

REGULATING ONLINE PHARMACIES

and Medicinal Product E-Commerce

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The internet has led to an increase in e-commerce of prescription and over-the-counter (OTC) medicinal products; one in four adults has purchased medicines online [1, 2]. This expansion of e-commerce in pharmaceuticals has greatly improved many companies' bottom lines. For example, in 2017, the Chinese company Ali Health reported a 739% rise in its revenue driven by e-commerce of OTC medicinal products alone [3]. For consumers, online pharmacies offer many advantages, including lower costs, convenience, privacy, and a wider range of choices [4]. For businesses, using online platforms and removing the need for physical storefronts translates into the multiplication of stock-keeping units and increased price competitiveness.

Although e-commerce of medicinal products has many benefits for patients and the pharmaceutical industry, it remains a concern for regulatory authorities (RAs) worldwide. RAs must safeguard the public from potential harm posed by illegitimate online pharmacies. Existing laws may need to be amended, and enforcement approaches changed, to address the transnational nature of e-commerce of medicines.

Note: In this article, "e-commerce" refers to the commercial transaction of buying and selling goods and services over the internet [5]. "Medicinal products" refers to prescription and OTC medicines, and excludes nutritional supplements. "Controlled substances" refers to substances likely to cause dependence when abused, such as amphetamines, morphine, and codeine [6]. "Counterfeit medicines" refers to medicinal products that are substandard or falsified, with fraudulent misrepresentation of their identity, content, or source [7].

SAFETY CONCERNS

According to a 2016 report published by the Center for Safe Internet Pharmacies, 96% of online pharmacies worldwide do not comply with the relevant laws of countries within which they operate [8]. In addition, some online pharmacies have sold counterfeit medicines, defrauded consumers, and stolen customer credentials and credit card information [9, 10].

Despite rigorous educational efforts, many consumers remain unaware of the safety risks posed by counterfeit medicines [10, 11]. Prescription-only medicines (POMs) can be easily purchased from online pharmacies and popular consumer-to-consumer e-commerce platforms, such as Lazada and Carousell, due to the lack of regulations from RAs [12, 13]. The availability of POMs from online pharmacies, whether legitimate or not, is a serious public health concern, especially as more consumers use the internet to self-diagnose and self-treat [14]. The unsupervised use and potential misuse of POMs can lead to severe adverse effects and even death [15].

CURRENT EFFORTS TO PROTECT CONSUMER SAFETY

At present, RAs rely on a collection of legal regulations, international law enforcement operations, and accreditation programs to address safety concerns related to the e-commerce of medicinal products.

US Legal Restrictions on Online Sales

Laws regulating the online sales of medicinal products vary from country to country. In the US, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 strictly restricts consumers' online access to controlled substances [16]. Online pharmacies dealing with controlled substances must register with the US Drug Enforcement Administration (DEA). Consumers must also complete an in-person medical examination by a qualified practitioner to obtain a valid prescription before they can purchase controlled substances. Hefty penalties serve as a deterrent to individuals who intend to engage in unauthorized sales of controlled substances [17]. Laws regulating online sales of medicinal products in other countries are reviewed later in this article, in the Regulatory and Enforcement Challenges section.

Laws Against Counterfeit Medicines

The Drug Supply Chain Security Act and the Falsified Medicines Directive (FMD) are legislative tools used by the US and the European Union, respectively, to address the dangers of counterfeit medicines. By creating an interoperable electronic track-and-trace system, RAs aim to prevent counterfeit medicines from entering the legitimate supply chain [18, 19]. To ensure that the supply chain is secure, key supply chain stakeholders such as manufacturers, repackagers, distributors, and pharmacies must ensure the authenticity of products at the point of receipt before handing them over to the next party in line [18, 19].

Under FMD, EU-based online pharmacies must obtain a common logo from the national RA to display on their website [20]. Clicking the logo directs the consumer to the pharmacy's entry on the RA's online list of authorized/registered pharmacies, thus verifying that the pharmacy site is legitimate.

International Law

The MEDICRIME Convention, an initiative of the Council of Europe, is the first international treaty to criminalize online sales of counterfeit medicinal products [21]. Individuals engaged in such sales will be prosecuted regardless of the country where the act was committed. For greater effectiveness, more RAs worldwide should ratify the MEDICRIME Convention and enact domestic laws to criminalize online sales of counterfeit medicinal products.

Launched in 2008, Operation Pangea is the leading international collaborative enforcement effort to eradicate illegal online sales of medicinal products. For example, in 2017, law enforcement

agencies such as customs, police forces, and RAs successfully seized US\$25 million worth of illicit and counterfeit medicines [22], illustrating the effectiveness of collaborative efforts among different agencies when dealing with transnational crimes.

Nonetheless, illegal online sales of medicines are still prevalent [22]. RAs may need to reevaluate Operation Pangea, expand its scope, and develop new approaches to address illegitimate online pharmacies, involving major pharmaceutical companies in their efforts where necessary.

Accreditation Systems

Accreditation systems can help improve information asymmetry and offer safety assurance to consumers [23]. For example, these systems provide tools such as accreditation seals or website checkers that verify the legitimacy of online pharmacies. However, many consumers are unaware of the existence and purpose of accreditation systems [24], and some illegitimate online pharmacies have used fake accreditation seals on their websites to deceive unsuspecting consumers [25]. Table 1 reviews selected accreditation organizations for online pharmacies [20, 26–31], and Figure 1 displays selected accreditation seals.

The lack of standardized criteria and other lapses in compliance checks have led to inadvertent accreditation of illegitimate online pharmacies, thereby threatening patient safety [26]. Hence, RAs need to apply standardized criteria for accreditation systems. They also must educate consumers on safer practices for purchasing medicines online, such as how to differentiate between authentic and inauthentic accreditation seals.

Table 1: Accreditation organizations for online pharmacies.

Accreditation Organization	Countries of Operation	Comments
National Association of Boards of Pharmacy (NABP)	US and Canada	<ul style="list-style-type: none"> Operates an FDA-endorsed voluntary accreditation program, i.e., Verified Internet Pharmacy Practice Sites (VIPPS) [27] (Figure 1a). To earn VIPPS accreditation, online pharmacies must comply with US laws, be physically located in the US, and meet listed criteria to ensure quality standards. Launched the “.pharmacy” domain initiative in 2014 to provide consumers worldwide with a way to identify safe, legal, and ethical online pharmacies [27, 28].
General Pharmaceutical Council (GPhC)	Great Britain	<ul style="list-style-type: none"> Operates a voluntary accreditation scheme for online pharmacies to help assure Great Britain consumers when purchasing medicines online [29] (Figure 1b). Issues the common EU logo (Figure 1c) to legitimate online pharmacies operating in Great Britain.
RAs of EU member states	EU member states	<ul style="list-style-type: none"> Under FMD, EU-based online pharmacies must display the common EU logo (Figure 1c) on their websites [20]. Online pharmacies must register with their respective national RA and comply with relevant laws to obtain the common EU logo. By clicking the national flag under the logo, consumers are directed to the RA website to verify the company's identity.
LegitScript	International	<ul style="list-style-type: none"> Third-party certification service helps consumers verify the legitimacy of online pharmacies (Figures 1d and 1e). Certification is recognized by many RAs worldwide, including those of Japan and Italy [30].
PharmacyChecker	International	<ul style="list-style-type: none"> Offers PharmacyChecker Verification Program to verify the legitimacy of online pharmacies. Provides miscellaneous services like price comparison of medicines among different online pharmacies [31].

Figure 1: Accreditation organizations' systems to show online pharmacy legitimacy: (a) VIPPS accreditation seal from NABP, (b) GPhC voluntary online pharmacy logo, (c) EU common logo for UK online pharmacies, (d) screenshot from LegitScript website indicating that online pharmacy is legitimate, and (e) screenshot from LegitScript website indicating that online pharmacy is illegitimate.



The “.pharmacy” Domain

The “.pharmacy” domain scheme complements national accreditation systems to verify the legitimacy of online pharmacies. It was launched by NABP in 2014 to provide consumers worldwide with a way to identify safe, legitimate, and ethical online pharmacies [27, 28]. As the owner of the “.pharmacy” domain, NABP determines which pharmacies to host on the domain and requires that they demonstrate legitimacy. RAs may audit NABP periodically to ensure its reliability and fairness in implementing this scheme.

REGULATORY AND ENFORCEMENT CHALLENGES

To ensure the safety of medicinal product e-commerce, RAs need relevant legislation as well as adequate resources to find and prosecute criminals. However, in many countries, laws are insufficient to regulate the sales of medicinal products. Moreover, jurisdictional and resource limitations often allow criminals to escape prosecution.

Lack of Strong National Laws Worldwide

Unfortunately, 66% of countries worldwide do not have laws that explicitly regulate or prohibit online sales of medicinal products [32]. POMs and OTC medicinal products can therefore be sold on e-commerce platforms by anyone. As a result, RAs in these countries are only able to employ the “buyers beware” approach and hope that consumers will remain vigilant when buying medicinal products online.

Without legislation, RAs cannot stipulate legal responsibilities for online pharmacies or mandate that they take on quality assurance responsibilities or undergo periodic inspections. In contrast, relevant legislation empowers RAs to implement well-defined frameworks to safeguard public health (Table 2) [28–30, 33–44]. RAs that allow POM online sales can use an official accreditation system and online registries to direct consumers to legitimate sites [29], whereas RAs that prohibit POM online sales make it clear that no one is allowed to sell them via e-commerce [33]. Additional restrictions may be imposed. For example, although China allows online sale of OTC medicines, it prohibits their sales on third-party e-commerce platforms, including its very own Tmall.com [44].

Jurisdictional Limitations and the Transnational Nature of Online Pharmacies

When individuals involved in illegitimate online pharmacies are based outside of an RA’s jurisdiction, prosecution can be a challenge [45, 46]. Although most countries criminalize such acts on the basis of counterfeiting and deception with intent to harm, existing legal frameworks are fundamentally bound by territorial boundaries [47].

To extend jurisdiction beyond their borders or request extradition to prosecute a suspect, RAs need a harmonized set of international agreements, such as treaties or conventions [48]. Even then,

Table 2: Approaches of RAs worldwide to control medicinal product online sales.

Country	Legislation Allows Online Sale of Medicines?	Comments
US	Yes: POMs and OTC medicines	State-licensed online pharmacies can sell medicinal products online [30].
Canada	Yes: POMs and OTC medicines	Licensed brick-and-mortar pharmacies can sell medicinal products online [28].
Germany	Yes: POMs and OTC medicines	Licensed brick-and-mortar pharmacies must register with the relevant RA, obtain a mail order permit, and display the EU common logo to sell medicinal products online [34].
Great Britain	Yes: POMs and OTC medicines	Online pharmacies must register with GPhC and have a physical location in Great Britain to sell POMs [29].
The Netherlands	Yes: POMs and OTC medicines	Online pharmacies must register with the relevant RA and display the common EU logo issued by the RA to sell medicinal products online [35].
Australia	Yes: POMs and OTC medicines	Brick-and-mortar pharmacies operating in Australia can sell medicinal products online as long as they adhere to all applicable laws and practice standards [36].
China	Yes: OTC medicines only	A bill to allow the sale of POM via online pharmacies has been delayed due to safety considerations [37]. The sale of OTC medicinal products on third-party e-commerce platforms is prohibited due to safety considerations [44].
Japan	Yes: specific OTC medicines only	The online sale of specific OTC medicines such as fexofenadine and loratadine is prohibited [38]. Other OTC medicinal products can be sold online.
South Korea	No: online sale of POMs and OTC medicines is prohibited	Medicinal products can only be sold at physical stores registered with the RA [33].
Russia	Yes: OTC medicines only	Online sale of any medicinal products was prohibited in Russia [39]. However, since December 2017, a draft law allows online sale of OTC medicinal products [40].
India	Law is unclear	Although the RA bans the online sale of medicinal products, the prohibition is not legislated [41].
Singapore	Yes: specific OTC medicines only	The RA employs a “buyers beware” approach to warn consumers of the risk involved in purchasing medicinal products online [42].
Malaysia	Yes: OTC medicines only	The RA employs a “buyers beware” approach to warn consumers of the risk involved in purchasing medicinal products online [43].
Indonesia	Law is unclear	Legal status of online pharmacies is unclear [30].

transnational jurisdictional claims are often met with controversies, and extradition may be difficult. Culprits may escape to countries with weak enforcement systems to avoid prosecution.

Limited Enforcement Resources

Customs agencies generally lack sufficient resources to inspect all incoming parcels. As a result, packages containing counterfeit medicines from illegitimate sources based in other countries can reach consumers, exposing them to potential harm. It is also challenging for law enforcement agencies to track down individuals involved in illegitimate online pharmacies on their own. Hence, RAs need to reevaluate their current strategies and develop international collaborative initiatives to increase the efficiency of resources spent.

Inadequacy of Cooperation by Private Organizations

Under existing laws, RAs often must rely on private companies such as delivery couriers, financial service providers, and internet companies to help enforce e-commerce regulations, and the agencies have limited options if those companies do not cooperate. For example, in 2012, delivery courier FedEx withdrew from the collaborative enforcement efforts to protest the US DEA's decision to investigate its role in facilitating activities of illegitimate online

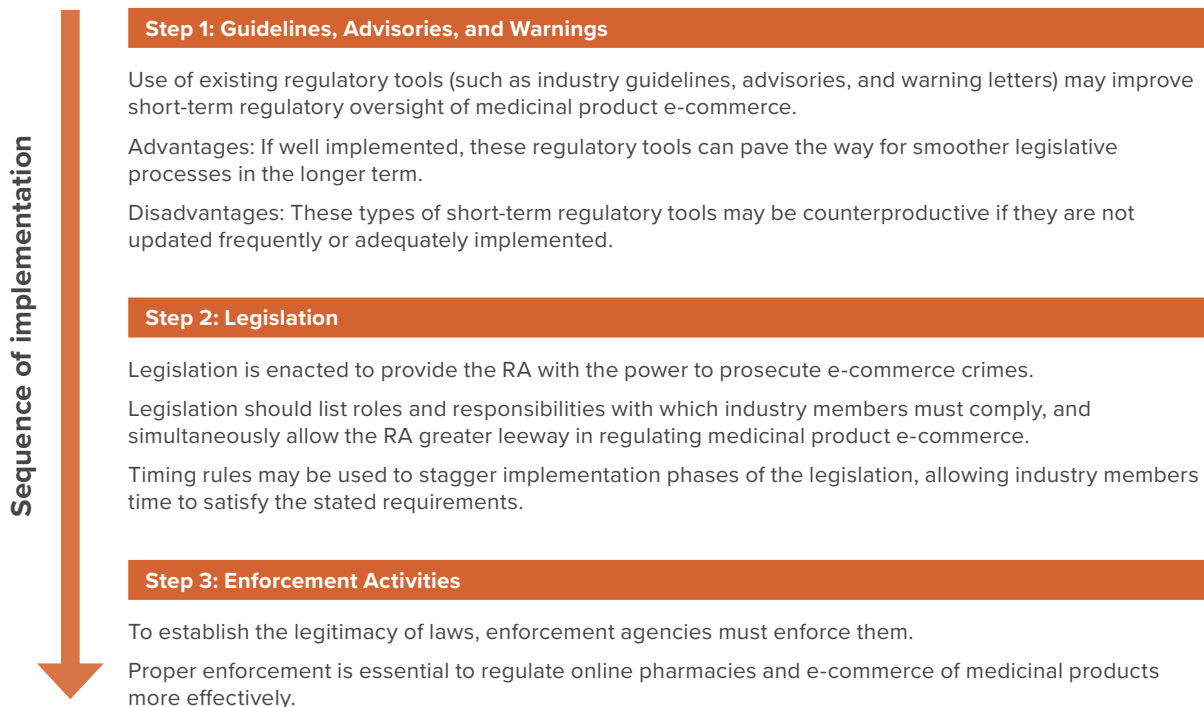
pharmacies. In 2016, the federal charges against FedEx were dropped, and FedEx publicly criticized the US government's decision to file charges against the company [49]. RAs must have effective legislation to mandate the involvement of private companies in eradicating illegal e-commerce, with due consideration for hold-harmless provisions.

A STRATEGIC AND HOLISTIC APPROACH TO REGULATE MEDICINAL PRODUCT E-COMMERCE

A strategic and holistic approach may help RAs more effectively regulate online pharmacies and e-commerce of medicinal products. This proposed strategic approach involves a stepwise implementation of a framework that comprises (a) guidelines, advisories, and warnings; (b) legislation; and (c) enforcement activities (Figure 2). Stepwise implementation grants companies buffer time to modify their in-house policies to align with directions set by the RA with oversight power. The success of the approach lies in the collaboration of the authorities (domestic and international) with various organizations (accreditation organizations, Interpol, and private companies).

In countries that currently lack laws to effectively govern e-commerce of medicinal products, the domestic RA should initiate a national licensure system for all online pharmacies operating

Figure 2: Stepwise implementation framework to regulate medicinal product e-commerce.



under their jurisdiction to allow for regulatory oversight. A mandatory inspection or accreditation framework may be included in the licensing requirement to ensure that the online pharmacies meet internationally recognized quality system standards.

Pharmaceutical companies may assist RAs to expedite the inspection process by reconciliation with their respective supply chain partners to confirm that medicinal products sold by the individual online pharmacies originate from a legitimate source. Upon satisfactory inspection, online pharmacies will be given country-specific accreditation seals for their websites and added to the online pharmacy registry found on the RA's website.

Ultimately, the online pharmacies licensed by the RA should be hosted on the ".pharmacy" domain operated by NABP, regardless of the countries in which they operate. This initiative will mold the ".pharmacy" domain into the standardized domain and international benchmark for legitimate online pharmacies worldwide, helping consumers verify a pharmacy's legitimacy from its web address. To address challenges beyond the scope of NABP and ensure neutrality of the accreditation system, ownership of the ".pharmacy" domain may be transferred to a neutral international nongovernmental organization such as the World Health Organization or an appropriate United Nations agency.

In addition to creating a safe e-commerce environment for medicinal products, it is vital for RAs to educate consumers on

how to access and use the secure e-commerce environment for medicinal products. RAs may consider collaborating with search engine providers such as Google to use online advertisements to spread educational messages; another option might be to employ behavioral advertising techniques, like retargeting, to direct educational messages selectively to consumers at risk of engaging in unsafe e-commerce practices [50].

Moving forward, RAs should consider working in partnership with private companies such as delivery couriers, search engine providers, domain name registrars, financial service providers, and online platform owners in the overall regulation of online pharmacies (Table 3 and Figure 3). These private organizations should have self-regulation guidelines or policies to curb the proliferation of illegitimate online pharmacies. The self-regulation guidelines, which should be agreeable to the RA, should contain reasonable precautions that private organizations could adopt to prevent individuals from exploiting their services, regardless of whether they are online or offline [51].

Subsequently, RAs should consider enacting legislation with adequate regulatory bite to mandate that private organizations implement reasonable precautions. RAs can also incorporate safe harbor procedures (Figure 3) into the new or amended legislation to incentivize private organizations to collaborate to stop illegal acts, to proactively investigate any illicit activity at their end, and

Table 3: Reasonable precautions private organizations can implement to prevent illegitimate online pharmacies from conducting illicit activities.

Type of Organization	Reasonable Precautions
Delivery courier	<p>Prohibit individuals from sending parcels containing illegal medicinal products.</p> <p>Verify parcel contents at point of acceptance to ensure that the parcel does not contain illegal medicinal products.</p> <p>Warn individuals who are caught attempting to send illegal medicinal products, and report to the RA when individuals are suspected to be involved in operating illegitimate online pharmacies.</p>
Search engine provider	<p>Verify the accreditation status of online pharmacies to ensure their authenticity before allowing them to advertise sponsored links.</p> <p>Develop smart algorithms to filter out illegitimate online pharmacies from search results.</p>
Domain name registrar	<p>Implement and enforce policies to prohibit the sale of illegal medicinal products.</p> <p>Actively monitor registries and remove websites engaged in illegitimate online pharmacy operations.</p>
Financial service provider	<p>Have a program to identify merchant accounts of illegitimate online pharmacies.</p> <p>Carry out investigations and disable merchant accounts if they are found to be linked to illegitimate online pharmacies.</p>
Online platform owner	<p>Prohibit sales of illegal medicinal products on their online platforms.</p> <p>Implement an active monitoring system to track listings and ensure illegal medicinal products are not sold via their online platforms.</p>

Figure 3: Safe harbor procedures private organizations must comply with to be immune to contributory liabilities from facilitating operations of illegitimate online pharmacies.

Private organization sets up a proper channel for the RA to notify it about probable illegal activities on its platform.



Private organization receives notification from the RA of probable illegal activities on its platform.



Private organization investigates notification from the RA, removes the infringement, and subsequently updates the RA.



Private organization has no contributory liability and is not prosecuted.



Private organization ignores notification from the RA and does nothing.



Private organization is prosecuted for contributory infringement liability.

“It is crucial for regulatory authorities to work together to step up international enforcement efforts against illegal sales of medicinal products online.”

to avoid any legal contravention [52]. The regulator and regulated should share a common understanding, with due consideration for hold-harmless provisions, to avoid any liability issues.


Concurrently, it is crucial for RAs to work together and with Interpol to step up international enforcement efforts against illegal sales of medicinal products online [53]. This will allow prosecution of suspects involved in illegal online sales of medicinal products, regardless of where the crime was committed. Penalties should be raised proportionately to provide deterrence.

Interpol needs to take on the central policing role of illegitimate online pharmacies and establish an independent international task force to conduct investigations at the global level. This task force would facilitate essential intelligence exchanges among RAs and lead a collaborative investigation with national law enforcement agencies to track down suspects [54]. Such international collaboration can vastly improve the efficiency of investigations and help authorities conserve resources.

CONCLUSION

E-commerce of medicinal products is expected to become an integral part of healthcare systems in the future. Increased e-commerce of medicinal products can bring about advantages such as lower cost, convenience, and consumer privacy. However, the shift from physical stores to online platforms also presents health risks.

Many RAs lack legislation to properly regulate online pharmacies. Jurisdictional and resource limitations have allowed criminals to escape prosecution. The lack of legislation to mandate private organizations' cooperation in investigations also impacts enforcement efforts negatively.

Going forward, a proposed strategic and holistic approach may help RAs regulate e-commerce of medicinal products more effectively. This strategic approach—which incorporates a stepwise implementation of industry guidelines, advisories, and warnings; legislation; and associated enforcement activities—can address the current risks associated with illegitimate online pharmacies and illegal medicinal product e-commerce. Although compliance costs may increase with tighter e-commerce regulation of medicinal products, safeguarding public health should ultimately be the overriding concern of all RAs and stakeholders in general. 

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