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Consumers Rights in the Field of Electronic Trade in Medicinal Products: Legal Challenges and Global Harmonization Trends

Vladyslav Teremetskyi[1*], Viacheslav Davydenko[2], Alla Kiryk[3], Iryna Tur[4], Ihor Diorditsa[5] and Andrii Varkhov[6]

[1]Department of International Private Law, Academician F.H. Burchak Scientific Research Institute of Private Law and Entrepreneurship, National Academy of Legal Sciences of Ukraine, 23-a Pavlo Zahrebelnyi st., Kyiv, 01042, Ukraine
[2]Rector, Odessa State University of Internal Affairs, 1 Uspenska st., Odesa, 65014, Ukraine
[3]Department of International and European Law, Leonid Yuzkov Khmelnytskyi University of Management and Law, 8, Maidan Heroes st., Khmelnytskyi, 29000, Ukraine
[4]Law Department of Humanitarian and Law faculty, National Aerospace University "Kharkiv Aviation Institute", 17 Vadym Manko st., Kharkiv, 61070, Ukraine
[5]Department of Private and Public Law, Kyiv National University of Technologies and Design, 2, Nemirovich-Danchenko st., Kyiv, 01011, Ukraine
[6]Department of Criminal Law and Administrative Law Disciplines Demianchuk International University of Economics and Humanities

Author Designation: [1,5]Professor, Leading Research Scientist, [2]Rector, [3,6]Associate Professor, [4]Laboratory Head

*Corresponding author: Vladyslav Teremetskyi (e-mail: vladvokat333@ukr.net).

Abstract The rapid expansion of electronic commerce in medicinal products has brought both new opportunities and significant risks for consumers worldwide. While e-pharmacies enhance accessibility, convenience, and price transparency, they also present challenges such as exposure to counterfeit medicines, misuse of personal data, and legal uncertainty across jurisdictions. This article aims to analyse the legal issues surrounding the protection of consumers' rights in the field of online pharmaceutical trade and to identify the prospects for harmonizing national and international standards. The study employs an interdisciplinary methodology combining legal, comparative, and policy analysis. It draws on international instruments (UN, WHO, OECD, EU regulations), national legal frameworks, and academic literature to assess the current state of consumer protection. Key findings reveal a high level of regulatory fragmentation, particularly in low- and middle-income countries, where legal safeguards and quality control mechanisms are insufficient. The article highlights international best practices, including the .pharmacy domain initiative, EU logo certification, and blockchain-based supply chain traceability. It concludes that effective consumer protection in the e-pharmacy sector requires coordinated action from international organizations, national regulators, businesses, and consumers. Recommendations are proposed to strengthen legal frameworks, improve enforcement, and foster global convergence of standards in the digital pharmaceutical market.

Key Words Consumer protection, e-pharmacies, electronic commerce, medicinal products, international standards, economic activity, control

INTRODUCTION

Over the past two decades, the pharmaceutical market has undergone profound changes under the influence of digital transformation and the global expansion of e-commerce. Since the emergence of the first online pharmacies in the late 1990s, the sector has experienced dynamic growth, spurred by advances in digital technologies, increasing Internet penetration, and the progressive digitalisation of healthcare services. This process was further accelerated by the COVID-19 pandemic, which reshaped consumer behaviour and created new expectations regarding the accessibility and convenience of pharmaceutical products. Consequently, e-pharmacies have become an integral component of healthcare systems in numerous countries.

Currently, online pharmacies operate both as digital extensions of traditional pharmaceutical networks and as independent e-platforms offering a wide range of medicinal products, often supported by electronic prescriptions and automated logistics. The digital format enables broader geographical coverage, reaching remote areas and populations lacking physical pharmacy infrastructure.

However, alongside these advantages-such as accessibility, speed, and user-friendliness-there are increasing concerns about consumer vulnerability. Key issues include exposure to counterfeit or substandard medicines, breaches of data privacy, deceptive commercial practices, and the absence of clear legal remedies in cross-border transactions. Of particular

concern is the fragmented nature of regulatory frameworks across jurisdictions. According to the International Pharmaceutical Federation, only 49% of countries have adopted legislation specifically regulating e-pharmacy operations, with vast regulatory gaps persisting in regions such as Africa and Southeast Asia [1].

A review of academic literature reveals that although scholarly attention to e-pharmacies is growing, most studies focus on the digitalisation of pharmaceutical services [2], consumer purchasing behaviour [3], indicators of service quality [4], and risks related to product safety and authenticity [5]. Regulatory uncertainty also remains a dominant theme [6,7]. In parallel, some researchers have explored the legal dimensions of protecting healthcare consumers, including issues related to legal capacity, the nature of medical services, and violations of patients' rights [8-10]. Still, there is a noticeable research gap regarding a comprehensive legal assessment of consumer protection in the e-pharmacy context. Particularly relevant is the need for comparative legal analysis and the harmonisation of national and international norms. Bessell *et al.* [11] have underscored the complexity of ensuring both quality and legal security in the global e-pharmacy landscape, emphasising the significant challenge of safeguarding consumer rights in a fragmented international environment.

Therefore, the purpose of this article is to explore the legal challenges affecting the protection of consumers' rights in the field of electronic trade in medicinal products, to identify disparities between national regulatory systems and international approaches, and to develop proposals for harmonizing legal standards in order to ensure consumer safety and legal certainty in the digital pharmaceutical market. The hypothesis of this study is that the current fragmentation of legal regulation, the lack of effective and unified instruments, and limited international oversight in the field of electronic trade in medicinal products create substantial risks for consumers, particularly in relation to product safety, data privacy, and enforcement of rights. The main conclusion drawn from the analysis is that only through coordinated efforts involving international organizations, national regulatory bodies, the pharmaceutical industry, and consumers themselves can a secure, transparent, and legally coherent model of e-pharmacy be established on a global scale.

METHODS

This study employs an interdisciplinary methodology aimed at investigating the legal challenges associated with the protection of consumers' rights in the field of electronic trade in medicinal products. The research is grounded in the analysis of normative legal acts, policy documents, recommendations of international organisations (including the UN, WHO, OECD, and UNCTAD), judicial decisions, analytical reports, and academic publications in the areas of e-commerce, pharmaceutical law, consumer rights, and digital regulation.

A combination of general scientific and specialised legal methods was applied to ensure the comprehensiveness and validity of the analysis. The method of systematic analysis and synthesis facilitated the structuring of information and identification of key patterns in the legal regulation of e-pharmacies. Comparative legal analysis was used to examine regulatory models in different jurisdictions, detect gaps and inconsistencies, and assess best practices. The abstraction method allowed the formulation of theoretical generalisations, while the modeling method was instrumental in constructing potential legal solutions and outlining directions for harmonization.

In addition, the generalisation method was applied to develop evidence-based proposals aimed at aligning national legal frameworks with international standards to enhance consumer protection in cross-border digital pharmaceutical markets.

This methodological framework enabled a nuanced assessment of both legal and socio-economic dimensions of e-pharmacies, supporting well-founded conclusions on the need for coordinated regulatory responses to current global challenges in the pharmaceutical e-commerce domain.

RESULTS AND DISCUSSION

Contemporary Challenges to Consumer Rights in the Digital Pharmaceutical Environment

The rapid proliferation of digital technologies has significantly altered consumer behaviour, contributing to the global shift towards electronic commerce. With widespread access to mobile devices and high-speed Internet, individuals now have direct entry into online marketplaces, including e-pharmacies, which are increasingly integrated into both national and global healthcare infrastructures. Today's consumers are not merely passive recipients of goods and services - they play an active role in shaping economic trends, accounting for up to 60% of GDP in OECD countries through daily transactions valued in the hundreds of billions of dollars [12].

Electronic pharmacies have emerged as a convenient alternative to traditional retail channels for medicinal products. Their benefits include the ability to quickly verify medicine availability - particularly relevant for rare or hard-to-find drugs -greater accessibility for individuals in remote locations or with limited mobility, time and cost savings, an expanded assortment of pharmaceuticals and related goods, and added-value services such as online consultations, price comparisons, drug interaction alerts, and user-generated product reviews [6].

However, alongside these advantages, the digitalisation of pharmaceutical trade has raised serious concerns regarding consumer safety and legal protection. Among the most pressing issues are the availability of falsified or low-quality medicines, lack of transparency in business practices, insufficient privacy safeguards, and the absence of effective remedies in the event of rights violations. These concerns have prompted increased international attention to the legal and ethical regulation of e-pharmacies. The United Nations General Assembly, through Resolution 70/186, urged

member states to develop and implement policy frameworks that guarantee a level of consumer protection equal to or greater than that in traditional trade. Key principles outlined include universal access to essential goods, special protection for vulnerable populations, product quality and safety assurance, fair pricing, informed decision-making, and access to redress and dispute resolution mechanisms [13].

Similarly, the OECD has stressed the importance of transparency in advertising, the accuracy and completeness of product information, data privacy, secure payment systems, and efficient mechanisms for resolving cross-border disputes [12].

Despite these international recommendations, the development of consumer protection legislation in the context of e-commerce remains inconsistent across jurisdictions. According to data from UNCTAD, out of 142 countries surveyed, only 115 have adopted legal frameworks regulating e-commerce. In Europe, such frameworks exist in 78% of states, compared to 52% in Africa and 71% in the Americas. Furthermore, although 158 countries recognise the legal equivalence of electronic and paper-based transactions, regulatory enforcement remains weak in many developing economies [14].

This global regulatory imbalance is attributable to several factors, including limited economic resources, underdeveloped digital infrastructure, lack of institutional capacity, and low levels of public digital literacy. Consequently, in many regions, consumers who purchase medicines online remain unprotected from significant health and legal risks. These disparities underline the urgent need to harmonise international standards and implement robust legal mechanisms capable of securing consumer rights in the sphere of electronic trade in medicinal products.

Legal Regulation of Consumer Rights in the E-Commerce of Medicinal Products

The legal regulation of electronic trade in medicinal products constitutes a crucial domain of digital governance and consumer protection. In light of the increasing reliance on online pharmacies for the purchase of both over-the-counter and prescription medications, legal mechanisms must ensure transparency, safety, and enforceability. Regulatory oversight must encompass the full transactional cycle: from the dissemination of information, through purchase and delivery, to post-sale redress. In many jurisdictions, this process is underpinned by general consumer protection laws, pharmaceutical regulations, e-commerce statutes, and privacy legislation.

The pre-contractual phase primarily concerns the availability and accuracy of information. Consumers must be presented with essential details such as the name, legal status, physical address, licensing data, and contact details of the seller. Importantly, information about the product - including its active ingredients, manufacturer, shelf life, potential side effects, and legal status - must be provided in clear, accessible language. In jurisdictions where electronic pharmacies are permitted, mandatory registration with health authorities and linkage to state-run verification platforms are legal conditions for operation. The absence of such transparency has been widely recognised as a key factor facilitating fraud and the proliferation of illegitimate online platforms [15,16].

The transaction phase involves digital contracting and the processing of sensitive data, such as medical history and financial information. Legal frameworks must ensure fairness in contractual terms and security in data handling. National laws typically require e-pharmacies to use secure servers (HTTPS), offer trustworthy payment systems, and disclose user data policies. The GDPR and similar regulations in non-EU countries set standards for obtaining informed consent, limiting data use, and ensuring users' rights to access, rectify, and erase data. Furthermore, digital contracts must comply with good faith principles and prohibit unfair clauses or non-negotiable terms that disproportionately favour the seller.

The post-transaction phase presents one of the most vulnerable points for consumers. Problems such as non-delivery, delayed shipment, incorrect medication, or receipt of counterfeit goods necessitate robust legal remedies. Refunds, returns, and complaint-handling procedures must be clearly outlined and accessible. For cross-border transactions, the challenges increase significantly: language barriers, absence of extraterritorial enforcement, and lack of ADR mechanisms often leave consumers without effective recourse. The harmonisation of complaint resolution platforms and development of international consumer protection protocols are needed to close this gap [17].

Beyond general e-commerce concerns, the specific nature of pharmaceuticals introduces heightened regulatory obligations. Medication safety depends not only on accurate composition but also on storage, transportation, and timely delivery. Heat-sensitive, light-sensitive, and humidity-sensitive medicines require cold-chain logistics and tracking systems. National pharmaceutical laws frequently require Good Distribution Practice (GDP) compliance, but enforcement is often inconsistent. Regulatory fragmentation across countries hinders mutual recognition of standards and undermines global consumer trust.

Counterfeit and Substandard Medicines: Scope, Impact, and Regulatory Gaps

The availability of counterfeit and substandard medicines via electronic channels has escalated into a global public health and consumer safety crisis. Counterfeit drugs may include substances that are toxic, inert, contaminated, or improperly dosed. These substances pose not only health risks but also legal risks, as their distribution often involves fraud, breach of regulatory law, and violation of intellectual property rights.

According to the WHO, an estimated 1 in 10 medical products in low- and middle-income countries is either substandard or falsified [18]. The consequences are devastating: compromised treatment, antimicrobial resistance, poisoning, or death. The financial burden is equally alarming, with developing countries losing over USD

30.5 billion annually due to substandard medicines [18], while the global black market in counterfeit drugs reaches USD 200 billion [19]. These statistics highlight the failure of both national systems and international cooperation to provide adequate safeguards in digital pharmaceutical trade.

A high-profile study by Watkins *et al.* [20] analysed the chemical composition of three medicines purchased online from unverified vendors. One of the drugs lacked any detectable active ingredient, while the others failed to meet minimum thresholds for therapeutic efficacy as defined by the FDA. In light of such cases, the role of pre-market authorisation, batch testing, and post-market surveillance becomes evident. E-pharmacies must be integrated into broader pharmacovigilance networks and reporting platforms.

The root of the problem often lies in asymmetrical regulation. While countries like Germany, the United States, and Japan operate with stringent requirements for licensing, monitoring, and reporting, other jurisdictions lack coherent legal frameworks or adequate administrative capacity [21]. Weak border control, corruption, and lack of technical resources create an enabling environment for pharmaceutical crimes. Even well-regulated markets are vulnerable due to the transnational nature of cyber-enabled trade.

Efforts to combat counterfeiting include the creation of trusted labels and domain designations. The .pharmacy domain, managed by the NABP in the U.S., is awarded only to verified pharmacies meeting specific operational and ethical standards [22]. Pharmacies must submit detailed documentation, undergo identity verification, and demonstrate compliance with prescription verification requirements. Similarly, in the European Union, Regulation No. 699/2014 mandates that e-pharmacies display a common EU logo hyperlinked to their national register, integrated with the EMA's centralised system [23].

Despite these initiatives, enforcement remains patchy. As Fittler *et al.* [24] demonstrated, 88.2% of e-pharmacy websites studied offered prescription drugs, but only 6.6% requested a prescription. Furthermore, 38.2% did not request any health-related information from users. These findings illustrate that regulation in itself is insufficient unless accompanied by active monitoring and prosecution.

Illegal pharmacies are often aggressive in their marketing. They rely on keyword optimisation, pay-per-click advertising, social media manipulation, and even affiliate marketing schemes. Some imitate the design of reputable platforms, use fake customer reviews, or falsely claim compliance with WHO or FDA standards [25]. Vulnerable consumers-elderly patients, those with chronic conditions, or residents of rural areas-are particularly susceptible to such deception. Language barriers, lack of health literacy, and cost pressures amplify this risk [26].

In some instances, platforms offer highly addictive or controlled substances without prescriptions. Studies in Denmark, Germany, Spain, and Sweden have documented cases where consumers obtained opioids, stimulants, and tranquilizers online without proper documentation [27]. Monteith and Glenn [28] showed that psychiatric medications were easily accessible via platforms that claimed to operate legally but failed to conduct even basic medical vetting.

Even when patients use what appear to be legal channels, counterfeit drugs can still infiltrate the system. In the UK, counterfeit medicines with professional packaging reached hospital pharmacies, illustrating the sophistication of criminal networks [29]. This underscores the importance of full-spectrum verification mechanisms - from production to point-of-sale.

Illicit E-Pharmacy Platforms: Marketing Strategies, Structural Weaknesses, and Enforcement Limitations

Despite the presence of legal instruments and international recommendations, illicit e-pharmacy platforms continue to flourish, exploiting gaps in regulation and enforcement. These websites often mimic the visual appearance and layout of legitimate pharmacies, use domain names similar to well-known brands, and operate with servers located in countries with limited jurisdictional cooperation. According to the analysis by Fittler *et al.* [24], a significant proportion of studied e-pharmacy websites provided prescription drugs without requiring a prescription, reflecting a widespread disregard for legal and medical norms.

Illicit platforms often engage in aggressive digital marketing strategies. These include Search Engine Optimisation (SEO) manipulation, fake reviews, paid advertisements, and social media campaigns targeting vulnerable consumers. In many cases, search engines do not adequately filter or label unverified sellers, thus exposing users to potentially dangerous options. Furthermore, affiliate networks and pay-per-click advertising models incentivise traffic redirection to these unlawful websites [30].

In addition to selling unapproved or mislabelled pharmaceuticals, these platforms frequently omit essential warnings about contraindications, interactions, or side effects. They may offer bundled discounts on medications, free shipping, or loyalty rewards - marketing techniques that mask the medical risk and legal liability involved. Some even provide optional 'online consultations' that are in fact automated forms generating scripted approvals without medical analysis. As shown by Meng *et al.* [31], such platforms particularly target patients seeking psychiatric medications, often bypassing diagnostic and prescription procedures entirely.

The exploitation of consumer vulnerability is another core issue. Consumers with low digital literacy, cognitive impairments, language barriers, or limited healthcare access are disproportionately affected. Demographic studies have shown that elderly individuals and those with chronic diseases are most likely to rely on the internet for pharmaceutical purchases, especially in rural or underserved areas [32]. The lack of clear, culturally adapted information about how to identify legitimate pharmacies further contributes to this issue.

The use of mirror sites-exact replicas of banned platforms hosted under new domain names-is a common tactic to evade regulatory takedown efforts. These mirrors may be generated automatically and hosted via anonymous cloud servers, complicating traceability. The use of cryptocurrency, VPN masking, and offshore company registration adds further layers of obfuscation. As a result, even when one illegal pharmacy is shut down, dozens may remain operational or resurface within days.

Jurisdictional Fragmentation and the Imperative for Global Regulatory Convergence

A key structural issue in regulating e-pharmacy activity is the fragmentation of national legal systems and the absence of a coherent international enforcement mechanism. While domestic laws may impose stringent requirements, their effect is often limited by jurisdictional reach. This creates a legal vacuum exploited by rogue operators who sell globally from jurisdictions with weak enforcement.

For example, a pharmacy registered in a low-regulation country may legally advertise and sell medicines online, including internationally, while escaping liability in the consumer's home country. In such cases, international cooperation becomes essential. However, Mutual Legal Assistance Treaties (MLATs), joint investigations, or data-sharing agreements are either lacking or poorly implemented. Furthermore, the absence of common definitions for terms like "legitimate pharmacy," "controlled medicine," or "prescription-only" complicates coordination [33].

International organisations such as the World Health Organization (WHO), World Trade Organization (WTO), and the United Nations Conference on Trade and Development (UNCTAD) have called for harmonised principles of regulation. Proposed frameworks include global certification databases, interoperable pharmacy registries, and international standards for logistics, packaging, and e-labelling. A notable initiative is the WHO's Member State Mechanism on Substandard and Falsified Medical Products, which fosters information exchange and joint capacity building.

Private sector actors also play a vital role in this ecosystem. Pharmaceutical manufacturers must commit to product serialization, secure packaging, and proactive supply chain monitoring. Payment processors, hosting providers, and domain registrars must be incentivised - or legally required - to deny service to unverified pharmacies. E-commerce platforms such as Amazon or Alibaba have introduced pharmaceutical category restrictions, but enforcement remains inconsistent.

Technological solutions, particularly blockchain, are increasingly promoted as tools to enhance supply chain integrity. The MediLedger project exemplifies how a decentralised ledger can provide real-time verification of transactions among authorised parties in the pharmaceutical supply chain [34]. When used in combination with AI-powered fraud detection, geolocation-based blacklists, and smart labelling systems, these technologies offer scalable and adaptable safeguards.

Third-party verification platforms such as LegitScript [35] are essential intermediaries. They evaluate pharmacy compliance with national and international norms, regularly update public blacklists, and work with payment companies to block unlawful transactions. Their reports are also used by regulatory agencies and journalists to expose systemic weaknesses.

International alliances - such as those among BEUC (Belgium), Consumers Japan, CUTS International (Geneva), ODECU (Chile), and the ICC-have advocated for transnational consumer rights enforcement and ethical marketing standards [36]. Such alliances can be formalised into legally recognised coalitions under the auspices of WTO or WHO, giving them authority to set benchmarks and monitor implementation.

Consumer Education, Awareness and Empowerment as a Protective Strategy

While institutional frameworks and technological innovations are essential, no protective mechanism is complete without a well-informed and vigilant consumer base. Consumer empowerment must become a strategic pillar of pharmaceutical e-commerce policy. Awareness-raising campaigns, public health education, and digital literacy training can significantly reduce the incidence of fraudulent or risky purchases.

The U.S. FDA's BeSafeRx initiative is a strong example of such engagement. It provides consumers with tools to identify legal pharmacies, interpret product labelling, and report suspicious activity [37]. The campaign employs websites, social media content, video explainers, and partnerships with medical institutions to extend its reach. Other countries have adopted similar programmes, often led by their health ministries or consumer protection authorities.

Education should address not only the signs of illegal platforms, but also the importance of legitimate prescriptions, correct dosages, and verified ingredients. Empowered consumers are more likely to consult healthcare providers before ordering medication, scrutinise unfamiliar websites, and report violations.

In the EU, consumer education is part of broader digital single market initiatives. Educational portals provide guidance on safe online shopping, while mobile apps help identify EU-certified pharmacy platforms. Some countries have integrated e-pharmacy awareness into high school health education curricula and community-based training.

Involving civil society and NGOs in awareness campaigns increases trust and outreach. Health consumer organisations can provide impartial advice, deliver materials in local languages, and conduct peer-to-peer workshops in vulnerable communities. In regions with high digital inequality, such outreach may be more effective than official channels.

The promotion of patient-centric tools - such as QR codes linking to verification databases, mobile alert systems, and dosage reminder applications-further enhances

protection. Legal requirements for online pharmacies to offer such features can create a universal baseline of transparency and consumer engagement.

Ultimately, legal, technical, and educational components must work in synergy. Legal safeguards establish the framework, technical innovations ensure implementation and oversight, and informed consumers complete the protective ecosystem. Without the latter, even the best-designed regulations may fall short in practical impact.

CONCLUSIONS

The analysis conducted in this study confirms that the rapid development of electronic commerce in medicinal products presents both opportunities and significant risks for consumers. While online pharmacies increase access to essential medicines, particularly for vulnerable and remote populations, they also expose users to counterfeit products, privacy violations, and inadequate legal protection in cross-border transactions.

The research highlights that the legal regulation of e-pharmacy services remains highly fragmented across jurisdictions. Although several countries have adopted national standards to govern the online sale of medicines, enforcement practices differ significantly, and international harmonisation is still limited. Initiatives such as the .pharmacy domain certification, the EU logo system, and national registries of verified e-pharmacies represent important steps forward, but they are insufficient without broader coordination and binding commitments among states.

The study identifies three critical dimensions of effective consumer protection in the field of electronic pharmaceutical trade. First, regulatory frameworks must be comprehensive, integrating pharmaceutical law, consumer protection legislation, digital commerce rules, and cybersecurity standards. Second, enforcement mechanisms must be strengthened both nationally and internationally, through cooperation, mutual legal assistance, and the application of emerging technologies such as blockchain for supply chain transparency. Third, consumers must be empowered through targeted education campaigns, access to verification tools, and the promotion of digital literacy.

Only a multi-stakeholder approach - uniting governments, international organisations, the private sector, civil society, and consumers themselves - can ensure the development of a safe, transparent, and equitable global e-pharmacy ecosystem. The research concludes that further convergence of national laws with international principles, coupled with technological innovation and active consumer engagement, is essential for safeguarding public health and upholding the rights of individuals in the digital pharmaceutical market.

Future research should focus on developing models for transnational regulatory cooperation, assessing the effectiveness of AI-based monitoring tools, and exploring the role of health data ethics in the context of pharmaceutical e-commerce.

Conflicts of Interest

The authors declare no conflict of interests. All authors read and approved final version of the paper.

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