists and Druggists Association v Union of India*⁷. The Writ Petition was filed praying for issuance of Mandamus directing the respondents (The State of Tamil Nadu, Netmeds Market Place Ltd, Digital Health Platforms, 91 Streets Media Technologies, Medlife International Pvt, M/s. Practo Technologies Pvt. Ltd, IMG Technologies Pvt. Ltd, M/s. TNMEDS, The Tamil Nadu Marunthalunar Sangam, Consumer Online Foundation) to block their website link catering to online sale of medicines prescribed under H, H1 and Schedule X which are in violation of Rules 65⁸ and 97⁹ of the Drugs and Cosmetics Rules 1945. Schedule H medicines are prescription only drugs and Schedule H1 drugs also require prescription and their sales require maintaining a prescription record for three years. Schedule X medicines are highly regulated psychotropic and narcotic drugs with high potential of abuse and addiction. Their storage and sale require dual lock storage and special licensing requirements. The contentions raised by the Petitioners are such that the Central Government has not passed the necessary rules and regulations for online/Internet sale of drugs. When the sold drugs have side-effects, there are provisions under the D & G Act for recalling drugs and this is only possible when the pharmacists are aware of the movement of the drugs. In the case of online sales, this includes storing of the medicines sold online which are inclusive of the information related to the disease and the treatment availed by the customer risking the aspect of data privacy concerns. Whereas

⁵ Power of Central Government to make rules (1) The Central Government may after consultation with or on the recommendation of the Board and after previous publication by notification in the official gazette, make rules for the purpose of giving effect to the provisions of this chapter:

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

⁶ Drugs and Cosmetics Act 1940

⁷ 2018 SCC OnLine Mad 3515 : (2019) 1 CTC 548

⁸ Condition of licences, Drugs and Cosmetics Rules, 1945

⁹ Labelling of medicines, Drugs and Cosmetics Rules, 1945

the respondents contended that the central Government did not restrict the online trading of medicines and as such the respondents would contend that only if the rules are notified by the Central government the same could be complied.

The important analysis raised are the benefits and advantages of online trading of medicines and also risks associated with online sales. While the prescription based drugs were sold based on online questionnaire methods instead of a valid prescription the same may result in side effects and the patient may receive counterfeit products which are sub-standard or super-potent or adulterated. Another important point raised was the misuse of medical, financial and electronic information of patients.

Issue No.2: Whether illegal e-Pharmacies create their own health data on their portal violating the Right to privacy of health care records?

Herein Issue No.2 needs to be broken into sub topics such as Illegal e-pharmacies operating without compliance to data protection laws which leads to unauthorized collection, storage, and processing of personal health information leading to threats to patient confidentiality and privacy breaches violating the health data policy under national health resource mission. Additionally identifying the breaches and ensuring for a stronger enforcement mechanisms and regulatory action.

To answer the preliminary aspect of Issue No.2, we need to understand what the regulatory framework for online pharmacies is. The primary legislation are the Drugs and Cosmetics Act 1940 and the Drugs and Cosmetics Rules 1945 regulating the manufacture, sale and distribution of drugs and cosmetics. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, information Technology provisions governing electronic transaction, cyber security and data protection. There is also the Draft E-Pharmacy Rules 2018 yet to be notified by the Central Government. The rules mandate the e-pharmacies to register having a physical pharmacy. Rule 67-I-a defines “e-pharmacy” as business of distribution or sale, stock, exhibit or offer for sale of drugs through web portal or any other electronic mode.¹⁰ Under the draft rules, the definition of Prescription¹¹ also includes the instruction form from a registered medical practitioner through an electronic mode as well.

¹⁰https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTkzOQ==

¹¹ Rule 67-I-d, Draft E-Pharmacy Rules 2018

The main theme of the article requiring for the registration of e-pharmacy is discussed under Rule 67L¹² wherein the person intending to conduct the business of e-pharmacy shall apply for the grant of registration to the Central Licensing authority in Form 18AA through the Govt. Portal. Additionally the application shall be annexed with information¹³ furnished with a notarised affidavit from the applicant with a fee of fifty thousand rupees and the information and documents as specified in Form 18AA.

There is a clear restriction¹⁴ on e-pharmacies for not to carry out e-pharmacy with respect to the drugs covered under the categories of the Narcotic and Psychotropic Statue 1985, tranquilizers and the drugs specified in Schedule X of Drugs and Cosmetics Rules 1945. Other provisions relating to e-pharmacies are as follows:

- 67M. Conditions of registration of e-pharmacy
- 67N. Grant of registration of e-pharmacy.
- 67-O. Periodic Inspection of e-pharmacy
- 67P. Procedure for distribution or sale, of drugs through e-Pharmacy
- 67Q. Validity of registration of e-pharmacy
- 67R. Renewal of Registration of e-pharmacy
- 67S. Prohibition of advertisement of drugs through e-pharmacy
- 67T. Suspension or cancellation of registration
- 67U. Complaint Redressal mechanism
- 67V. Monitoring of e-pharmacy
- 67W. Mode of payment of fee

The second sub question relates to protecting the data collected by e-pharmacies. Cyber data attacks have been reported frequently¹⁵. The Digital Personal Data Protection Act, 2023 aims to protect the individual privacy and especially within the healthcare sector which focuses on the management of confidentiality of patient data. The Act also mandates the health care providers to obtain explicit consent before collecting, processing or sharing any personal health

¹² Draft E-Pharmacy Rules 2018

¹³ Documents or Information to be enclosed by the applicant: (i) A copy of identity and address proof of the applicant, any one of the followings: valid passport, voter ID card, valid permanent driving license, adhaar card; (ii) Constitution details of the applicant; whether proprietorship or partnership or limited liability partnership or company; Details of mode of helpline facility for counselling the patient or his representative with respect to drug usage, its method of administration, warnings, contra-indications and any other information relating to the drugs sold through e-pharmacy; (iii) any other relevant information which may be required for the purpose of verifying the correctness of the statements made by the applicant, if any;" (Form 18AA, Draft E-Pharmacy Rules 2018)

¹⁴ Rule 67 M (5), Draft E-Pharmacy Rules 2018

¹⁵ <https://cms.thewire.in/health/aiims-servers-cyberattack-ransomware-rajya-sabha>

information of the consumer. The Act focusing on the health care sector aims to foster increased patient trust and confidence with improved data security and privacy. The Act also mentions the transfer of data across borders for opinions and specialised treatments which requires enhanced compliance requirements. The second sub question focuses on the data collected by pharmaceutical applications on online platforms at the risk of sensitive health data being leaked or misused. An important element to be identified is that the health data is owned by the patient while the actual records are owned by the care providers who act as custodians of the collected data. The health data includes the illness the patient is suffering from, the physician's observation and diagnostic tests confirming the illness.

Conclusion

Online pharmacies have made it easy to get medicine for people, and particularly in poor communities. But it has also caused some valid problems regarding patient safety, data protection, and drug control. Ensuring stronger regulation, proper licensing, and compliance measures are essential to minimize such risks and render the online pharmacy sector safer.

Suggestions

1. **Implementation of Robust Regulatory Framework:** In order to guarantee that e-pharmacies function within a well-organized legal framework, the government ought to expedite the notification of the Draft E-Pharmacy Rules, 2018.
2. **Stronger Data Protection Measures:** Enforcing strict compliance with the Digital Personal Data Protection Act, 2023, to safeguard sensitive health data and prevent unauthorized access or misuse.
3. **Mandatory Licensing and Registration:** Ensuring all e-pharmacies register with the Central Licensing Authority to enhance monitoring and accountability.
4. **Regular Audits and Compliance Checks:** Conducting periodic inspections of online pharmacies to verify compliance with existing laws and prevent the sale of counterfeit drugs.
5. **Public Awareness and Consumer Protection:** Educating consumers about the risks of unregulated e-pharmacies and encouraging them to purchase medicines from verified platforms.
6. **Stronger Enforcement Against Illegal E-Pharmacies:** Implementing stricter penalties for unlicensed online pharmacies engaging in the unauthorized sale of drugs, particularly those involving Schedule H, H1, and X medicines.