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**REGULATION OF E-PHARMACIES: AN ANALYTICAL STUDY OF EXISTENCE
AND EVOLUTION**

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ABSTRACT

The e-commerce sector of India has boomed ever since the country digitized itself making the maximum utilisation of technology even in its remotest areas. One industry to have recently adopted the e-commerce model is the health industry through 'E-pharmaceuticals'. E-pharmacies have built their consumer base largely benefitting from their edge over conventional brick and mortar pharmacies in terms of quality, doorstep delivery, choice of selection etc. The present rules governing digital dispensing of drugs aim at protection of the citizens from malpractices on online retail platforms. The article seeks to analyse the evolution of e-pharmacies, in consideration to the challenges faced while gaining the trust of the consumers and in aligning themselves with the statutory legislations. It is believed that e-pharmacies are the future face of health industry and their exigency during the trying times of COVID-19 has proved it further.

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The medicare as we see today has scaled many heights; we have come far ahead of the conventional doctor-nurse-pharma circle. With superior internet and globalization we stand today, just a tap away from the medical attention that we require. Online appointments, doctor's consultation on chat and video calling both nationally and internationally, placing orders for medicines and easy delivery and payment options round the clock has made our lives hustle free. One latest boom in the health industry is e-pharmacies i.e. the online sale of medicines, due to their obvious edge over conventional brick and mortar pharmacies in terms of quality assurance, economical prices, zero human interaction, schemes and discounts, incentives, packaged delivery, time convenience and liberty of choosing among others. The current e-pharmacy market is widening on three major segments, namely, generic drugs, OTC drugs and patented products. Some major market players dominating the market are IMG, NetMeds, mChemist, Medlife, Medstar, Pharameasy, SaveOnMedicals, BigChemist etc.

Under their metamorphic existence these 'cyber pharmacists' have faced numerous challenges relating to some serious legal issues.ⁱ Thus, the cyberspace is not immune from the regulations of cross border sale of drugs and rules governing the general pharmaceutical service. Only in April 2018, did they receive the certification to exist legally, in the form of amendment in the Drugs and Cosmetics Rules 1945 by insertion of Part VI B titled as 'Sale of Drugs by E-Pharmacy'. The clause read as, "business of distribution or sell, stock, exhibit or offer for sale of drugs through web portal or any other electronic media." Needless to say, in order to subscribe this identity the e-pharmacies are required to apply for grant of registration to the Central Licensing Authority (CDSCO) in Form 18AA through online portal along with prescribed fee.ⁱⁱ

CHALLENGES FACED BY E-PHARMACIES

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The very attractive union of e-commerce and pharmaceutical industry is not immune from issues and challenges in execution. Not only complex governmental norms are to be adhered to very stringently but also various other regulations relating to procurement, processing, sale and distribution of drugs have to be followed sincerely.

A very apparent advantage of ordering medicines online is that one need not worry about the source of delivery, the pharmacy can be right on the nook of your sector or maybe an altogether different country. As much as this eases the customer experience, it lays the onus on the e-pharmacies and intermediaries (delivery partners) to manage the cross-border or inter-state transactions. The regulations are highly ambiguous in this regard, as different states have different restrictions in matters of drug licensing. A drug maybe legally licensed in one state and may still be violating the pharmaceutical laws of another state; also the problem is multi-dimensional as it is not limited to the origin and destination of the drug consignment but also the states where e-commerce channel operates.

Further, the convenience of payment offered to the customers by e-pharmacies comes at a cost to these cyber pharmacies themselves. Alike any other e-commerce website, most e-pharmacies also provide their customers the comfort of going cashless and making advance payments through payment aggregators, credit/debit cards and e-wallets. However, certain drug laws mandate payment of medicines post-delivery only. This again proves to be a matter of concern for the e-pharma industry.

Based on the nature of drugs they are categorized under different heads by the Drugs and Cosmetics Rules, 1945 (elaborated further), these laws require the drugs to be sold only on advice of a registered medical practitioner in the form of prescription. However, loopholes exist in this law, further burdening the e-pharmaceutical industry, to verify, monitor and ensure that the same prescriptions are not being used multiple times by patients for obtaining NDPS drugs.

Lastly, the rules direct the e-pharmacies to maintain a proper infrastructure for the storage and handling of the medicines as per the standards, which comes at an extra cost for the cyber

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pharmacies. These are major barriers to entry in the market and the reasons for limited number of existing players.

However, the possibility of e-pharmacies exploiting the customers, by the virtue of specialized skill industry and high information asymmetry cannot be overlooked completely. A number of e-pharmaceutical websites have been found to have scandalized their customers in violation of the laws. The flaws have been found with respect to the quality of medicines, availability of stock and fraudulent scams. The government of India, under the Department of Health and Family Welfare initiated for the formation of a seven member subcommittee headed by Dr. Harshadeep Kamble (Commissioner of Food & Drugs Administration, Maharashtra) to study and recommend on issues of online pharmacies and making comparisons with different countries.ⁱⁱⁱ The committee recommendations included setting up of national platform for transacting and monitoring online sale of drugs, regulations regarding e-prescription, audit trail by linking Aadhar Cards and prohibition on sale of **Schedule X** drugs.

GOVERNING LEGISLATIONS

The transition from physical to mobile pharmaceutical markets was originally not well supported by the pre-colonial legislations. The e-commerce business comes under the realm of Information Technology Act, 2000, while the pharmaceutical arena is governed by legislations like *Drugs and Cosmetics Act, 1940*, *Drugs and Cosmetics Rules, 1945*, *Pharmacist Act, 1948*, *Indian Medical Act, 1956*. As, pharmacy business is that of a sensitive nature, the storage and sale of products is under strict legislative scrutiny; therefore the abovementioned list of legislations is only indicative and not exhaustive. Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 provide rules relating to manufacture and sale of prescribed drugs only under a license^{iv}, the infrastructural requirements for storage and sale^v, sale of drugs on verified prescription^{vi} and prohibition on sale of drugs of certain categories^{vii}.

Having more access to the digitization, the e-commerce pharmacies are likely to endorse their products by false and catchy advertisements through electronic media to enhance their client

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base. This possibility is ruled out by the The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 ("**DMRA**"), which prevents such advertisements which suggest the cure to certain specified diseases and conditions for which there are normally no accepted remedies. Thus, safeguarding consumers against false advertisements and induced buying.

Dwelling on the same argument as before, the brick and mortar pharmacies are more trusted, provided the long standing relations or a driven trust factor among people of a colony and their local pharmacist. It is for the high skill profession of medicine that there exists information asymmetry among the buyers and sellers. The buyers are therefore likely to dispenseless confidence in a web page than a human interaction with their local medico, amounting from its reputation. The Pharmacy Act, 1948 ("**Pharmacy Act**") prescribes for the constitution and composition of a council at the central and state level, to regulate the profession of pharmacy in India in addition to prescribing the educational qualifications for pharmacists^{viii}. In consonance with the Act, the Pharmacy Council of India framed Pharmacy Practice Regulations, 2015 to enforce the obligations and level of care by the pharmacists in preparation of the drugs.

The Drugs & Cosmetics Rules, 1945 provides for issuing of licenses to drugs other than homeopathic medicines under two categories of 'prescription drugs' and 'non-prescription drugs.' The prescription drugs as listed in **Schedule H^x**, can be distributed on the basis of a valid prescription issued by a registered medical practitioner^x. Non-prescription drugs are listed in **Schedule X** (inclusive of NDPS based drugs) and do not require prescription. However, even such drugs are mandated to be sold by only a registered pharmacy that has a retail license. In line with the same, Federation of Indian Chambers of Commerce and Industry (FICCI) had launched 'Self- Regulation Code of Conduct for the E-Pharmacy Sector' which lays down guidelines for professional standards to ensure the safety of consumers. The non-prescription drugs (or habit forming) have special guidelines under the Code, therefore further normalizing and increasing the efficiency of e-pharmacies.

In the latest set of legislation, The Department of Health and Family Welfare under the directions of Ministry of Health and Family Welfare (MOHFW) drafted amendments to the Rules in 2018.

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The 'Draft E-pharmacy Rules' provide for appropriate monitoring mechanisms by primarily setting out requirements and conditions for sale of drugs by e-pharmacies^{xi}.

CRITICAL ANALYSIS: COVID-19 ANGLE

In this segment of the paper, we aim to present both sides of the coin. It must be taken into consideration that the modern times are that of high ended technology and novelty; therefore, the state cannot afford to totally compromise on innovation and technological development further losing its status of a developed nation. Equally significant, the basic legal jurisprudence, consumer protection laws and the Constitution of India do not permit the State to promote technology at the cost of safety and security of its citizens who maybe the users of that technology. Therefore, the governing legislations must be stringent enough to protect the consumers of e-commerce and at the same time flexible enough to let the e-pharmacy culture span and grow in the Indian market. As the e-pharmacy culture is foresighted to a longer run, there is a need that the legislations regulating e-pharmacies must not only limit to citizens' fundamental rights or consumer protection laws of the land, but also focus on the unenumerated rights like the Right of Privacy.^{xii} As sensitive personal information of the patient is shared with the website, it is extremely pertinent for them to preserve it. This might contradict with the blockchain software of certain e-pharmaceutical websites, and thus demand immediate attention of the law.

Another common argument against the e-pharmacy model can be related to the affected business of brick and mortar pharmacies; and has resultantly faced a backlash in the form of nation-wide strike of members of All India Organization of Chemists and Druggists (AIOCD) in September 2018^{xiii}. Here, one needs to apply a broader perspective and realise that the e-pharmacies and B&M pharmacies are not complimentary to each other, rather they cater to the different needs of consumers; where latter satisfies the immediate and generalised needs of the patient, and the former caters to the specific and chronic care medication for longer run.

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Also, the no human interface working of e-pharmacies have come handy and proven commendable for their services during the global pandemic. In light of the ongoing nation-wide lockdown, as a precautionary step to beat COVID-19 virus, Government of India issued *consolidated guidelines* directing commercial establishments to shut. However, essential commodities were made available through e-commerce platforms following the social distancing protocol. Furthermore, the e-pharmacies were not left un-regulated and the MOHFW prescribed certain additional conditions on retail and doorstep delivery of drugs pertaining to the business model of e-pharmacies.^{xiv} E-pharmacies have lent a backbone to the society in these testing times by meeting the healthcare needs of citizens both domestically and in quarantine centres or hospitals. Therefore, it can be evidently deduced from the current situation, the need for inclusion of cyber pharmacy culture and their unambiguous regulating laws at the earliest.

CONCLUSION

Many e-pharmacies have made protection of the interest of their consumers as the mission and vision of their business and have been enthusiastically engaged in adding several milestones of safety procedures. The existing laws to a large extent are ambiguous and not well supportive of the cyber pharmacy culture, which needs to be mended. Comparisons can be drawn from other nations like EU, Canada and USA having denser e-commerce and pharmaceutical companionship. The sceptical mindset needs to be changed for preparedness to tackle future emergencies such as COVID-19. Health industry requires a strengthened model with the e-pharmacies in terms of quality assurance, economical prices, zero human interaction, schemes and discounts, incentives, packaged delivery, time convenience and liberty of choosing among others.

ⁱhttps://www.indianbarassociation.org/wp-content/uploads/2019/05/E-Pharmacy-in-India-Last-Mile-Access-to-Medicines_v6.pdf

ⁱⁱ<https://health.economicstimes.indiatimes.com/news/policy/health-ministry-comes-out-with-draft-rules-on-sale-of-drugs-by-e-pharmacy/65641297>

ⁱⁱⁱ<http://ficci.in/pressrelease/2600/ficci-press-nov21-e-pharmacy.pdf>

^{iv} Drugs & Cosmetics Rules, 1945, 62-B

^v Drugs & Cosmetics Rules, 1945, 64

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^{vi}Drugs & Cosmetics Rules, 1945, 65

^{vii}Drugs & Cosmetics Rules, 1945, 65(11-A)

^{viii}Sec. 42 of Pharmacy Act, 1948

^{ix}Drugs & Cosmetics Rules, 1945, 65(9)(a)

^xDrugs & Cosmetics Rules, 1945, 2(ee)

^{xi}Dr. Zaheer Ahmmed v. The Union of India & Ors., Writ Petition (C) No. 11711/2018

^{xii}<https://www.pharmatutor.org/articles/current-status-of-e-pharmacy-in-india-2019-review>

^{xiii}<https://www.financialexpress.com/opinion/e-pharmacy-rules-clear-regulatory-direction-needed/1792529/>

^{xiv}<https://www.mohfw.gov.in/pdf/Doorstepdelivery26B.pdf>, <https://knowledge.leglobal.org/corona/country/india/india-augmenting-the-fight-against-covid-19-how-businesses-are-stepping-up/>



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