LEGAL AND REGULATORY FRAMEWORK FOR ONLINE SALES OF PHARMACEUTICAL: A COMPARATIVE ANALYSIS ON THE INFORMATION TECHNOLOGY AND DRUGS AND COSMETICS ACT

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ABSTRACT

Online sales have surged due to the enormous impact of digital technology and the introduction of e-commerce platforms in the pharmaceutical and healthcare sectors. However, this expansion has also created issues with consumer safety, data security, and regulatory compliance. In the context of online pharmaceutical sales, this study investigates the relationship between the Drugs and Cosmetics Act of 1940 and the Information Technology Act of 2000. This study examines regulatory requirements, obstacles, and recent developments, including the draft E-Pharmacy Rules of 2018, through a review of the literature, comparativeanalysis, and case studies. The study also addresses egalitarian rights-based philosophy, communitarianism, and utilitarianism as jurisprudential ideas, which clarify ethical issues with healthcare distribution. Recommendations for flexible legal frameworks suited for Internet sales are included in the conclusion.

Introduction:

The evolution of digital technology and the widespread adoption of e-commerce platforms in sectors like Pharmaceuticals and Healthcare have shown its significance and need in the contemporary world. Notably, in recent years the usage of e-commerce platforms has been rampant due to factors like accessibility, convenience, and cost-effectiveness. However, this intense growth in the field of online sales in the sector of pharmaceutical has caused various challenges related to data protection, consumer safety, breach of privacy, and non-compliance in the cases of the Drugs and Cosmetics Act as well as the Information Technology Act. These two pieces of legislation provide comprehensive guidance relating to governing aspects like electronic transactions, cyber security, and digital signatures on the other hand the main objective of the Drugs and Cosmetics Act is to ensure the safety, efficacy, and quality of pharmaceutical products. This convergence of both the Information Technology Act and the Drugs and Cosmetics Act helps the reader to understand the interplay between both the legislation and the unique viewpoint on the e-commerce platform for healthcare and pharmaceuticals and the extent of applicability in e-commerce operations.

Research Questions:

1. *What are the regulatory requirements in the case of the IT Act and the Drugs and Cosmetics Act in cases of Online Sales of Pharmaceuticals?*

2. *How does the IT Act in Interplay with the Drugs and Cosmetics Act look into thechallenges like data privacy, and consumer protection in cases of e-commerce?*

3. *What are the recent implications of the developments in these regulatory regimes, suchas E- Pharmacy rules?*

Concepts of Jurisprudence that are applicable in both legislation, The InformationTechnology Act, of 2000, and The Drugs and Cosmetics Act, of 1940

The theory of Utilitarianism given by the theorist Jeremy Bentham brings out the most controversial right which is the right to health. This also stems from Article 12 of the International Covenant on Economics, Social and Cultural Rights also known as (ICESCR). To understand the present situation on the one of human rights we need to delve into the basic

understanding of the concept of utility, which simply says the greatest happiness of greatest number, simplifies, that the majority or maximum happiness matters the most. So the concept in the healthcare system would simply imply that a right to healthcare would contribute to the overall maximum of net social utility. It only looks into the concept of aggregate welfare and benefit and doesn't include distributive challenges. A popular framework in health economics and policy analysis, utilitarianism places a strong emphasis on increasing overall social benefit, which is frequently expressed in terms of Quality-Adjusted Life Years (QALYs). It does not impose moral restrictions on actions intended to maximize value, which could result in significant inequality, and it supports the distribution of health care according to net social utility. But it disregards issues of distribution, downplays the essential worth of freedom, and places a great deal of reliance on personal preferences, which can be pliable and flexible, particularly when there are deeply ingrained disparities. This presents difficulties for reliable interpersonal utility comparisons in health policy, in contrast to the capability approach, which takes into account people's capacities to accomplish basic functions.

Communitarian theories of justice, which are grounded in common community values and offer a relativist viewpoint on health care allocation and public health, are best represented by scholars such as Michael Sandel and Michael Walzer. Communitarianism contends that communities generate several "spheres of justice" over time based on internal principles rather than a single, overarching standard of justice. According to this theory, access to healthcare isdependent on the norms and values of the community, which may or may not emphasize healthas a particular benefit. To promote democratic communities that engage in deliberation and share ideas about justice and meaningful life, Ezekiel Emanuel interweaves libertarian and communitarian ideas. Under the communitarian theory, the US free-market heritage might takeprecedence over the idea of universal health care access in the US.

The egalitarian rights-based philosophy of health care put forth by Norman Daniels and associates is founded on the idea of "equality of opportunity." They contend that social structures should be designed to allow people to take advantage of a fair number of possibilities in society, including access to healthcare. But when it comes to identifying the different kinds of health care duties that citizens have, their method is vague. Daniels' approach prioritizes health care initially, but it does not distinguish between different health care demands, which might be problematic given the variety of circumstances determining opportunities. Amartya Sen is among the critics who claim that this strategy ignores more significant justice issues and

oversimplifies health equity. Daniels' emphasis on allocating resources for healthcare ignores the inherent worth of human flourishing and health.

Although this point of view emphasizes equitable distribution and equal opportunity, it might not be as effective in addressing health outcomes, the efficiency of resources, and wider public policy consequences.

The idea of Online Sale of Pharmaceuticals has emerged from the ongoing usage of e-commerce platforms. The simple question that has to be understood is whether any trade or commercial activities in the public domain and usage are always governed by various stakeholders and factors, which include the public and service providers. The underlying objective is to promote welfare in society and bring a just and equitable atmosphere. This paper mostly discusses the Online Sales of Pharmaceuticals and the regulations regulating such activities and discusses the research questions in a comparative analysis method[1].

The Information Technology Act of 2000[2] plays a vital role in the aspect of data and privacy-related aspects along with regulating online platforms, this act's objective was to majorly deal with all the intricacies involving the e-commerce and digital signatures that were been collected by electronic means and to protect all the transaction that involved any electronic medium of use, it also provides for the protection of any communication that is made, and digital signatures wherein required for legal authentication this act also keeps checks on its intermediaries, and regulates the protection towards the sensitive personal data or any other data that is stored under various social media platform, along with providing the penal provisions for any offenses committed against any individual.

This Act's entire model was based on the model law on e-commerce which was been considered using guidelines from the UNCITRAL Model Law. It also has extra-territorial jurisdiction and protects all the contracts that are made via online platforms and are considered valid and provide authentication of e-signature, the committee is been formulated under this act known as the Cyber Regulation Advisory Committee which has the primary duty of informing and advising the matters related to e-commerce or any digital signatures, etc are the various features that have to be looked into moreover the research is based on the online sales the Information

[1] Importance of E-Pharmacies for a Digital India: Benefits and Future.
[2] Information Technology Act of 2000

Technology Act plays a vital role, as in the e-commerce platform various data is been collected about the consumer which has a potential threat from data leakage.

Though there are certain protections ensured under this act, there are several loopholes as well, that being no provisions for breach of data as the act only provides the ideas on collection of the information and data of the citizen which is disseminated but does not provide any remedy for the breach of the same, also does not hold anyone accountable for such data breaches, does not address to any matters to issue related to privacy, that simply means any intermediary could save the sensitive data of any individual or give to government authorities for the surveillance purposes which directly breaches the right to privacy of the individual, these concerns are always neglected under this act. After the 2008 amendment the act brought in a provision wherein corporations are held liable for data breaches only in the cases wherein they have not implemented effective data security practices[3].

However, as the scope of the paper, the important act that has to be looked into is the Drugs and Cosmetics Act, of 1940 India being a developing country has brought in developments towards various areas that include technological advancements, medical sciences, etc. Recently Covid-19 wherein the country has shown its participation in protecting the health and advancement towards safety of the citizens of the country[4]. But to maintain the same pace it has to be backed up by the regulatory regime that simply states that the laws should be dynamic in nature and evolve according to the needs of the society. The main objective of this act is to regulate medical technology and any pharmaceutical companies that are governed under this law. These few objectives are important to understand the scope and intent of the act. This act regulates the sale, import, and distribution of drugs and cosmetics using licensing ensuring that only qualified entities engage in such commercial practices, to ensure the prevention of such substandard or counterfeits from the market and to promote the best medical treatment standards. It has also formed two committees namely, the Drug Technical Advisory Board known as DTAB and the Drugs Consultative Committees DCC for any recommendationto be made in case of any approval of Drugs or Medical Devices, only after which the license is been granted by the Drugs Controller General of India or Drugs Control and Licensing Authorities of States who are the part of administrative wing of the Drugs and Cosmetics Act of 1940. All these authorities mentioned above consist of experts known as ex officio members

[3] Digital India Program A Overview, Dr. Sushama Yadav, 2021 IJCRT | Volume 9, Issue 2 February 2021
[4] India Pharma 2020: Propelling Access and Acceptance, Realizing true Potential 14 Feb 2020

and are elected members from the Pharmacy Council of India [PCI], India Council of Medical Research [ICMR], Indian Pharmaceutical Association [IPA], and Indian Medical Association [IMA]. There are also nominated members consisting of, the Drugs Control Department of the state or union territory followed by the government analyst and industrialist representing pharmaceutical industries. This shows that there are stakeholders who are responsible for various matters relating to the approval and have a strict procedure to comply with.[5]

But this act cannot be read on its own the Drugs and Cosmetic Rules of 1945 play a vital role as well because the rules were been amended to bring the draft of the E-Pharmacy Rules into itsambit. With the Draft E-pharmacy Rules, 2018, the Ministry of Health and Family Welfare has put regulations and modernization measures into place for the e-pharmacy industry. The purpose of these rules is to guarantee the dependability, safety, and quality of Internet pharmacies that do business in India. A crucial clause requires all operators and e-pharmacy platforms to register with the appropriate authorities. The purpose of this registration requirement is to uphold accountability and standards within the industry. To resolve any issues or complaints from stakeholders, registered e-pharmacies are also required to offer 24/7 customer service and grievance redressal procedures. To further protect customer privacy, stringent regulations are in place that forbid sharing private information—such as sensitive medical records collected through prescription drugs or other sources—with other parties. A structured licensing process, which includes submitting an online application and paying certain fees, is necessary for aspiring e-pharmacy enterprises. Professional supervision is also stressed, with certified pharmacists required to confirm patient information and supervise medicine distribution to guarantee compliance with safety procedures and moral principles[6].

Several significant initiatives are included in the Indian government's Digital India plan, which aims to transform healthcare accessibility and effectiveness. These include the e-Kranti program, which provides public services electronically with authenticity and affordability, and the E-Hospital Application, which enables online healthcare services like registration, fee payment, and appointment scheduling. In addition, the Jan Aushadhi Program encourages the use of reasonably priced generic medications, and Common Services Centers (CSCs)[7] provide telemedicine and digital infrastructure services, especially to isolated locations. The Integrated

[5] Drugs and Cosmetic Act,1940 No. 23 of 1940
[6] Drugs and Cosmetic Rules of 1945
[7] Common Services Centers, Ministry of Electronics and Information Technology, Government of India

Health Information Program publicly controls medical records to improve care continuity, while the proposed National E-Health Authority aims to control the use of electronic healthcare for quality and cost-effectiveness. Furthermore, the government's dedication to promoting healthcare through digital innovation is demonstrated by SUGAM[8], an online licensing gateway by the CDSCO that quickly accelerates healthcare service processes. Through programs like the National Digital Health Mission (NDHM) and Ayushman Bharat Digital Mission (ABDM), the Government of India is leading the charge to establish a strong digital healthcare infrastructure. By utilizing digital technology to improve accessibility, cost, and efficiency, these projects seek to completely transform the way that healthcare is delivered. The creation of an integrated digital ecosystem that utilizes current infrastructure, including the Unified Payments Interface (UPI), Jan Dhan-Aadhaar-Mobile (JAM Trinity), and Aadhaar Unique Identity (UID), to optimize healthcare services is essential to this project. The government intends to close current gaps in the healthcare ecosystem by building more digital highways, which will enable smooth communication and information sharing amongst different players. The main objective is to increase the availability of high-quality healthcare services while maintaining the affordability of medications for general public use. In addition, the aforementioned measures emphasize the advancement of the domestic pharmaceutical sector, to augment its competitiveness in the worldwide market and ensure the accessibility of superior pharmaceutical commodities for both local and foreign consumption[9]. The government is working to create a framework that would allow India's healthcare infrastructure to grow and improve over time.

Nevertheless, groups who advocated for chemists and pharmacists opposed these efforts in court, raising issues about possible drug abuse because of their easy accessibility online. The proposed regulations require e-pharmacy operators to register, protect patient information, and pay an application fee to do so. Currently, there are difficulties because there are no systems in place to confirm the legitimacy of medical prescriptions, which might result in unregulated practices and fraud susceptibility. Final rules are needed, according to stakeholders like the All India Organization of Chemists and Druggists. Regulations are required to protect traditional brick-and-mortar businesses from the projected disruption caused by the increasing popularity

[8] Sugam Online Portal-A Brief Overview
[9] Evolution of E-Pharmacies in India – Booming Present, but an Uncertain Future 18 July 2018 by Sarthak Sarin and Bharat Gupta,Khaitan & Co LLP

of e-pharmacies. Like in the US, rules might stipulate that internet pharmacies must be physically present to be legitimate, which would call for strict legislation and enforcement.

It is essential to make sure that consumers are informed of safe practices and that data protection laws, like the Personal Data Protection Bill and the Information Technology Act, are followed. When the regulations are finalized, it is expected that e-pharmacies will gain credibility and clarity, enabling them to function similarly to traditional chemists and pharmacists.

Some of the challenges faced by the online sales of pharmaceuticals are as follows:

1. On such an e-commerce platform, there are no particular regulations.
2. The online dispensing of medications raises questions about the need for in-person supervision and puts the patient's safety and the provided medical data at risk.
3. Poses a risk to the retail pharmacist's employment.
4. May lead to an increase in the selling of spurious and counterfeit medications,breaking established laws and regulations, and altering conventional practices.
5. It also compromises the privacy and confidentiality of the doctor's patients and raisesthe risk of drug abuse and medicolegal responsibility.[10]

Conclusion and Recommendation:

Although the Drugs and Cosmetics Act and Rules, as well as the Information Technology Act of 2000, have already undergone several amendments, the market has evolved into a competitive environment that requires dynamic laws that address all issues by the necessities. Since online pharmaceutical sales are conducted through e-platforms, the appropriate regulations must be in place. Both pieces of legislation assist users and interpreters in making the best decisions by interpreting the most difficult problems. However, since India is becoming more economically viable across all platforms, a specific piece of legislation is required so that it addresses all the problems relating to the challenges and does not hold any ambiguity. E-

[10] The Advantages and Disadvantages of Using an Online Pharmacy-Find Tips.

commerce platforms do require a suitable technical infrastructure to promote online commerce but to realize this ideal, security and safety precautions must be taken when handling any personal data. Unfortunately, current data laws do not go far enough in this regard; ideally, the recently passed Digital Personal Data Protection Act will bring about these improved safeguards. Along with this Drugs, Medical Devices, and Cosmetic bills are been bought which address a few issues but have not been passed yet. Furthermore, since the majority of people in India live in rural areas, the government should take steps to promote e-pharmacy so that, unlike in the past, those who are afraid of using such a platform are not shunned but rather see it as a positive step towards progress as in the case of an online payment method, the e-pharmacy sector has the potential to grow significantly in the coming years and create an enhanced space and regulatory regime in the commercial activities and spaces.