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ONLINE SALE OF DRUGS IN INDIA - LACUNAS IN THE LEGAL SYSTEM

Abstract

India, is rapidly adopting online shopping as their main mode for shopping. Everyone likes to sit back at their homes and order things from the ease of their hands. India being a country with a population of over 7 billion has a lot of opportunities for budding entrepreneurs to establish their business online. Online sale of drugs is the topic that will be discussing in this paper. This study will mainly revolve around a few shortcomings and gray holes that are present in the online sale of drugs from the legal and regulatory standpoint and also how the advent of online medical sites have been financially obstructing the day to day running of physical medical stores. Another issue that will be dealt with in this paper will be the mode of pricing of online medical sites over the physical medical stores. There has been a significant price and taxation policy discrimination among these two and the physical stores have been the ones who have been suffering from heavy taxation, licensing and pricing policies. The online sites have been undoubtedly benefiting over the pricing policy and the government has by far not made any changes to its policies. While online shopping is a boon for both the seller and the buyer, I believe the sale of medicinal drugs is not the sector of market to be shifted online. A major gray space in the current policies is that the online medical sites cannot sell prescription drugs whereas the majority of consumers buy prescription drugs than general drugs. But if you have a replica of this process of verification of the prescription at a local pharmacy, you can buy prescriptions drugs online.

Keywords:-

Online medical sites, taxation, licensing, pricing, shortcomings

1. STATEMENT OF PROBLEM:-

The research shall focus on the shortcomings and loopholes in the current law that regulates the online sale of medical drugs in India and shall also discuss about the discrepancies in the pricing policy between the online medical stores and the physical medical stores. The absence of physical communication and separate set of laws for the online market can make it ineffective most of the times and in a country like India where there is a history of drug abuse it will simply add on to the misery. These issues have to be addressed and proper regulatory bodies have to be set up and the existing laws have to be amended for better functioning of the online drug market.

1. OBJECTIVE OF THE STUDY:-

- **To identify** the factors that cause discrepancies in price between the online medical stores and the physical medical stores.
- **To examine** the issues present in the current law governing the sale of online drugs in India
- **To suggest** measures to reduce such discrepancies and issues.

2. HYPOTHESIS:-

It has been presumed while conducting the research that both online and retail stores are been governed by the same set of laws and that the pricing policy of both are same. It is also presumed that online medical stores are accessible all across the country for everyone.



3. RESEARCH METHODOLOGY:-

A Doctrinal Method of research has been adopted with the use of both primary and secondary sources for reaching a conclusion.

4. PROLOGUE:-

Online stores are on a rise in India, with cheap and easily accessible internet now almost every one can shop online. Most of the people prefer to shop sitting in their homes or office and not physically going to a market. Like everything, online shopping also has its advantages and disadvantages. Online shopping can now help a person to avoid the hustle and crowd to buy stuff while coming from the office or simply help an old man order a pair of spectacles while he is sitting comfortably in his couch. The sector of online marketing that I have focused on this paper is medicine and cosmetic. As the people are more dependant on online shopping, some large scal

sellers have now shifted to the online platform to sell medicine. People can now consult to a doctor online 24/7 and almost immediately if they want to. Unlike other sectors, this sector of the market requires more regulations and guidance as drugs can be easily misused and making them available online without monitoring them is just like adding fuel to the fire. Recently the Delhi High Court had banned the sale of online drugs on the plea of a doctor. A doctor named Zaheer Ahmed filled a petition in the high court to ban the online sale of drugs. The high court listened to his plea and banned all sale of medical drugs stating the reason that several online pharmacies are selling drugs online without a drug license and cannot be regulated in the present regime. Unregulated and unlicensed sale of medicines will increase the risk of spurious, misbranded and sub-standard drugs being sold. His petition also stated that the online sale of drugs is against the provisions of Drugs and Cosmetics Act, 1940 but sadly, even after that, lakhs of drugs have been sold online in India and there was no one to monitor them. There is no proper mechanism to stop selling of counterfeit drugs and this can cause health hazards. After this plea High Court had ordered the government to make necessary regulatory bodies to look after the sale of online drugs and make a special team to track down all the fake online medical stores that are selling drugs without a license. The High Court also put a ban on the sale of prescription drugs from all stores. The High Court has listed this matter for further hearing. Now, considering the plea and the advise of the court, there are several gray spaces that have not been touched and on detail examination one can easily find loopholes in the current laws regulating the sale of drugs. The other area which is not properly monitored is the discrepancies between physical and online medical drug stores.

● ***Discrepancies between physical and online medical drug stores :-***

Firstly, the physical medical stores have to go through a lot of legal procedure in order to legally establish a store. These legal procedure include licensing that has to be done on a regular basis and the taxes that have to be borne by the sellers. Until now, the online stores were selling drugs without a valid drug license and there was no one to monitor them. There is no specific law to deal with the online sector. So the question that arises here is that what is the government providing there physical retail stores in return of the taxes and the licensing money. It takes a lot more capital to establish a store, capital required to purchase land, capital required to build a

store, capital required to maintain stock and many more such expenses, whereas the online stores require lesser capital as compared to them. The online sites directly take orders from the customer and forward the order to a producer or a whole seller and cut off all the cost of a middleman. But that is not the case in a physical retail store, the proprietor has to contact agents and salesman for purchasing drugs from the whole sellers. There are several invisible costs that have to be borne by a proprietor before he can actually sell a medicine. All that considered, the proprietor of a physical stores earns much less profit from selling a single medicine than the store that sell the drugs online, and in some cases illegally.

SECONDLY,

The pricing policy is on a totally different footing for both the physical and online retail stores with the late being more profitable. The online stores are like any other stores and have to follow the same rules and regulations. Now considering the pricing policy, the government has its say in determining the prices of a drug and there is also a price floor of a particular medicine that has to be sold in retail. In a competitive market two sellers of a same commodity can not change the price at which they sell the commodity but can give incentives and increase their sale by other factors. Now what happens in the case of these two is that a physical retail store sells a medicine for a particular price and earns some amount of profit from them. But an online retail stores sells the same medicine at much lower price and gives several incentives. The price at which they sell their products is much lower than that of a retail store. This makes the costumers bound to shift towards the online platform as it gets them their medicines as fairly cheap prices. Is it legal? Well if this happened between two physical retail stores then the store selling his medicines so cheaply could be sued. And considering the costs incurred to buy the medicines in the first lace wont allow a seller to sell his medicines so cheaply. But since the online stores directly forward the order to the producer, the have comparatively much less costs and can afford to sell the medicines at a much lesser price. Considering all of the above, we can say that the online stores have very less costs to incurred and selling medicines on a retail platform at the price of a whole sale store. The only difference is that physical whole sale stores take orders from retail stores only in bulk but provide medicines to customers online in the quantity the desire.

All of this goes unnoticed by our government and it is high time the physical stores get their equal share of profit. If there are two sellers selling the same commodity to a customer then the government has ought to set a price floor that prevent such online sellers to sell medicines at a low price and attract customers towards them. There are three stages of selling that a commodity has to follow, producer-whole sale- retail but the online store are bridging the gaps and selling commodities at prices they desire and are not getting charged for it. Whereas the physical stores who are paying a premium to sell these commodities are slowly and steadily losing their customers. The customers are no where to blame in this scenario as who would not want to save their hard earned money and buy stuffs from places that offer them at a cheap price. The customers think they are also the ones who are gaining in this transaction but are they? What about the quality of the drugs the stores sell online? What about their genuineness? What about their packaging? Well these factors are all covered in the physical store but are they covered online. There are more news of fake drugs being sold online than being sold in physical retail stores. One can easily escape from the liabilities if they sell drugs illegally online. And have the customers considered the fact that their kids also use network. Now consider a teen who has a habit of drug abuse. He needs some drugs that are only sold on prescription. He approaches a physical retail stores and asks for those drugs without prescription and gets denied by the seller. He returns back home and visits an online drug store. He sends a fake prescription that can easily be generated online and buys those drugs. He gets his drugs easily and cheaply. The life of that kid is spoiled so easily and no one bothers to correct what's wrong. Even the court allows sale of prescription drugs but they ignore the fact that the very sites that sell those prescription drugs also ignore fake prescriptions and sell drugs to whosoever in need. Because who would reject easy money? There are so many life threatening side effects of this easy money that not even one of them can be ignored.

● ***Overview of Laws Governing Online Sale of Drugs:-***

The utilization of internet to access medications and diagnostics which started long back but now has become a full fledged market that has matured into virtual drug stores, commonly known as “internet pharmacies”. The advent of drug store via internet and access of medications and diagnostics is gaining popularity and is becoming prevalent because of cost adequacy, speedy delivery and specially for the door to door service popularly known as “Home Delivery” service.

Prescribing medications on internet is basically a framework assisted with technology which makes it easier for doctors to help their patients by means of internet such as sending a prescription to the pharmacy that is working online for sale of drugs instead of handwritten prescriptions. Firstly I would like to put forth the regulations governing the sale of drugs in India and hence would then try to comprehend over issues relating to it. Right now administrative power and duties have been dispersed between the Central government and the State governments where the former is responsible for licensing of drug imports and the state governments are responsible for the manufacture, sale and distribution of drugs. Central Government exercises regulatory control over drugs by New Delhi based Central Drugs Control Organization headed by the Drugs Controller General India. State authorities exercises regulatory control over drugs by state based Drugs Control Administration headed by the State Drugs Controllers. Every state has its own Drugs Control Administration. The laws governing Pharmacies in India are derived from Drugs and Cosmetics Act, 1940; Drugs and Cosmetics Rules, 1945; Pharmacy Act, 1948; Indian Medical Act, 1956 and Code of Ethics Regulations, 2002. All these governing regulations came into effect before the introduction of computers to the people so actively and hence the conclusion we could possibly draw from such a situation is that there is precisely no law governing online sale of drugs in India. The Information Technology Act, 2000 administers all exercises and issues related to the internet. At this point when e-drug stores guideline is the issue which needs immediate attention from the authorities, there is a clear cut absence of precisely and unambiguously expressed laws and obvious rules to manage, control and screen e-drug stores. For ensuring productive and authentic running of e-drug stores, it is a need of the hour to make hassle free rules for e-pharmacies. E-drug stores come under the domain of the Drugs and Cosmetics Act, 1940 and the Information Technology Act, 2000. Be that as it may, current Drugs and Cosmetics Act, 1940 doesn't differentiate between online and offline drug stores. So amendments in the law are required to Drugs and Cosmetics Act, 1940 in order to bring e-drug stores under the purview of Drugs and Cosmetics Act, 1940. The players associated with the Online drug stores make elucidation of laws and principles according to their benefit for exploiting for their business when there is uncertainty on the applicability of these laws to this model. It appears that online players don't act according to these guidelines and attempt to often disregard and bypass them. There is a major misinterpretation that application of the current laws to both online and offline models would

prove to be beneficial and is an efficient way to manage this sector as well, it is a big fallacy as understood by the above arguments. This may prompt dangerous results and might be demonstrated as perilous pattern in future. There are not clear arrangements with respect to sale of drugs online, it appears to be extremely hard to control, screen and track sell of medications through e-drug stores.

- **Drugs and Cosmetics Act, 1940:-** Sec 10A of this act clearly states that “Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do then, that Government may, by notification in the Official Gazette, prohibit the import of such drug or cosmetic.” Section 27 of Drugs and Cosmetics Act has provisions for penalty for manufacture, sale, etc., of drugs in the form of imprisonment and monetary fine.
- **The Pharmacy Act, 1948:-** According to Sec 42(1) of Indian Pharmacy Act 1948, “No person other than a registered pharmacist shall compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner.” Section 42 (2) also states, “whoever contravenes the provisions of sub-section (1) shall be punishable with imprisonment for a term which may extend to six months, or with fine not exceeding one thousand rupees or with both.”
- **Indian Medical Council Act, 1956**
 - i. Regulation 5.3 of MCI Code of Ethics stipulates that pharmacists and doctors should work together. If e-pharmacies are allowed, then this relationship will be lost.
 - ii. Regulation 7.14 of MCI Code of Ethics 2002, also does not allow a registered medical practitioner to disclose the secrets of a patient that he/she may have been learnt in the exercise of his/her profession. Declaration (g) given to doctors at the time of registration states: I will respect the secrets which are confined in me.
 - iii. Regulation 6.4 of MCI Code of Ethics prohibits from giving or receiving any rebates or commissions. E-pharmacies may provide rebates and commissions to doctors to provide

prescriptions on the basis of online information that has been filled by the patient. This way doctors will be vulnerable to malpractice suits.

- iv. Not only doctors, Pharmacists too have a role in ethical dispensing of prescription medicines. Safe and effective use of medicines is a complementary effort and subsequent amendments have some provisions in it that are of relevance to the pharmacists.
- v. Regulation 1.9 of MCI Code of Medical Ethics Regulations, 2002 requires all doctors to abide by the laws of country that regulate the practice of medicine. Neither the doctor nor the pharmacist should be a party to helping others evade these laws.
- vi. Regulation 7.19 of MCI Code of Medical Ethics Regulations, 2002 does not allow doctors to use touts or agents for procuring patients. So, a pharmacist should not indulge in such activities

- **Information Technology Act, 2000:-** The Information Technology Act 2000 governs some of the legal issues pertaining to online dealings but it is silent on the aspect of e-pharmacy. As a result, illegal e-pharmacies have been increasing in India. There is clear ambiguity in the provisions of the Indian law whether a pharmacy is allowed to take money prior to delivery of medicines. Certain provisions of the law mandate, money to be collected from the customer only after medicines are physically handed over to the customer.
- **Pharmacy Practice Regulations, 2015:-** It creates the impression that electronic prescriptions ought to be valid particularly in the terms of the Pharmacy Practice Regulations of 2015 put forth by the Pharmacy Council of India in January 2015. In these guidelines, "Prescription" is defined in the guideline 2(j) where it states it to be a direction via electronic means from a Registered Medical Practitioner or other appropriately authorized specialists, for example, Dentist, Veterinarian, and so forth to a Pharmacist to compound and administer a particular kind and amount of pre-assembled medication to a patient. On premise of existing guidelines it creates the impression that a copy which is scanned, that of a prescription will be considered as a valid document as a prescription. Be that as it may, regardless of whether such electronic prescriptions can be utilized to purchase medication from e-pharmacies is under question.
- It ought to be noted here that there was/is no guideline by Indian Government on 'Online clearance of e-drug store' in India; Until as of late (finish of 2018), Delhi and Madras Hon.

High court gave an order on the Public Interest Litigation (PIL) filed by an Indian citizen who was concerned with the need for prohibition on 'illicit' use of prescriptions in India through e-drug store and The Delhi High Court imposed an interim ban on sale of drugs online till January 8, 2019. The further points made were that the drug specialist who is selling the prescription ought to have a Government of India permit (expert) for selling such medications. Further, medications ought to be sold on the 'medicine by a rehearsing specialist' – without which it is considered as 'illegal'. Such illegal sale of medications all over the country would cause drug abuse resulting into various other dangerous factors. In contrast to consumer products, drugs are exceptionally strong potent materials and use of it incorrectly like consuming it in the wrong proportion, fake medications or where the expiry date suggested for use has already passed medication can have lethal outcomes on the patient. Normally, such sort of issues don't emerge in the ordinary course where selling of drugs take place through physical drug stores; as these considered shops are moreover situated in the area of a rehearsing specialist who recommends the prescription and guarantees that the patient has gotten the right medication. Such care is typically taken by specialists for uneducated patients. Additionally, since the patient is visiting the drug store shop; physical check of the 'prescription' can be effectively done by the drug specialist in a Physical Drug store which practically is not really happening in a virtual store selling drugs online.

● *US Law on E-Pharmacies*

In US, E-pharmacies are governed by both federal and state legislations. Amongst existing regulations governing E-pharmacies in US, a few notable measures include –

1. Mandatory registration for sale of controlled substances: Every pharmacy that dispenses controlled substances must be registered with the Drug Enforcement Administration (DEA)

2. Electronic Prescription for Controlled Substances (EPCS): While maintaining control on controlled substances, under this rule, practitioners are enabled to issue electronic prescriptions for controlled substances.
3. In-person Medical Evaluation: Under the Ryan Haight Online Pharmacy Consumer Protection Act, 2008, any practitioner issuing a prescription for controlled substance must conduct in-person medical evaluation at least once every 24 months.

5. RECOMMENDATIONS :-

- A website shall be designed to check whether the online platform selling drugs is authorized or not, also a uniform website should be designed on a national level which could monitor transactions related to online sale of drugs within the country.
- A proper guideline should be released by the government in order to ensure that consumers buy medications from authorized stores online and also to help them buy these medications safely which would prevent any fatal results in future.
- A list should be put forth before the consumers where the illegal and blacklisted virtual drug stores would be listed which would in turn make it very easy for a patient to differentiate between an authorized and illegal store, this would be a major step taken for the protection of consumers from illicit sale of drugs.
- It is critical to ensure personal data of the patients confidential in accordance with the Information Technology Act and hence steps should be taken in this regard as well.
- It shall be mandatory for e-pharmacies dealing with online drugs importation and re-importation to be registered and to get licence for the same from regulating body.
- Government schemes like National Rural Health Mission can help in promoting proper procedures to acquire drugs and can prevent self-medication through campaigns on television, radios and social media.
- Also a very important point is that the e-pharmacy is an intermediary its functions, responsibilities, procedure for registration need to be fixed and should be expressly mentioned.

6. CONCLUSION:-

Guidelines on E-drug stores is unquestionably ineluctable considering the significant effect they can have on individuals' well being and security. As put under direction by the Madras and Delhi High Courts, the Rules on E-Pharmacies ought to be presented with extreme urgency as there is an immediate need for it. The Indian Laws on E-drug stores should mull over the measures presented by different other created nations like US and EU, for example, following framework, basic logo, electronic solution for specific medications and so on to handle issues related with powerful execution and guideline of E-drug stores.



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