



Digital Governance of Public Health: Towards a Regulatory Framework for Internet Pharmacies

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Discussion Paper prepared for the Internet Governance Forum 2019

In 2005, the International Telecommunications Union published the *Tunis Agenda for the Information Society*. In that seminal document, *Internet governance* was defined as the “development and application by governments, the private sector and civil society, in their respective roles, of shared principles, norms, rules, decision-making procedures, and programs that shape the evolution and use of the Internet”.² Even for its time, the *Tunis Agenda* represented a progressive model of promoting norm-based, inclusive and multi-stakeholder approaches to regulating the Internet. Almost 15 years later, however, a survey of over 200 key internet governance experts revealed that almost 80% believed there was “insufficient international coordination and coherence to address cross-border legal challenges on the Internet”.³ That *Internet & Jurisdiction Global Status Report* furthermore argues that lack of international coordination and regulation not only impact digital innovation, but also risk exacerbating legal uncertainties and competing assertions of jurisdiction. The subsequent diagnosis by the *Global Status Report* laid out three main challenges: a lack of commonly agreed norms, a lack of consensus in defining key terms/concepts, as well as increasing distrust (particularly when stakeholders are governed by rules developed in other jurisdictions).

The objective of this discussion paper will be to explore these challenges (but also opportunities) through a case study at the intersection of public health and Internet governance:

¹ Author declaration: financial support for the research, drafting of the discussion paper and travel to IGF 2019 was provided by the Dahdaleh Institute for Global Health Research (York University, Canada). The author has no competing financial, professional or personal interests that might have influenced this work. Special thanks to Dan Svantesson, Gabriel Levitt, James Orbinski, Jillian Kohler, Natasha Tusikov, Patrick Kane, Ron Andruuff and Tim Smith for helpful comments during the drafting process. Contact email: ariaaria@yorku.ca.

² ITU (2005) "Tunis Agenda for the Information Society," *International Telecommunications Union*. Available: www.itu.int/net/wsis/docs2/tunis/off/6rev1.html

³ Internet & Jurisdiction (2019) "Global Status Report 2019" *Internet & Jurisdiction Policy Network*. Available: www.internetjurisdiction.net/uploads/pdfs/GSR2019/Internet-Jurisdiction-Global-Status-Report-2019_web.pdf

the regulation of Internet Pharmacies. Driven largely by lack of access and affordability, Internet Pharmacies represent one of the fastest growing markets. While millions of consumers increasingly turn to the Internet for medicines, there are critical gaps in regulatory standards and best practices within and across national boundaries. Instead, we have a patchwork of largely discretionary regulatory regimes that are developed and enforced by particular stakeholders, with impacts that ripple across varying jurisdictions. This has at least two implications with respect to public health and consumer choice. On the one hand, the lack of regulatory coherence can undermine access to affordable and quality medicines from legitimate Internet retailers. At the same time, current efforts have failed to adequately respond to the risks posed by Rogue websites selling falsified or substandard products, often without a valid prescription.

In order to address this public health moral hazard, we need reasonable and proportional regulatory guidelines for Internet Pharmacies with coherence across jurisdictional boundaries. This case study also raises broader questions. For one, is it possible to augment outdated *analog laws* with *digital standards* in order to address jurisdictional challenges associated with the Internet. Moreover, how do norms, processes, and institutions impact Internet governance. That question is particularly pertinent as legitimate competing interests are presenting increasingly complex regulatory and legal challenges.

This discussion paper will begin with a brief overview of the Internet Pharmacy sector. Next, it will survey the various state- and non-state approaches to regulate Internet Pharmacies, including the *Brussels Principles for the Sale of Medicines Over the Internet*. Lastly, a series of reflections will be offered to guide our discussion around the following questions:

1. Appropriate and proportional regulation of Internet Pharmacies requires balancing public health while ensuring consumer safety and choice, as enumerated in the *Brussels Principles for the Sale of Medicines Over the Internet*. **Can the multi-stakeholder approach that led to the *Brussels Principles* serve as a model for developing standards and best practices to ensure access to safe medicines over the Internet?**
2. Global problems cannot be addressed by national law. Meanwhile, the *Internet & Jurisdiction Global Status Report* highlights deficits in international coordination to address cross-border legal and regulatory challenges associated with the Internet. **What is the most appropriate transnational forum for inclusively and transparently addressing the digital governance and public health issues associated with Internet Pharmacies?**
3. Internet Intermediaries have emerged as key actors in digital governance. With respect to Internet Pharmacies, this has led to a number of technical and policy approaches aimed at balancing public health and consumer choice. **What are the opportunities and challenges associated with intermediary-mediated approaches to regulating Internet Pharmacies such as the .Pharmacy Top-Level-Domain and Trusted Notifier programs?**

Digital Governance of Public Health

Towards a Regulatory Framework for Internet Pharmacies

Access to safe and affordable medicines is a fundamental human right, and a key target of the UN Sustainable Development Goals. According to the World Health Organization (WHO), however, over two billion people lack regular access to essential medicines.⁴ While this access gap is most acute in lower income countries, many advanced economies have also experienced public health emergencies due to rapidly rising costs and medicine shortages.⁵ Among patients and health experts, one marketplace that increasingly promises the potential to improve access and affordability is the Internet. A number of terms are used to describe websites that market and sell medicines (e.g. Internet-, Online-, Cyber-, e-Pharmacies), as well as the practice (e.g. distance dispensing, distance sales). Other terms, meanwhile, refer to websites that pose a clear public health risk by violating regulatory, legal and/or safety standards (e.g. Rogue websites, Illicit Online Pharmacies). In order to advance to a discussion on regulatory framework, and because these terms are frequently used interchangeably, it is important to begin with a shared understanding of the digital marketplace from a public health perspective. In the absence of a commonly agreed definition, this paper proposes a working definition of an *Internet Pharmacy* as one that markets and sells legally-manufactured and market authorized medical products over the Internet, dispensed by a licensed pharmacy to patients with a valid prescription.⁶

There can be many reasons why consumers turn to Internet Pharmacies. These include familiar benefits of e-commerce such as convenience and privacy, as well as price transparency, comparison shopping, and access to medicines when there are shortages locally.⁷ Across multiple studies, however, cost-related issues remain the most commonly stated motivation by consumers for seeking out Internet Pharmacies.⁸ That is particularly true when high prescription drug costs and out-of-pocket spending contribute to rationing or skipping medication, a practice increasingly reported among seniors and chronic disease patients.⁹ In the U.S. alone, medical non-adherence to attributed to an estimated 125,000 deaths and up to US\$300 billion in preventable health care costs each year.¹⁰ To demonstrate the potential cost savings of Internet

⁴ WHO (2017) "Ten Years in Public Health: 2007-2017," World Health Organization: Geneva.

⁵ Morgan SG, Lee A (2017) "Cost-related non-adherence to prescribed medicines among older adults: a cross-sectional analysis of a survey in 11 developed countries," *BMJ Open*, 7:e014287.

⁶ This working definition is informed by the Quality by Design (QbD) framework adopted by various regulatory authorities and premised on the notion that quality can be planned by focusing on process design. See: Yu, Lx, et al (2014) "Understanding Pharmaceutical Quality by Design," *AAPS Journal*, 16(4):771-83.

⁷ Rajamma, RK, Pelton, LE (2009) "An Empirical Investigation of Consumers' Procurement of Pharmaceutical Products via Online Retail Channel," *Psychology & Marketing*, 26(10):865-887.

⁸ Bate, R, et al (2014) "In Whom We Trust: The Role of Certification Agencies in Online Drug Markets," *B.E. Journal of Economic Analysis & Policy*, 14(1):111-150.

⁹ Kleinsinger, F (2018) "The Unmet Challenge of Medication Nonadherence," *Perm J*, 22:18-033.

¹⁰ Bosworth, HB, et al (2011) "Medication Adherence: A Call for Action," *American Heart Journal*, 162(3): 412-424.

Pharmacies, a recent study compared the price of 100 most commonly prescribed medicines in the U.S. Medicare program, and found that credentialed Canadian Internet Pharmacies selling Health Canada-approved products were on average 72% cheaper.¹¹

It is difficult to establish an accurate estimate of the scale and scope of the global Internet Pharmacy market. This is partly due to the distributed nature of the Internet that enables digital marketplaces to operate across jurisdictions, while the absence of regulatory harmonization makes it challenging to capture cross-border market data from these private companies. Consumer surveys represent one source of data on market size. According to the *Global Online Consumer Report* by KPMG, for example, 20% of respondents indicated that they had bought medicines and other healthcare products online, echoed by surveys conducted by pharmaceutical companies in Europe.¹² The U.S. National Center for Health Statistics, meanwhile, estimates that approximately 4.7 million Americans rely on personal medicine importation, which include Internet Pharmacies.¹³ The region that presents the biggest knowledge gap is low- and middle-income countries. While adoption of stringent restrictions on Internet Pharmacies in some of these countries is partly responsible, this also reflects broader evidence gaps on health systems utilization and digital consumer behaviour. Gaps in our understanding can pose public health and policy challenges. That is exacerbated in this case by significant access and affordability gaps coupled with vulnerabilities in physical and digital regulatory systems.¹⁴

In the absence of reliable and comprehensive data, a scoping review was undertaken, revealing a diversity in the functions and forms across Internet Pharmacy websites. With respect to the functions that were advertised on the websites, there was divergence in the markets targeted (e.g. domestic vs cross-border, personal vs wholesale importation), products sold (e.g. maintenance medication, controlled substances), certification of suppliers (e.g. pharmacies, wholesalers, distributors), as well as supplementary services (e.g. consultation/prescription review by physician/pharmacist, price transparency across markets). There is also diversity across Internet Pharmacy forms, ranging from brick and mortar pharmacies that have an online extension, prescription referral services that fill prescriptions through one or more pharmacies, and Rogue websites which increasingly extend to social media platforms.

In their examinations of Internet pharmacies, the academic literature, state regulatory attention and international public health bodies (including the WHO), have mostly focused on Rogue websites. This is largely due to the potential public health risks, which can arise from

¹¹ Kim, SH, et al (2017) "Prescription Drug Price Paradox: Cost Analysis of Canadian Online Pharmacies versus US Medicare Beneficiaries for the Top 100 Drugs," *Clinical Drug Investigation*, 37:957–63.

¹² KPMG (2017) "The Truth about online consumers: Global Online Consumer Report," Available: <https://assets.kpmg/content/dam/kpmg/xx/pdf/2017/01/the-truth-about-online-consumers.pdf>

¹³ Kohler, JK (2018) "Avoiding Rogue Internet Pharmacy Suppliers in the Effort to Improve Access to Medicines," *Arizona Rural Health Conference*, 26-27 July 2018. Available: <https://crh.arizona.edu/sites/default/files/pdf/events/annual-conference/Avoiding%20Rogue%20Internet%20Pharmacy%20Kkohler.pdf>

¹⁴ WHO (2011) "Safety and security on the Internet: challenges and advances in Member States: based on the findings of the second global survey on eHealth," *World Health Organization*: Geneva.

falsified or substandard medical products, controlled substances without a valid prescription, as well as misuse of addictive or inappropriate medicines. In the best case scenario where the medicine is not life-saving and the patient experiences no adverse events, the loss is mainly financial. In most cases, unfortunately, the public health impact is significantly more severe, ranging from prolonged illness, adverse drug events and death. Rogue websites, often run by criminal networks, take advantage of a 'low risk, high reward' environment. On the consumer side, the demand for lower cost medicines is not always matched by digital health literacy in differentiating between legitimate Internet Pharmacies and illicit online markets. The biggest signs that a website is likely not safe or legal include: not requiring a valid prescription, allowing purchase of scheduled/controlled substances, the lack of third-party certification, as well as no physical address or contact number.¹⁵ Meanwhile, the networks operating Rogue websites take advantage of cross-border barriers, with a recent study showing the failures of existing deter to legal tools and regulatory policies deterring this potentially profitable activity.¹⁶ The ease of setting up websites poses a challenge in permanently shutting down these illicit markets.

The factors that facilitate Rogue websites have contributed to a broader erosion of trust in Internet Pharmacies. The combination of public health risks and the potential criminal dimension to Rogue websites has furthermore justifies more restrictive regulatory and law enforcement approaches, particularly when it comes to personal prescription importation. There are at least four major arguments that such systematic restrictions have a negative impact on public health and consumer choice. In the first instance, the lack of access to affordable medicines constitutes a global public health threat that affects over two billion people. While the problem is most acute in lower income countries, it has also affected advanced economies such as the U.S., where the price of the most commonly prescribed medicines increased by 208% in the past decade.¹⁷ Secondly, it is important to remember that medicines are controlled, yet legal products that patients with a valid prescription are able to obtain in many countries. In other words, certain prescription drug formulations can be approved by multiple regulatory authorities, who can enter mutual agreements on regulatory equivalence. Taking advantage of this practice forms a major component of the proposed response by the U.S. Administration to the issue of rising drug costs (i.e. creating more legal mechanisms for medicine importation from countries like Canada).¹⁸

The third risk with systematic restrictions on personal medicine importation is the fact that consumer demand won't simply go away. When safe and legal Internet Pharmacy websites are not more widely made available, consumer demand can shift to riskier marketplaces, including social media platforms (e.g. Twitter, Instagram, Facebook) where criminal networks are able to

¹⁵ Gray, NJ (2011) "The Evolution of Online Pharmacies," *SelfCare*, 2(3):76-86.

¹⁶ Mackey, TK, Nayyar, G (2016) "Digital danger: a review of the global public health, patient safety and cybersecurity threats posed by illicit online pharmacies," *British Medical Bulletin*, 118:115–131.

¹⁷ AARP (2017) "Why Drugs Cost So Much," *American Association of Retired People*, Available: <https://www.aarp.org/content/dam/aarp/health/healthy-living/2017/04/drug-prices-download-final.pdf>

¹⁸ Galewitz, P (2019) "Trump Admin 'Open For Business' On Drug Imports From Canada," *Kaiser Health News*, 31 Jul 2019, Available: <https://khn.org/news/trump-administration-open-for-business-on-drug-imports-from-canada/>

operate.¹⁹ Although this practice and related public health risks are increasingly being reported, the response has largely been more enforcement. This ‘whack-a-mole’ approach of closing these channels of Rogue drug distribution is not only slow and inefficient, but it also doesn’t address the underlying demand-side problem that is best achieved by a regulated online market for safe and legal medicines. Lastly and relatedly, there is extensive evidence from a growing market of Internet Pharmacies (in some cases operating for over two decades) that it is possible to provide access to affordable medicines while protecting public health and consumer choice.²⁰ Rather than suppressing demand for and supply of legal, safe and affordable medicines over the Internet, this paper approaches the problem from a cross-border regulatory perspective. As the *Internet & Jurisdiction Global Status Report* notes, a regulatory challenge is one where competing legitimate interests are difficult to reconcile.²¹ The following section will survey these interests across state, non-state and internet governance stakeholders, including their varying regulatory approaches towards Internet Pharmacies.

Regulatory Regimes of Internet Pharmacies

Regulation is a word that rarely inspires enthusiasm, including in the case of Internet Pharmacies. Formally, regulations are defined as processes to set, implement and enforce rules and/or standards, by state or non-state actors.²² Colloquially, however, regulations have garnered an unfavourable reputation as time and resource intensive processes (fair) to blame for any policy or market failure. Unfortunately, as both a process and an outcome, regulation remains increasingly essential. That is particularly true with the increasing unification of the digital and physical world. In fact, digital innovation frequently outpaces the capacity to identify and respond to unintended consequences to consumer safety and choice. The *Internet & Jurisdiction Global Status Report* notes that gaps in Internet regulation not only increase transaction costs, but they can erode consumer safety and limit consumer choice.²³ At the same time, there are growing complexities in establishing the required multi-stakeholder processes needed to enable common understanding of problems, as well as a platform where competing interests can be openly shared and discussed.

Not all digital governance issues require complex multi-stakeholder structures and processes. Where possible, the default framework has typically been allowing for self-regulatory approaches. The voluntary self-regulation paradigm is premised on the capacity and incentives

¹⁹ Moyle, L, et al (2019) "#Drugsforsale: An exploration of the use of social media and encrypted messaging apps to supply and access drugs," *International Journal of Drug Policy*, 63:101-110.

²⁰ Bate, R (2019) "Catch 22: Credentialed online pharmacies are so safe that peer review literature is no longer interested in results showing it," *AEI*, Available: www.aei.org/health-care/catch-22-credentialed-online-pharmacies-are-so-safe-that-peer-review-literature-is-no-longer-interested-in-results-showing-it/

²¹ See 3 (Internet & Jurisdiction, 2019).

²² Eberlein, B, et al (2014) "Transnational business governance interactions: Conceptualization and framework for analysis," *Regulation & Governance*, 8:1-21.

²³ See 3 (Internet & Jurisdiction, 2019).

of the members to ensure compliance with legal, ethical and safety standards, including mechanisms for conflict resolution. When self-regulation is insufficient, or when legitimate competing interests exist, alternative regulatory approaches are needed. These regulatory regimes can include state- and non-state actors from the public, private and/or civil society sector. Within this context, regimes are understood as the “full set of actors, institutions, norms and rules” that comprise a particular regulatory arrangement.²⁴ As Tusikov notes, the concept of *regulatory regimes* allows for a deeper inquiry into the emergence and operation of particular regulatory arrangements, along with all the stakeholders and their converging or diverging interests.²⁵ In order to apply this analytic framework to Internet Pharmacies, the first task will be to map the relevant stakeholders that are directly or indirectly involved. What that will result is a hybrid regulatory regime involving a range of actors across multiple overlapping jurisdictions.

State-based Regulatory Regimes of Internet Pharmacies

Due to the cross-border aspect of Internet Pharmacies, nation-states are critical actors. With sovereignty over domestic territory and rule-making, the task of regulating medicines is typically mandated to Ministries of Health and/or National Medicines Regulatory Authorities (NMRA). That includes the power to grant market authorization, schedule controlled substances (i.e. guidelines for prescribing and dispensing), and to enforce Good 'X' Practices (e.g. Manufacturing, Distribution, Dispensing, Pharmacovigilance etc.) to ensure the safety, efficacy and quality of medical products across the domestic supply chain. Globalization of pharmaceutical supply chains has required many NMRAs to adapt to the growing dependence on foreign manufacturers, distributors and wholesalers, among other intermediaries.²⁶ Within that regulatory paradigm, one perspective is to view Internet Pharmacies as an extension of the jurisdictional scope of NMRAs. While NMRAs retain a role in stewarding the regulation of Internet Pharmacies, there are other authorities within countries that play a role. Because of the cross-border and consumer safety dimensions, law enforcement authorities as well as customs and border authorities can be involved. That can include coordination within and across national jurisdictions. The most notable example of the latter is the International Criminal Police Organization (INTERPOL), which facilitates cooperation among law enforcement agencies in 194 countries. During its annual week-long *Operation Pangea*, for example, INTERPOL coordinates a number of activities among member-states around the world that target global aspects related to pharmaceutical crimes, including Rogue websites.²⁷ Beyond enforcement authorities, the regulation of Internet

²⁴ Eberlein, B, Grande, E, (2006) "Beyond delegation: transnational regulatory regimes and the EU regulatory state," *Journal of European Public Policy*, 12(1):89-112.

²⁵ Tusikov, N (2015) "Chapter 20: Transnational non-state regulatory," In *Regulatory Theory: Foundations and Applications*, Peter Drahos (editor), ANU Press:339-357.

²⁶ PharmacyChecker.com (2018) "FDA's drug importation data is wrong," Available, <https://www.pharmacychecker.com/news/fdas-drug-importation-data-is-wrong/>

²⁷ INTERPOL (2019) "Pharmaceutical Crime Operations," Available: <https://www.interpol.int/en/Crimes/Illicit-goods/Pharmaceutical-crime-operations>

Pharmacies can also include national telecommunications agencies, as well as consumer protection bodies that play a role in risk communication and public reporting mechanisms.

There is significant diversity across nation-states in how they regulate Internet Pharmacies. The importance of jurisdictional sovereignty, coupled with potential public health risks posed by Rogue websites, have led some countries to outright banning Online Pharmacies. As a result, countries such like China, Russia, Japan, and Italy either adopt explicit laws, or their rules around prescribing and/or dispensing make the practice illegal.²⁸ Of particular concern from a public health perspective are low- and middle-income countries that may have limited capacity to regulate their pharmaceutical supply chains. The regulatory deficit, along with the lack of data on health system utilization and digital consumer behaviour can lead to public health concerns. At the other end are countries that provide some legal mechanisms for consumers to use Internet Pharmacies. Many nation-states that allow the practice require that all medicines be approved by their NMRA. This results in only permitting Internet Pharmacies that sell domestic products to domestic consumers, thereby banning cross-border importation. While there can be justification for this requirement, it curtails the ability of consumers to lawfully obtain lower drug prices from other markets. A study this year by the *U.S. Ways and Means Committee* estimated that prices on a basket of 79 prescription medicines were on average 75% lower across 11 other countries.²⁹ These obstacles to accessing lower-cost medicines are, from a public health viewpoint, particularly troubling where international medicine sales are within the supply chains of countries with regulatory equivalence agreements.

Across the European Union, for example, the 28 member-states have individual NMRAs, but there is also an umbrella regulatory agency called the European Medicines Authority. The continent, however, is also unique for voluntarily transferring elements of national sovereignty on political, economic and regulatory matters to multi-lateral forums such as the European Commission. Albeit slowly at times, this arrangement has allowed European member-states to adopt quite radical regulations that affect over 800 million people (e.g. General Data Protection Regulation). The one that is most relevant to Internet Pharmacies is the Falsified Medicines Directive (FMD) that was adopted in 2011.³⁰ Aimed at strengthening medicines supply chains across the European Economic Area, the FMD include harmonization in track and trace systems and registration for online retailers. The regulatory tool that most recently went into effect is the Common EU Logo.³¹ The idea is that Internet Pharmacies registered in member-states place a uniform logo onto their websites (differing only by the flag of the country and a unique serial number), that when clicked by consumers links to the NMRA's website confirming the Internet

²⁸ LegitScript (2015) "Internet Pharmacy Policy Guide," Available: https://www.legitscript.com/download/DRAFT_-_COUNTRY-BY-COUNTRY_RULES.pdf

²⁹ U.S. House Ways and Means Committee (2019) "A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices." Available: https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf

³⁰ Ogden, J (2019) "Implementing the EU Falsified Medicines Directive," *Prescriber*, 30(3):30-33.

³¹ European Commission (2016) "EU logo for online sale of medicines." Available: https://ec.europa.eu/health/human-use/eu-logo_en

retailer's registration. The objective of the Common EU Logo is to increase risk communication among online consumers (i.e. only purchase medicines from websites that have the common logo), but also in encouraging Internet Pharmacies to register with NMRAs.

Reviewing every national policy on Internet Pharmacies is beyond the scope of this paper. It would be difficult, however, to ignore the U.S., which represents over 45% of the global market for medicines.³² In addition to hosting the biggest digital consumer health market, the U.S. Food and Drug Administration (FDA) is also a critical actor in shaping the regulatory landscape that other countries either adopt or adapt to. The FDA has two relevant policies. Broadly, Section 21 U.S.C. § 331 of the U.S. Federal Food, Drug, and Cosmetic Act (FDCA) prohibits the shipment of unapproved new drugs. For domestic Internet Pharmacies selling to U.S. consumers, the FDA relies on the Verified Internet Pharmacy Practice Sites (VIPPS) program of the National Association and Boards of Pharmacy (NABP) to certify websites. With respect to importation, however, FDCA Section 21 U.S.C. § 384 provides flexibilities under the Waiver Authority for Importation by Individuals in clause (j) Waiver authority for importation by individuals³³ This Personal Importation Policy (PIP), which is enforced by U.S. Customs and Border Protection, allows U.S. consumers to import up to a 90-day supply of non-controlled prescription medicines for personal use.³⁴ These guidelines are discretionary, however, resulting in occasional reports of prescriptions confiscated by customs, and Internet Pharmacies operating within the PIP either sanctioned directly, or compelling internet intermediaries to issue take-down notices.^{35,36}

As the *Internet & Jurisdiction Global Status Report* notes, there can often be an incongruence between the global scope and reach of a free Internet, and regulations that are developed in, by and for specific jurisdictions.³⁷ Diverging policies across countries and legal uncertainties with the discretionary enforcement of guidelines, has led to a number of sub-national jurisdictions to adopt independent policies on Internet Pharmacies. While these sub-national jurisdictions are often bound to national laws, regulatory systems of shared power can also provide flexibilities to interpret laws and regulations. With respect to Internet Pharmacies, sub-national jurisdictions such as states, provinces, and cities have exercised this sovereignty. In the U.S., for example, an increasing number of cities, counties and states have adopted, or are in the process of drafting,

³² Statista (2017) "U.S. Pharmaceutical Industry - Statistics & Facts." Available:
<https://www.statista.com/topics/1764/global-pharmaceutical-industry/>

³³ U.S. Federal Food, Drug, and Cosmetic Act (2006) "Section 21 U.S.C. § 331 and § 384. Available:
[https://uscode.house.gov/view.xhtml?req=\(title:21%20section:384%20edition:prelim\)](https://uscode.house.gov/view.xhtml?req=(title:21%20section:384%20edition:prelim))

³⁴ U.S. Food and Drug Administration (2018) "Personal Importation Policy (PIP) Frequently Asked Questions," Available: <https://www.fda.gov/media/83411/download>

³⁵ Malcolm, J (2016) "How Big Pharma's Shadow Regulation Censors the Internet," *Electronic Frontier Foundation*. Available: <https://www.eff.org/deeplinks/2016/09/how-big-pharmas-shadow-regulation-censors-internet>

³⁶ Bate, R (2019) "Bing's Disservice to Online Drug Safety," *American Enterprise Institute*. Available: <https://www.aei.org/research-products/report/bings-disservice-to-online-drug-safety-2/>

³⁷ See 3 (Internet & Jurisdiction, 2019).

laws that establish clearer pathways for medicine importation.³⁸ The National Association for State Health Policy has emerged as a key body in assisting states in drafting these regulations with a view to balancing public health and consumer safety.³⁹

Non-state Regulatory Regimes of Internet Pharmacies

Professional health associations constitute another important stakeholder group. In addition to accrediting members, professional associations play an important role in developing and refining best practices to safeguard the public interest and sanction misconduct. Professional associations such as physicians and pharmacists are also often entrusted with a “public-spirited commitment to distributive justice.”⁴⁰ With respect to Internet Pharmacies, relevant professional associations include those governing upstream pharmaceutical supply chain actors (e.g. wholesalers, distributors), as well as pharmaceutical and medical associations that govern pharmacists and physicians. Since professional accreditation is jurisdictional, there can be overlap but also divergence between and across professional associations. The aforementioned NABP, for example, represents 54 member and 12 associate member pharmacy boards within and beyond the U.S., including 10 Canadian provinces. The latter provincial pharmacy boards, meanwhile, also have overlapping membership in the National Association of Pharmacy Regulatory Authorities.

Canada also offers an example of divergence across professional associations that is relevant in the context of Internet Pharmacies. Physicians are typically allowed to only issue prescriptions to patients they see face-to-face. This means that a patient in the U.S. who wants to purchase cheaper Canadian medicines would either have to visit a clinic in Canada to obtain a prescription, while the practice of dual medical licensing has also become more popular (i.e. legally-practicing in a U.S. state and a Canadian province).⁴¹ Meanwhile, pharmacists are also only able to fill prescriptions by legally-practicing physicians within their state/province. In order to enable U.S. consumers to purchase medicines from Canadian Internet Pharmacies, the patient first obtains a valid prescription by a U.S. state-certified physician. The Canadian Internet Pharmacy then forwards the prescription to a Canadian provincially-certified physician, who upon satisfactory review of the patient file, ‘co-signs’ a new script that a legally-practicing pharmacist within the province is able to fill and ship to the patient in the U.S. While this form of ‘distance dispensing’ seems elaborate – and there have been (unsuccessful) efforts to challenge it – at least two

³⁸ Galewitz, P (2017) “Cities, Counties and Schools Sidestep FDA Canadian Drug Crackdown, Saving Millions,” *Kaiser Health News*, 8 Dec 2017, Available: <https://khn.org/news/cities-counties-and-schools-sidestep-fda-canadian-drug-crackdown-saving-millions/>

³⁹ NASHP (2017) "Managing High Drug Prices through Importation: We Can Get to YES," National Academy for State Health Policy. Available: <https://nashp.org/managing-high-drug-prices-through-importation-we-can-get-to-yes/>

⁴⁰ Schafer, A (2008) "Canadian Internet pharmacies: Some ethical and economic issues," *Can Pharm J*, 141:191-97.

⁴¹ Davie, E (2019) "Quiet resurgence: Americans coming north to fill prescriptions on the rise again," CBC, 20 May 2019, Available: <https://www.cbc.ca/news/canada/nova-scotia/u-s-canada-prescriptions-border-1.5137350>

Canadian provincial medical associations deemed the practice safe and legal, as have professional associations in a number of other jurisdictions, including the United Kingdom.

There are other non-state actors with varying levels of regulatory functions, both formally and informally (e.g. through funding and advocacy). Among the latter is the pharmaceutical industry, along with their respective trade associations (e.g. the Pharmaceutical Research and Manufacturers of America). In addition to lobbying policy makers and regulators directly, the private pharmaceutical industry has also increasingly turned to funding and/or supporting non-profit entities. This includes, for example, the Alliance for Safe Online Pharmacies, the Center for Safe Internet Pharmacies (CSIP), and Partnership for Safe Medicines. These organizations have played an important role in promoting vigilance among online consumers, while raising legitimate consumer safety concerns around Rogue websites and falsified medicines. At the same time, their uncompromising and unequivocal position against medical importation has been challenged by digital and consumer rights groups. The CSIP, for example, has a self-described mandate of providing the “first-ever private sector solution” to the problem of illicit online pharmacies.⁴² Its members, likewise, include pharmaceutical companies, credentialing agencies, as well as major internet intermediaries (e.g. domain registrars, major payment providers, search engines). Tusikov describes particular “beyond-compliance regulation” strategies, whereby CSIP pressures Internet intermediaries with taking proactive enforcement actions on complaints of infringements beyond their legal or regulatory remit.⁴³ Critiques against CSIP and other state and non-state actors has most vocally come from digital and consumer rights groups. These include the Electronic Frontier Foundation, Campaign for Personal Prescription Importation, Public Citizen, and the Pharmacy Checker Blog (affiliated with PharmacyChecker.com), among others.

Voluntary self-regulation approaches also play an important role for mediating trust between consumers and Internet Pharmacies. Although a variety of terms are used in the literature, the term *credentialing* is adopted from Bate et al to refer to the various systems of regulatory standards, rules and policies that attempt to delegate the safety and legitimacy of Internet Pharmacy websites.^{44,45} The fundamental problem that credentialing aims to address is the market inefficiency that can arise when consumers have less information about product quality than sellers.⁴⁶ This information asymmetry can be addressed in two ways. A public sector response includes risk communication, providing consumers with a whitelist of trusted sellers, while also prohibiting specific market actors. A private sector response, meanwhile, could appeal to free market principles (i.e. consumers will return if you provide a quality product), or by establishing verifiable certification mechanisms. Credentialing represents the latter approach,

⁴² Clifton, M (2012) “The Fight to Combat Illegal Online Pharmacies,” *BiotechNow*, 1 Aug 2012, Available: www.biotech-now.org/health/2012/08/the-fight-tocombat-illegal-online-pharmacies

⁴³ Tusikov, N (2016) “Chokepoints: Global Private Regulation on the Internet,” University of California Press: LA.

⁴⁴ A variety of terms are used in the literature, including: accredited, certified, credentialed, validated, verified, etc.

⁴⁵ See 8 (Bate et al, 2014).

⁴⁶ Akerlof, GA 1970. “The Market for ‘Lemons’: Quality Uncertainty and the Market Mechanism,” *Quarterly Journal of Economics*, 84(3):488–500.

i.e. maintaining a trusted network of wholesalers, distributors and pharmacies that undergo regular and thorough inspection. A number of studies have highlighted the benefits of credentialing Internet Pharmacies to consumer safety and consumer choice.⁴⁷ That includes the value of publishing regulatory standards, rules and policies that can help facilitate trust and lead to refinement. Credentialing furthermore establishes a mutually beneficial network of trusted stakeholders across the supply chain. Most importantly, however, studies have shown that credentialing of Internet Pharmacies has had a significant impact on the safety and quality of medicines that are dispensed to consumers. In fact, one researcher who has conducted field studies in over a dozen countries claims that credentialed Internet Pharmacies have become “so safe that peer review literature is no longer interested in results showing it.”⁴⁸

There are four major Internet Pharmacy credentialing agencies. The previously mentioned VIPPS program represents the most authoritative, in part, because it is managed by the NABP and endorsed by the U.S. FDA. Another third-party service is LegitScript, founded by a former White House aide on drug policy. Like the VIPPS program, however, the list of LegitScript-certified Internet Pharmacies exclude any website that market or sell imported medicines into the U.S. Two other certification agencies that have adopted the broader interpretation of the FDA Personal Importation Policy are the Canadian International Pharmacy Association (CIPA) and PharmacyChecker.com. The CIPA is a trade association that since 2002 has provided information on certified Internet Pharmacies that operate legally in Canada. Both CIPA and PharmacyChecker require websites to submit an application and pay a verification fee. PharmacyChecker, meanwhile has a broader network of pharmacies, wholesalers and distributors around the world that it certifies for a fee. Both of these certification agencies have been endorsed by physicians, professional associations and consumer groups as a source of information for Internet Pharmacy websites where consumers are able to obtain safe and affordable medicines.⁴⁹

Internet Intermediary-based Regulatory Regimes of Internet Pharmacies

Transnational non-state regulation enables reach beyond jurisdictional boundaries, and regulation in ways or at scale that nation-state agencies are not able to.⁵⁰ That is also the case with Internet Pharmacies, where a number of Internet governance actors play an increasingly important regulatory role. Not least of these are Internet intermediaries, endearingly described as the network of Internet plumbing that connects online users with providers of content, products and/or services. The category of intermediaries is expansive, including for- and non-

⁴⁷ Ersin, OH, Naistat, DM (2015) "Criteria-based Certification and Validation of Online Pharmacies: Opportunities for Improved Quality and Safety," *Innovations in Pharmacy*, 6(3): Article 212.

⁴⁸ See 20 (Bate, 2019).

⁴⁹ Levitt, G (2019) "Consumer Reports' Deafening Silence about Safe Foreign Online Pharmacies," Prescription Justice Blog, Available: <https://www.pharmacycheckerblog.com/consumer-reports-deafening-silence-about-safe-foreign-online-pharmacies#more-6952>

⁵⁰ Graz, JC, Nölke, A (2008) "Introduction: Beyond the fragmented debate on transnational private governance," In *Transnational private governance and its limits*, New York: Routledge.

profit actors that ensure the stability of the internet, to domain name registrars, web hosting services, internet service providers, certification authorities, payment service providers, search engines, content delivery networks, and third party platforms that include online marketplaces. Most intermediaries operate across borders, mediating their relationship with one another as well as with consumers through Terms of Service Agreements. At the same time, intermediaries both incorporate and operate within countries, which can impose national laws and regulations. Because they have material interests in protecting their corporate reputations from association with illicit activity, Intermediaries have an interest in adopting measures that improve consumer confidence. As Tusikov notes, large, U.S.-based intermediaries in particular have increasingly, and perhaps reluctantly, been tasked with a gatekeeping role of policing online content and behaviour.⁵¹ With respect to Internet Pharmacies, for example, intermediaries such as DNS, ISPs, search engines and/or payment providers can be impelled by state regulatory authorities to censor or take down content providers that they claim are breaching laws.

Internet Intermediaries are also increasingly tasked with responding to DNS Abuse, which can impact the stability and trust of the domain space. DNS Abuse can either be technical (e.g. bots, spam, phishing, malware) or content based (e.g. hate speech, child exploitation, Rogue marketplaces). Many intermediaries have publicly stated opposition to regulating content. In part, that is due to the enormous resources they argue it would require to review all content on their platforms. There is also the risk that that discretionary application of laws and regulations could affect an open and free Internet (although one could argue Terms of Services agreements already grant intermediaries discretionary gatekeeping capacity). The problem with DNS Abuse, then, is identifying when and which intermediary should take what action. One of the approaches currently being piloted is a Trusted Notifier system, which is a mechanism where privileged notification channels are provided by an intermediary to a third party, which is particularly knowledgeable or has particular expertise to identify unlawful content. This was initially piloted between the Motion Picture Association of America and Donuts Inc, a domain name registry to address piracy and copyright infringement.⁵² A current pilot exists between the National Telecommunications and Information Administration (NTIA) and the U.S. FDA to address the illegal sale of Opioids from Rogue websites.⁵³ Working with two domain name registries – Public Interest Registry (PIR) (.org) and Verisign Inc (.com) – a small number of notifiers would report to these registries, who would follow-up with the websites before determining whether a take-down or court order is warranted.

Despite the stated reluctance by intermediaries to take on a content regulator role, there are critics of the Trusted Notifier system. Depending on intermediaries, Trusted Notifier models can be seen as a voluntary expedited-enforcement layer, but also as an extension of existing notice-

⁵¹ See 43 (Tusikov, 2016).

⁵² MPAA (2017) "One Year Later: Trusted Notifier Program Proves Effective," Available: <https://www.motionpictures.org/press/one-year-later-trusted-notifier-program-proves-effective/>

⁵³ NTIA (2019) "Supporting the President's Call to Action Against Opioid Abuse." Available: <https://www.ntia.doc.gov/blog/2019/supporting-president-s-call-action-against-opioid-abuse>

and-takedown regimes.⁵⁴ In addition to the need for formal legal basis for non-judicial enforcement regimes there are also questions about selecting Trusted Notifiers in a transparent and accountable manner. Otherwise, there is a risk about entrusting a broad room of autonomy with private parties. Whereas models involving public authorities are subject to general administrative law principles as well as constitutional and human rights safeguards, the framework for private regulation (i.e. without intervention of public actors) is less clear.

Another critical Internet governance approach to regulating Internet Pharmacies is the system for assigning domain names. Since 1998, Internet Corporation for Assigned Names and Numbers (ICANN), a non-profit organization has been tasked with ensuring the stability of the Internet, as well as coordinating the domain name systems. Among its most important functions is the management and assignment of the Top Level Domains (TLD). Some TLDs are not publicly available, including country codes, trademarked brands and those for highly regulated industries such as banking. There are also a small number of domain name registries that manage many and/or widely used TLDs (e.g. Verisign, PIR, Donuts). Between 2011 and 2014, however, ICANN received 1,930 applications as part of the *New gTLD Program* that invited public, private and non-profit organizations to apply to operate new domains. Among the 1,500+ domains currently listed on the Internet Assigned Numbers Authority is the .Pharmacy TLD. With significant expertise in pharmaceutical practices, the NABP was able to secure delegated authority by corporate partners and the U.S. government, and assigned as primary operator of the .Pharmacy domain in 2014.

Assignment of the .Pharmacy to the NABP was not without objection by major digital rights and other civil society organizations (as well as petition with over 24,000 signatories).⁵⁵ These persistent objections largely fall into two categories. The first relates to the potential conflict of interest due to the NABP's mostly U.S. members primarily representing the interests of State pharmacy boards. As an independent body, the NABP has also received support from the pharmaceutical industry, which ironically includes significant funding for the NABP application for the .Pharmacy TLD.⁵⁶ A second concern draws on the NABP's management of the VIPPS program. As previously noted, the VIPPS-certification program excludes any website that markets or sells imported medicines into the U.S., despite the flexibilities provided by Section 21 U.S.C. § 384 of the FDCA, and the FDA Personal Importation Policy which allows cross-border importation under certain instances.⁵⁷ This difference in interpretation becomes critical as the NABP claims Rogue websites constitute 96% of the over 11,000 websites it regularly monitors. That figure can be potentially misleading, however, as 85% of these websites were classified as 'Rogue' for

⁵⁴ Schwemer, SF (2019) "Trusted notifiers and the privatization of online enforcement," *Computer Law & Security Review*, 35(6): doi.org/10.1016/j.clsr.2019.105339.

⁵⁵ RxRights (2014, October 22) "Your 24,349 signature petition had an impact!" *RxRights.org*, Available: <https://web.archive.org/web/20170902085334/http://www.rxrights.org/24349-signature-petition-impact/>

⁵⁶ NABP (2016, Mar 8) "Coalition Support," NABBP Website. Available: <https://web.archive.org/web/20160308062428/http://www.nabp.net/programs/pharmacy/pharmacy-and-nabp/coalition-support>

⁵⁷ See 35 (Malcolm, 2016).

marketing prescription medicines to U.S. consumers or not requiring a U.S. prescription.⁵⁸ The apprehension, particularly among international stakeholders, is the exporting of the NABP's strictive and U.S.-centric criteria to the .Pharmacy domain. That concern is not unfounded, as a number of applications have already been rejected, and the NABP was issued a *Notice of Breach of Registry Agreement* by ICANN, in part for failing to operate the .Pharmacy domain transparently.^{59,60} From a public health perspective, .Pharmacy represents a lost opportunity, as a TLD could greatly facilitate risk communication to consumers (i.e. only buy medicines from .Pharmacy websites). This represents a 'White List' model – similar to the Common EU logo – that can provide an opportunity for a more transparent approach to identifying safe websites. It could furthermore move us away from the current resource-intensive 'Black List' approach that require monitoring of all known threats, often by discretionary criteria of what constitutes a Rogue.⁶¹

Final Reflections: A Call for Multi-Stakeholder Processes

The aim of this Discussion Paper was to define the problem (from a human rights and global public health perspective), develop a taxonomy of the stakeholders (along with their interests), and survey the range of existing regulatory approaches to Internet Pharmacies. What has been made clear is that competing legitimate interests exist within and between stakeholders. The delegation of regulating Internet Pharmacies to a country or organization can meanwhile have significant implications to public health and consumer choice. That is particularly true given the jurisdictional and cross-border regulatory challenges that are illustrated in this paper. This regulatory patchwork includes state, non-state and intermediary approaches to Internet Pharmacies. As the *Internet & Jurisdiction Global Status Report* quips, however, "while every problem has a solution, every solution has a problem." In the case of the existing regulatory patchwork, that includes jurisdictional challenges undermined by a lack of cross-border coordination, as well as hybrid regulatory regimes that generate legal uncertainty, competing assertions of jurisdiction and greater mistrust (particularly in low- and middle-income countries, where profound medicine access gaps intersect a proliferation of Internet access).

In many ways, this case study embodies broader contemporary challenges that the Internet governance community is currently wrestling with. In a recent paper, the former CEO of ICANN argued that we need "digital norms" that are developed through "co-governance systems" in order to cultivate the necessary trust.⁶² That brings us back to the *Tunis Agenda for the Internet*

⁵⁸ Pharmaceutical Commerce (2015) "NABP updates rogue-pharmacy data and its .pharmacy programs," Available: <https://pharmaceuticalcommerce.com/legal-regulatory/nabp-updates-rogue-pharmacy-data-and-its-pharmacy-programs/>

⁵⁹ Andruff, R (2018) "Enough With Blacklisting Online Pharmacies, Isn't It Time to Consider White Lists?," CircleID. Available: www.circleid.com/posts/20181020_enough_with_blacklisting_online_pharmacies_time_to_white_list/

⁶⁰ ICANN (2018) "Re: Notice of Breach of Registry Agreement." Available: https://www.icann.org/uploads/compliance_notice/attachment/1049/serad-to-allain-11jul18.pdf

⁶¹ See 43 (Tusikov, 2016).

⁶² Chehadé, F, Abusitta, N (2019) "Digital Norms: Co-Governance System for a Trusted Digital World," Available: <https://blogs.bsg.ox.ac.uk/wp-content/uploads/2019/02/DIGITAL-NORMS-Chehade-Abusitta-JAN19-1.pdf>

Society, and its progressive advocacy of an Internet governance process that is norm-based, inclusive and occurring within multi-stakeholder forums. The *Brussels Principles on Sale of Medicines Over the Internet* represents one such effort.⁶³ Emerging organically out of a panel at the RightsCon 2017 Conference in Brussels, the *Principles* subsequently returned the following year. At the RightsCon 2018 Conference in Toronto, a multi-stakeholder process was used to actively debate, refine and ultimately adopt a set of seven principles that reflect a norm-based approach grounded in a right to health perspective.⁶⁴ In order to advance the discussion, there is a need for broader consensus on foundational norms such as the *Brussels Principles*. That is true regardless of whether the future forum is in the Internet governance domain (e.g. IGF, ICANN, I&J, RightsCon, etc.) or in the regulatory space (e.g. WHO, International Coalition of Medicines Regulatory Authorities, International Council of Harmonization, etc.) or elsewhere. In order to stimulate discussion, below are a number of questions organized around broader themes that the paper explores:

1) Balance of Interests

- Competing legitimate interests present regulatory challenges (e.g. consumer safety, consumer choice, market protection). There is also a public health risk in under-regulation (exposure to Rogue websites) and over-regulation (restricting affordability and access). How can competing legitimate interests be reconciled in order to find a regulatory ‘sweet spot’?

2) Internet and Jurisdiction

- Global problems cannot be address by national law. At the same time, there is a deficit in international cooperation to address cross-border regulatory and legal challenges on the Internet. Can regulatory models such as harmonization, equivalence and EU common logo models inform some of the jurisdictional challenges associated with Internet Pharmacies? How can the jurisdictional issues with NABP’s management of .Pharmacy be resolved?

3) Regulatory Regimes (States, Non-States and Intermediaries)

- Intermediaries are increasingly tasked with additional regulatory responsibilities, despite their reluctance to take on the task of content management. What is the role of voluntary self-regulation? How can Trusted Notifier programs be managed in a fair and transparent manner? What is role of certification agencies?

4) Norm-based Rule-making

- Norms are important in informing the formulation of laws and regulations. The lack of multi-stakeholder forums limit capacity to contest norms and engage in rule-making. What international organization can be a forum to discuss the regulation of Internet Pharmacies? Is it in Internet governance (ICANN), global health (WHO), trade (WTO), standards (ISO)? Can the multi-stakeholder process that led to the Brussels Principles serve a model?

⁶³ See www.brusselsprinciples.org.

⁶⁴ KEI (2017) "Brussels Principles on Medication Sales over the Internet," Available: <https://www.keionline.org/23396>

Brussels Principles on the Sale of Medicines over the Internet

<https://www.brusselsprinciples.org>

Recognizing that:

- The World Health Organization estimates that over two billion people lack regular access to essential medical products (i.e. medicines, vaccines, and diagnostics), which is exacerbated by a lack of affordability and local availability.
- The Internet has served as a disruptive force to traditional industry in the practice of pharmacy and trade in pharmaceutical products, allowing for the international sale of medical products to patients with a prescription.
- Failure to regulate the sale of medical products over the internet, including failure to differentiate between legitimate online pharmacies and rogue websites, poses a major public health risk.
- Governments are neglecting their human rights obligations when their populations do not have adequate access to affordable healthcare, including access to medical products.

We affirm the following principles relating to the sale of medical products ordered for personal use over the Internet:

- Access to affordable medical products is a fundamental component of the right to health.
- Patients with a prescription should be able to use the Internet to order safe, quality and affordable medical products for personal use.
- National and regional legislation, regulation, and enforcement policies and actions should not prevent and/or deter patients with a prescription from importing safe, quality and affordable medical products for personal use.
- Governments, international organizations and non-governmental organizations should promote a competitive online marketplace for safe and quality medical products in order to protect and facilitate affordability and access for all populations.
- Policies that affect online access to medical products should aim to be evidence-based and patient-centered, including consideration of the fact that affordability and local availability can be significant barriers to access.
- National, regional and international regulatory efforts should promote guidelines and best practices to ensure that online pharmacies are a reliable and safe source of medical products for patients. They should also identify and, through enforcement actions, sanction those online marketplaces engaging in the intentional sale and distribution of falsified and substandard medical products, as defined by the World Health Organization, as well as the sale of medical products to patients without a prescription.
- Internet intermediaries, such as domain name registries, advertising networks, payment processors, financial institutions as well as physical and electronic mail and delivery services should not misuse their commercial power to disrupt online access to safe, quality and affordable medical products.

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