# LEGAL FRAMEWORK OF PRODUCT LIABILTY IN E-PHARMACY

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**ABSTRACT**

India being one of the leading countries in pharmaceutical drug manufacture, sale, distribution and export has well established supply chain management from manufactures to that of the consumers (end-users). Human health and drug safety being paramount, the stakeholders of pharmaceutical drug supply chain management owe greater diligence for what they market to the end consumer is free from causing any health hazard. Unlike any other products for sale in market, the marketing of drugs requires strict compliance to various drug regulatory laws in addition to consumer related laws. Whether the sale of drugs is through pharmacy outlets or e-pharmacy, the safety of the drugs has to be ensured without any compromise. The research paper covers the working of e-Pharmacies in India, product liability in e-Pharmacy system, pros and cons of e-Pharmacy, licensing and marketing trends, progress of its regulatory framework compared to conventional pharmacies, contributions of various committees in ensuring safety standards and pricing, analysing regulatory framework in select countries for e-Pharmacy.

**Keywords:** E—Pharmacy, Product liability, Public Health, CDSCO.

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## INTRODUCTION

The advent of e-Commerce supported by internet, access to technology with use of artificial intelligence has drastically changed the ease of doing business in every sphere of commercial activity including sale of pharmaceutical products. E-Commerce offers tremendous benefits to the stakeholders including consumers, ecommerce companies, intermediaries and government. Some of the benefits include low cost of investment, transnational sale, trace consumer buying habits, effective advertisement strategy using analytics, minimise travel cost, flexi timing 24X7, convenient payment mode, remote manpower management, etc. The current development in e-Commerce facilitates use of mobile applications (apps) which is popularly known as m-commerce i.e mobile commerce nurtured by compatible smartphones and access to internet facility.[1]

The sale of pharmaceutical products in electronic platforms differs from the conventional mode of its sale through pharmacies in physical mode which calls for the special attention to address the marketing and ethical issues. The e-commerce mode of buying and selling goods and services has multiplied due to pan India promotion of digital platforms, most preferred consumer choices for online shopping, pandemic induced breakthroughs of various e-commerce marketing channels including online pharmacies. The e-pharmacy is of recent origin coming under the purview of the Drug Controller General of India like any other traditional pharmacy outlets. The e-pharmacy breakthrough can be very well felt due to pandemic induced trends and lifestyle modification, where the overall consumer buying habits have been impacted to rely upon the online mode and that is further continued post pandemic period as well.

## ABOUT E-PHARMACY

Pharmacy includes every store, shop or any other place where a) Drugs are dispensed, b) where drugs are prepared, or c) where prescriptions are compounded or a place which by sign/symbol or indication gives the impression that operations mentioned as above are carried in the premises or which upon it displaced the words “Pharmacy” or “Pharmacist” or “Dispensing Chemist” or “Pharmaceutical Chemist”.

[1] AMMU CHARLES, *E-COMMERCE LAWS – LAW AND PRACTICE* (2019).

The pharmaceutical marketing in general is lucrative and risky professional activity. E-Pharmacy in simple is the kind of pharmacy functioning in the online space or digital network. Unlike rest of other e-commerce activities, the rise of e-pharmacies invites debates and special attention towards legal and regulatory framework including product liability concern. In the initial stage, however there is hiccups and mixed reaction towards e-pharmacy among the stakeholders to switch to the new trend but even before we could react the e-pharmacy has set its path and become widespread across the nation, surprisingly, received enormous positive response from its stakeholders for the merits of any other e-commerce activity. Since its introduction the e-pharmacy has set an alternate to pharmaceutical product marketing globally as well as in India. By 2015 the e-pharmacy has received widespread accolades and drew the attention of the Union Health Ministry to constitute an expert committee to study the viability of e-pharmacy and the coverage of regulations under the existing drug laws in India.[2] E-pharmacy operations to function in complete digital medium and every information and transaction are retrieved in the National Digital Health Mission (NDHM)[3].

## ADVANTAGES OF E-PHARMACY

The main advantage of e-pharmacy include: a) Access to medicine or pharmaceutical products – with technology driven electronic network, b) Availability – due to aggregation of supplies from multiple licensed pharmacies, c) Authenticity and Transparency – of the pharmaceutical products linked with licensed manufactures, d) Convenience – to the customer for delivery of the order at ones' doorsteps or place of stay at convenient time and possibility of tracking, cancelling the order or use the consumer helpline facility, f) Affordability – ensured through broad margin base in the supply chain management and cost cutting mechanism in the online portal for other marketing or infrastructural expenses.[4]

[2] Sakshi Shairwal, *E-pharmacy in India*, Lexology (Apr. 16, 2021), https://www.lexology.com/library/detail.aspx?g=233a81d0-1faf-4de6-8ce0-8dc9ab3d6d95. (accessed 19 March 2023).

[3] '*e-Pharmacy: The Next Big Scope in Pharmabiz*, Elets eHealth (Apr. 12, 2021), https://ehealth.eletsonline.com/2021/04/e-pharmacy-the-next-big-scope-in-pharmabiz/. E-Pharmacy: The Next Big Scope in Pharmabiz - Elets EHealth' <https://ehealth.eletsonline.com/2021/04/e-pharmacy-the-next-big-scope-in-pharmabiz/> accessed 25 March 2023.

[4] *FICCI : Industry's Voice for Policy Change*, https://ficci.in/api/press_release_details/3852..

## DISADVANTAGES OF E-PHARMACY

Disadvantages of e-Pharmacy, to highlight the few, include a) No proper information on the stores or physical infrastructure, b) e-Pharmacy through electronic portals or apps may limit the consumers to itself, c) Health concerns of the consumers are at peril, even though the e-pharmacies follow the requirement of prescription, but still there are all chances of substandard/counterfeit drugs procured in the stores which when consumed cause health hazard[5], d) like any danger posed in common e-commerce transactions, e-pharmacy too may result in misuse of personal and financial information of the customer, e) e-pharmacy impacts the business of local pharmacy outlets, retail pharmacy in the long run.

## WORKING OF E-PHARMACY

The working of e-Pharmacy can be denoted with simple steps, as follows: Step 01 - The consumer login into the website or web link or mobile based app of e-pharmacy (of choice) and provides details of the prescription (scan copy) and the order is placed. Step 02 - the registered pharmacist verifies the details and validates the prescription. Step 03 – after validation the registered pharmacist passes the order to the store for dispatch of medicines. Since the entire transaction takes place with the support of internet, the e-pharmacy transactions are governed by Information Technology as any other e-commerce activity[6]. The popular business models of e-pharmacy include Marketplace, Inventory-led hybrid (offline or online) and Franchise-led hybrid (offline or online). These models are widely adopted by Netmeds, Medlife, Pharmeasy, 1mg, Practo, Apollo Pharmacy etc.

## CONVENTIONAL PHARMACY

The conventional pharmacy is very old model and it is the traditional pharmacy. It exists in a local place with a physical shop or outlet with are regulatory requirements such as licence, registered pharmacist, stock, etc. Conventional pharmacy too dispenses drugs, medicines or pharmaceutical products to the patient or consumer based on doctors' prescription after due verification. Besides, the pharmacist shall provide counselling to the customer, necessary information about the medicine such as its dosage, contraindication, alternate medicines if need be, participate in health

[5] *E-pharmacy vs conventional pharmacy*, IP Int J Compr Adv Pharmacol https://www.ijcap.in/article-details/8313.
[6] Id.

camps or programmes etc. The advantages of conventional pharmacy shall be put as follows: a) proper handling of prescription and dispensing medicines, b) involve in patient care, monitors drug supplies, its usage or adverse drug reaction of medicines (i.e participates in pharmacovigilence activities), c) advice patients/consumers with regard to mild ailments or contraindications and suggest alternate medication, d) inform necessary information to the public and the health care authorities and check for spurious or counterfeit drugs etc as part of pharmacy ethics. Likewise, the disadvantages of conventional pharmacy include: cost, delay in dispensing drugs or medicines due to non-availability, inconvenience caused to consumers to reach the pharmacy outlets.

## PHARMACY RETAIL SECTOR

In India the retail pharma covers three main areas such as branded generic drugs, non- prescription drugs and patented products having approximately 70%, 21% and 9% market shares respectively. The flow of distribution channel in pharmaceutical market can be depicted in the following order: Manufactures to Distributor (in certain cases) to Wholesaler to Retailer to Consumer. The core objective of pharmaceutical manufacture is to sell quality drug formulations to the consumers or patients. The manufacture of drug is both art and science, requiring strict compliance to the Good Manufacturing Practices (GMP).[7]

## DRUG LICENSING FOR PHARMACY

As per the Drugs and Cosmetics Act, 1940 and Rules thereto, a licence for a conventional pharmacy (existing in physical form) can be obtained for sale of drugs in the following ways: a) sale of drugs by wholesale, b) sale of drugs by retail sale, c) sale of drugs by retail without engaging service of a qualified person (Restricted licence), d) sale of drugs by wholesale from a motor vehicle, e) sale of Homeopathic medicines by wholesale or retail. If in case if the drugs are sold and stocked for sale at more than one place, separate licence should be obtained for each such place.[8] The licence granted for sale of drugs unless suspended or cancelled shall be valid for a period of one year and followed by renewal licence. The licence for pharmacy shall be issued on the satisfaction of conditions, among others, the licence in Form 20 and 21 can be granted only when requirements prescribed for a pharmacy in Schedule N are complied with. The supply, other

[7] N K JAIN, *TEXT BOOK OF FORENSIC PHARMACY* (2017).
[8] DR. LILY SRIVASTAVA, *LAW & MEDICINE* (2ND ED. 2013).

than by way of wholesale dealing (retail sale) of any drug supplied on the prescription of a registered medical practitioner, shall be effected only by or under the personal supervision of a qualified person.

In case of e-pharmacy the law is evolving and there are no concrete regulations available exclusively to handle e-pharmacy. During August 2018, the Department of Health and Family Welfare published draft rules to govern e-pharmacy, further after the consultation with the Drug Technical Advisory Board the central government shall be conferred with the power to amend the Drugs and Cosmetics Act, 1940 by invoking Section 12 and Section 33 of the said Act. The proposed draft rules covers provisions relating to registration, application for registration, conditions for grant of registration, suspension and cancellation of registration, procedure for sale of drugs etc. Further, the e-pharmacy is required to set up physical infrastructure as that of the physical pharmacy and meet the regulatory requirements applicable thereto. Until the government notifies the appropriate regulations, the e-pharmacy is partially brought under the provisions of Drugs and Cosmetics Act and Rules.[9]

## GENESIS OF PRODUCT LIABILITY

The emergence of product liability in many nations has its origin in contractual principles later got its transition to tortious liability being interpreted under negligence in the beginning and to later to that of the No-Fault Liability principle such as strict liability and absolute liability basis for recovery of any harms arising from products use, and the trend toward a standard of absolute liability of manufacturers. In USA there is complete absence of contractual principles in determining the product liability but it is dealt with the strict liability principle as the basis for recovery for harms arising out of such claims and further, there is growing trend towards absolute liability for manufacturers. In UK the European Economic Community (EEC) directed to members States of the Community to maintain uniformity in product liability laws. The strict liability principle has been introduced in UK and the same has been incorporated in the Consumer Protection Act, 1987. The proof of negligence on the part of the manufacturer is no longer necessary. For the claim under product liability one has to prove that a) the product was defective

[9] Ajay Kamboj, *How To Start E-Pharmacy Business In India?,* Pharma Franchise Help https://pharmafranchisehelp.com/how-to-start-online-pharmacy-sell-medicines-internet-drug/.

and b) the defect was the cause of injury to the claimant and c) he suffered damages as a result of the defect.[10]

The strict liability principle has materially altered the manufacturers or sellers liability for the dangerous characteristics of the product causing injury or harm of any other kind. Drug or cosmetic which is regarded as bad product or dangerous have come under the consumer's attention. The consumer has the right to know or be informed about the product's dangerous characteristics and be protected in consumer interest. As far as drugs and cosmetics are concerned there are three principle categories for applying strict liability, they are: a) products with side effects that are apparent at the time of sale, b) beneficial products whose harmful side effects are preliminarily unknowable and c) products whose harmful side effects outweigh their beneficial properties.[11]

In *Davis v. Wyeth Laboratories Inc.,*[12] the plaintiff aged 39 years contracted polio after administration of Sabin oral polio vaccine during a mass immunisation project. The court except for one judge dissenting, applied strict liability where the manufacturer was found to have taken no effort to provide any warning about the risk of contracting polio from the vaccine. It was observed that *"the manufacturer should be regarded as guaranteeing to each and every user that the drug was fit and safe for his individual use, rather than merely that it was reasonably fit and safe for public consumption."*

Dean Posser said that when a products liability case involves the question of reasonable warning, the liability is not distinguishable from that which would be found in an ordinary negligence case.[13] In *Basko v. Sterling Drug, Inc.,*[14]– a drug with trade name Aralen for chloroquine phosphate was developed and sold for the treatment of arthritis was subsequently, found to cause blindness in some users for using it for considerable period. The above cases support the proposition that a manufacture is not liable for the resulting from a good product until after the manufacturer know

[10] K C Gopalakrishnan, *LEGAL ECONOMICS - INTERACTIONAL DIMENSIONS OF ECONOMICS AND LAW* (2022).
[11] Page Keeton, *Products Liability - Drugs and Cosmetics*, Vanderbilt Law Review https://scholarship.law.vanderbilt.edu/vlr/vol25/iss1/13>.
Prosser & Wade, *CASES AND MATERIALS ON TORTS* 727 n.2 (5th ed. 1971).
[12] 399 F. 2d 121 (9th Cir. 1968). Id.
[13] KEETON (Supra 10).
[14] 416 F.2d 417, 426 (2d Cir. 1969). Id.

or should have known of the risk of harm and failed to give adequate warning.[15]

In India as well the product liability is still majorly governed by negligence and partly by the contract based remedies. In *Bhopal Gas Tragedy*,[16] the strict liability principle was invoked to compensate the victims. However, the claims of the large number of victims could not be settled by the Union Carbide Company in spite of the interim relief of Rs. 2500 million. The judiciary felt the need for a special enactment to provide immediate relief to the victims of accident while handling hazardous substances with an insurance kind of arrangement to be effected by the occupier of such activity. The government enacted the Public Liability Insurance Act in 1991 with an objective to provide immediate relief to the victims of accident and also to discharge the occupier's liability to settle large claims out of such major accidents.

The pharmaceutical company Ranbaxy was found guilty for the act of mischief under Section 17(c) of the Drugs and Cosmetics Act, 1940 as the injection marketed for sale was without 2ml water, although the carton and the leaflet stated the presence of 2ml water.[17] In another case,[18] about 791 bottles of drug labelled medicik liquid paraffin sold were not of standard quality and the manufacturer was charged for the offence under section 27 of the Drugs and Cosmetics Act, 1940. Chapter IV of the Drugs and Cosmetics Act, 1940 contains provisions relating to the Manufacture, Sale and Distribution of Drugs and Cosmetics. The sale of allopathic drug (Ozomen capsule) cannot be done without the valid licence. [19] By virtue of Section 18 of the Drugs and Cosmetics Act, 1940 dealing with Prohibition of manufacture or sale of certain drugs and cosmetics, prohibits any person from manufacture or sell or stock or distribute or exhibit or offer to sale any drug which is not of standard quality or is misbranded[20] or adulterated[21] or spurious.[22]

## PRODUCT LIABILITY CLAIMS IN PHARMACEUTICALS

The product liability relates to the area of law that enables compensation for physical injuries and

[15] Bexis, *Drug and Device Law*, (Apr. 28, 2011), https://www.druganddevicelawblog.com/2011/04/comment-k-some-of-way.html>.
[16] M.C. Mehta v. Union of India, AIR 1987 SC 1086.
[17] Ranbaxy Laboratories Ltd v. Madhya Pradesh, MANU/MP/0301/1995.
[18] *Chemical and Pharmaceutical Enterprises v. State of Madras,* MLJ 52 (Mad 1959).
[19] *Fizikem Laboratories Pvt. Ltd. & Ors. v. The Drugs Inspector & Ors,* MANU/AP/ 0753/2012.
[20] The Drugs and Cosmetics Act, 1940. § 17.
[21] The Drugs and Cosmetics Act, 1940. § 17A.
[22] The Drugs and Cosmetics Act, 1940. § 17B.

property damage resulting from defective and unreasonably dangerous products and manufacturer or seller failing to disclose the dangers and provide warnings.[23] The product liability claims in pharmaceutical products commonly relates to defect in manufacture, drugs with serious or dangerous side effects, drugs being marketed improperly, spurious drugs, adulterated drugs, misleading advertisements, design, formula, preparation, testing, warning instruction, marketing etc of any product. The action for product liability claims in pharmaceutical may lie against the manufacturer, the testing laboratories, marketing executives or medical representatives, the doctors, the hospitals and the pharmacy.[24] The basis for product liability claims against the stakeholders arises both under contract law and tortious liability. However, the Drugs and Cosmetics Act, 1940 and relevant Rules, 1945 majorly govern the product liability in pharmaceutical products in India. In addition, in effect to the Consumer Protection Act, 1986, the manufacturers may be held liable for defect in their products as well as deficiency in their services whether or not there is negligence on their part (strict liability). Presently, the product liability aspect has been separately dealt in the Consumer Protection Act, 2019.

## GLIMPSE OF PRODUCT LIABILITY UNDER CONSUMER PROTECTION ACT, 2019

The Consumer Protection Act, 2019 incorporates provisions for product liability in Chapter VI Sections 82 to 87 for product liability claims which was not found in the previous Consumer Protection Act, 1986. The basis for such product liability actions is the No Fault Liability principle. The product liability action enables a person to file a complaint before a District, State or National Commission for claiming compensation for the harm caused to him either due to defect[25] in the goods/product manufactured or deficiency[26] in service serviced by a product manufacturer (Section 84 – Liability of Product Manufacturer) or product service provider (Section 85 Liability of Product Service Provider) or sold by a product seller (S. 85 – Liability of Product Seller). By inclusion of the work 'negligence' under the definition of 'Deficiency', the law explicitly covers

[23] Dr. Lily Srivastava, Law & Medicine - Google Books' <https://books.google.co.in/books?id=A5_TSdG13M4C&pg=PA253&lpg=PA253&dq=bambooweb+dictionary+and+product+liability+overview.htm&source=bl&ots=8TU3yQKc7Z&sig=ACfU3U3c4dW_AzzQXpJ6hhtsIhYk2Kn1sQ&hl=en&sa=X&ved=2ahUKEwiUjsHy2eb2AhUNUGwGHcD3DzoQ6AF6BAgCEAM#v=onepage&q=bambooweb dictionary and product liability overview.htm&f=false> accessed 27 March 2023.

[24] 'Product Liability Claims Involving Pharmaceutical Drugs | Nolo' <https://www.nolo.com/legal-encyclopedia/product-liability-claims-pharmaceutical-drugs-30314.html> accessed 25 March 2022.

[25] The Consumer Protection Act, 2019. § 2(10).

[26] The Consumer Protection Act, 2019. § 2(11).

the acts of negligence in general and 'medical negligence' in particular. Spurious Goods are the goods which are falsely claimed as genuine. Further, whoever involves or permits in the manufacture of 'spurious goods'[27] is said to have indulged in 'unfair trade practice'[28] of the Consumer Protection Act, 2019.

Section 87 contains exception to product liability action which stipulates that the product liability seller cannot be held liable for the product liability action, if, at the time of harm, the product was misused, altered or modified.[29] However, the exceptions to the product liability actions, exempts only the product seller from liability and not the product manufacturer.[30] Any person, who manufactures or stores or sells or distributes or imports any 'spurious goods,' which results in either injury or grievous hurt or death of the consumer, shall be punished with imprisonment for a term ranging from one year to life imprisonment under Section 91 of the 2019 Act.[31]

*Section 87. Exceptions to product liability action:*[32]

1) *A product liability action cannot be brought against the product seller if, at the time of harm, the product was misused, altered or modified.*
2) *In any product liability action based on the failure to provide adequate warnings or instructions, the product manufacturer shall not be liable, if –*
    c) *The product was one which was legally meant to be used or dispensed only by or under the supervision of an expert or a class of experts and the product manufacturer had employed reasonable means to give the warnings or instructions for usage of such product to such expert or class of experts; or*
    d) *The complainant, while using such product, was under the influence of alcohol or any prescription drug which had not been prescribed by a medical practitioner.*
3) *A product manufacturer shall not be liable for failure to instruct or warn about a danger which is obvious or commonly known to the user or consumer of such product*

[27] The Consumer Protection Act, 2019. § 2(43).
[28] The Consumer Protection Act, 2019. § 2(47)(iv).
[29] *India Code: Section Details*, https://www.indiacode.nic.in/show-data?actid=AC_CEN_21_44_00007_201935_1596441164903§ionId=50111§ionno=87&orderno=87.
[30] G B Reddy & Baglekar Akash Kumar, *CONSUMER PROTECTION ACT – A COMMENTARY* (2021).
[31] *Supra* 1.
[32] *Supra* 20.

*or which, such user or consumer, ought to have known, taking into account the characteristics of such product.*

## CHALLENGES IN RETAIL PHARMACY

Without a proper regulatory framework the retail pharmacy either physical mode of online mode shall face the following challenges causing public health concerns, like dissemination of drug information to the patients, habit forming drugs or drug abuse practices when the drugs are sold without prescription, circulation of prohibited drugs in the market, traceability and recall problems when drugs are sold without bills, lack of inventory of drugs which are sold beyond expiry date, lack patient counselling mechanism etc. In case of e-pharmacy, following are the risks identified by the stakeholders in the sale of drugs through internet: fake and illegal pharmacy, authenticity of scanned copies of prescription, multiplicity of dispensing the single prescription on various portals, increase in drug addiction among youth due to misuse of prescription, dangers of increase in self-medication, lack of control over controlled medications such as diet pills, libido enhancers, cosmetic fillers etc, sale of substandard and spurious drugs being sold in online pharmacy in promoting unhealthy competition with physical pharmacy outlets, delivery of drugs may reach the hands of minors during home delivery which otherwise is to be handed over the adult in ordinary situation, loss of potency of sensitive drugs while improper handling during transportation, confidentiality of data of patient information, insufficient drug inspectors to monitor online pharmacy, requirement of IT professionals and compliances during interstate transport.

## E-PHARMACY REGULATIONS IN SELECT COUNTRIES

The sale of drugs over the internet has come into practice in many parts of the world, however, some countries have already framed strict compliance rules and regulations and some countries in the process of evolving regulatory laws. It is pertinent to note that developed countries like Italy, Spain, Ireland, Korea, Japan, Thailand and Russia Federal have not recognised e-pharmacies. In United Kingdom MHRA – Medicines and Healthcare products Regulatory Agency has serious concern for public health and to ensure the availability and accessibility to medicines in online mode. In UK registered pharmacy can work in the internet, provided the regulatory requirements for conventional pharmacy are met in total without any compromise. Moreover, Prescription Only Medicines (POM) and Pharmacy Medicines (PM) be legally sold or supplied to the public through

registered pharmacy, by or under the supervision of a pharmacist. The prescriptions must meet the usual requirements set down in medicines legislation. According to the European Union (EU) Directive, anybody in UK selling medicines online to the general public must be registered with the MHRA and to be found on the MHRA's list of registered online sellers. Moreover, the General Pharmaceutical Council (GPhC) operates the Internet Pharmacy Logo by which the public can identify whether the online pharmacy is operated legitimately in UK. [33]

In USA the online pharmacies are permitted but need to be domiciled within the US. The online pharmacies must be registered with the Drug Enforcement Administration (DEA) for sale and supply of 'controlled drugs', further, must comply with Federal Food, Drug and Cosmetic Act, Federal Controlled Substances Act. In addition subject to federal rules the online pharmacy must comply with state-specific rules. Verified Internet Pharmacy Practice Sites (VIPPS) certification programme will define the rules and standards for the online pharmacies. According to VIPPS e-prescription and original paper prescription is the only allowable form for prescription for dispensing medicines. In China, the online pharmacies are mandated to display certification on their websites, online pharmacies operate on a market place model and are allowed to sell OTC (over the counter) drugs, the China FDA (CFDA) database can be accessed by the public to get the domain name or the registration number of the online pharmacy. In Australia, medicines can be dispensed online only when the prescription (scanned) authenticated by the doctor is sent by the doctor to pharmacy directly.

## E-PHARMACY REGULATION IN INDIA

The primary concern of the Central and State Government is to ensure that the drugs are safe, efficacious and conforms to prescribed quality standards to reach the overall objectives of public health. The sale, distribution, offer for sale and other areas are regulated under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. Usually in the existing conventional pharmacy, the drugs are required to be dispensed to the patient or consumer through licenced retail sale premises on the prescription of the registered medical practitioner, for the drugs specified under Schedule H, H1 and X, by the registered Pharmacist. The licence is granted in Form 20 &

[33] Central Drugs Standard Control Organization and The Drugs Consultative Committee, 'Report Of Sub-Committee Constituted By The Drugs Consultative Committee To Examine The Issue Of Regulating The Sale Of Drugs Over Internet Under The Drugs And Cosmetics Rules, 1945' [2016] Central Drugs Standard Control Organization 1.

21of the Drugs and Cosmetics Rule, 1945 for sale of drugs on compliance to certain conditions given for that purpose. Subject to such condition the licence may be granted, renewed, suspended or cancelled by the Drug Authorities. As per the report, there are already around 8,50,000 licensed pharmacy outlets in India.

As far as e-pharmacy is concerned, until relevant regulations are framed for e-pharmacy, the sale of drugs over internet has to meet the requirement under the existing licencing provisions under the Drugs and Cosmetics Act, 1940 and Drug and Cosmetics Rules, 1945. The existing rules are binding on every person indulging in sale, distribution, stock, exhibition or offer for sale of any drugs. In addition to the primary regulatory law of Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 there are other regulatory laws such as the Pharmacy Act, 1948, Indian Medical Act, 2017 and Code of Ethics Regulations, 2002, Narcotic Drug and Psychotropic Substances Act, 1985, the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 and the Information Technology Act, 2000 govern the retail pharma in India.

Draft Rules for Amendment of Drugs and Cosmetics Rule, 1945: The Draft Rule proposes incorporation of new chapter to the Drugs and Cosmetics Rules, 1945 – Chapter VI B – Registration of e-Pharmacy Service Providers to Carryout e-Pharmacy with Section 67I – Definitions such as E-Pharmacy. E-Prescription, E-Pharmacy Service Provider, Section 67 J (A) – Application for grant of registration of e-pharmacy service providers and Section 67 J (B) – Application for grant of registration of chemist and druggist to carryout e-Pharmacy.

Following the recent crackdown of 20 e-pharmacies[34] operating in the shadows and undertaking unlicensed drug and medicine sales, the DCGI first banned the online sale of medicines in December 2015. The latest draft New Drugs, Medical Devices and Cosmetics Bill, 2022, has comprehensive provisions including periodic inspections, complaint redressal mechanisms, monitoring e-pharmacies and others. The trade body representing retail chemists, known as the Confederation of All India Traders (CAIT) has accused online pharmacies of predatory pricing and violating the standing provisions under the DCA and DCR. Recently, DCGI notified that until

[34] Tata1mg, Netmeds, Amazon, Flipkart, Practo, Apollo, PharmEasy and others - Timsy Jaipur, *CDCSO issues show cause notices to over 20 online pharmacies for violation of drug regulations*, CNBCTV18 (Feb. 10, 2023), https://www.cnbctv18.com/healthcare/cdsco-issues-show-cause-notices-to-over-20-online-pharmacies-for-violation-of-drug-regulations-15909721.htm.

proper online pharmacy regulations are in place, such pharmacies operating as intermediaries without proper permits, prompting the CDSCO and state regulators are prohibited from operating. While regulating drugs and medicines is crucial to public health and safety, the efficient and legitimate functioning of e-pharmacies can be ensured with comprehensive norms[35]. It is the lack of unambiguous laws regulating, controlling and monitoring online players that can lead to an adverse effect on the health of the nation. However, there is a major setback on the part of the government officials have expressed reluctance to formalise the online sale of drugs and medicines[36].

## DRUGS CONSULTATIVE COMMITTEE

In 2016 a statutory body called the Drugs Consultative Committee (DCC) was constituted under Section 7 of the Drugs and Cosmetics Act, 1940 by the Directorate General of Health Services – Central Drugs Standard Control Organisation to examine the issue of regulating the sale of drugs over internet under the Drugs and Cosmetic Rule, 1945. The DCC constituted sub-committees to discuss and deliberate online sale of medicine with the present provisions of the Act and Rules, to analyse the online pharmacy, its legal implications, impact on consumer health care, online pharmacy practices in developed countries, best suitable model for India. The DCC placed its report after comprehensive consulting various stakeholders including a) Industry Associations such as Federation of Indian Chambers of Commerce and Industry (FICCI), Indian Pharmaceutical Alliance, Indian Drug Manufacturers Association, Organisation of Pharmaceutical Producers of India, Confederation of Indian Industry; b) Professional Association Perspective – Indian Medical Association, Pharmacy Council of India, Indian Pharmaceutical Association; c) Trade Association Perspective – All India Organisation of Chemist and Druggist Association, Indian Internet Pharmacy Association; d) Regulatory Association Perspective – All India Drug Control Officer's Confederation; e) Consumer Association Perspective – Consumer Online Foundation; f) Other Government Agencies Perspective etc.

[35] Editorial, *Regulate e-Pharmacies, end sale of shady drugs*, The New Indian Express, (Feb. 27, 2023).
[36] Business, Monika Yadav, *Government unwilling to formalise ePharmacies*, The New Indian Express, (Aug. 27, 2023).

## RECOMMENDATIONS OF DCC[37]

Based on the suggestions and comments offered by various stakeholders in the manufacture, sales and distribution of drugs, consumer, medical and pharma associations, regulatory agencies etc and after examining the international practices followed in some select countries, the Committee gave the following recommendations (among others):

a) To leverage the technological advancements in e-marketing, its ease of doing business and reach the online sale of medicines benefits to patients.
b) To adopt cautious approach towards online pharmacy due to its inbound risk to public health.
c) To allow e-pharmacy in limited way after institutionalising strict monitoring and supervisory approach.
d) To adopt Geographical restrictions for effective recall of drugs and better pharmacovigilance.
e) To amend the Drugs and Cosmetics Act and Rules.
f) To create National Portal for handling transactions of online sale of drugs.
g) To consider the status of intermediaries to e-pharmacy service providers.
h) E-pharmacy service providers to effect sale only from the respective State.
i) No unregistered entity shall be permitted to undertake online sale of medicines.
j) Online sale of drugs may be permitted either on e-prescriptions or scanned copy of the prescription, verified by the prescriber through the National portal along with the provisions of IT Act, 2000 and Rules etc.

## CONCLUSION

Substandard or misbranded or spurious or adulterated drugs have paramount health concerns as they can cause havoc on consumer health. On the basis of human health and safety the production, distribution, marketing and export of every drugs is scrutinised under regulatory laws, if need ban the drugs or withdrawn from market supply. Health being a State subject requires coordinated efforts between the Central Drug Standard Control Organisation (CDSCO) and State Drug Regulatory Authorities (SDRAs). Currently there is vast disparity in the practice of inspection of

[37] Id.

pharmacies also e-pharmacies among SDRAs. This may be attributable to the shortage of drug testing laboratories and qualified testing professionals or manpower. The requirements and infrastructure varies among States. This situation becomes a hurdle for ensuring the quality and potency of the drugs and for deciding the product liability of the manufacturer, supplies, seller etc.

The drug inspectors are required to conduct inspection periodically covering every licenced pharmacy outlets or e-pharmacy but in practice the drug inspectors pay random visits or perform poor monitoring, lack of proper updated digital database (repository) of the licenced pharmacies, shortcomings in testing laboratories etc add further impediments to keep a check on the supply, circulation and sale of spurious, misbranded, black marketing, adulterated drugs.[38] Such problems were aggravated during the COVID-19 pandemic as there was huge demand for prescription drugs which encouraged black marketing and stocking of prescription drugs and the like.

Currently, India is striving to achieve unique status in manufacture, sale, distribution and export of pharmaceutical drugs, the regulatory laws needs to be prioritised in granting licence to manufacturers, conduct inspections, collect samples, test the quality of the product, recalling defective products, effective product liability measures, remedial actions, consumer vigilance etc need utmost importance in maintaining public health and drug standards. The role of pharmacist is laudable as they are in close proximity in supply of drugs to the patients or customer both e-pharmacy and pharmacy outlets. The Consumer Protection Act, 2019 too is to be put on serious viewing as far as the effectiveness of the product liability aspects in e-pharmacies in India. From time to time the Government of India constituted various committees, to mention few Drugs Enquiry Committee in 1930, Hathi Committee in 1975, Mashelkar Committee, Lentin Commission in 1986, Parliamentary Committee (59$^{th}$ Report) etc to suggest appropriate drug policy reforms, to review the law and practice of the Drugs and Cosmetics Act, 1940, to establish fairness and accountability in trade and marketing of pharmaceutical drugs, to assess the drug regulators etc. Adding to the above, the recent developments, the DCGI notification and the progress of initiations of the regulatory agencies for adopting stern regulations on e-pharmacies brings hopes in effective legal framework of e-pharmacies.

[38] Nupur Chowdhury and others, 'Administrative Structure and Functions of Drug Regulatory Authorities in India'. (Sept. 19, 2015), https://icrier.org/pdf/PolicyBrief_1_health.pdf.