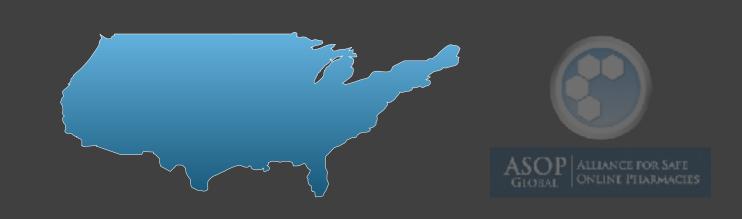


# **ASOP GLOBAL – LEGITSCRIPT ONLINE PHARMACY MARKET**



# SPOTLIGHT REPORT: THE UNITED STATES

# Abstract

The information presented in this report, compiled and analyzed by LegitScript at the request of the Alliance for Safe Online Pharmacies (ASOP Global), provides an overview of the Internet market for prescription drugs in the United States. This analysis summarizes the state of regulations and regulatory action in the US, and also assesses the risk presented to US Internet users who search for a prescription drug or pharmacy online. Data used in this analysis includes US search engine results for a range of prescription drug queries.

As detailed in this report, LegitScript finds that almost two-thirds (65%) of search results for prescription drug terms facilitate the sale of unapproved and dangerous medication to the US populace, leading to so-called "rogue" Internet pharmacies, most of which are operated by Russian or Eastern European organized criminal networks. A substantial portion of these illicit results are also represented by "so-called Canadian" online pharmacies that may have a business or pharmacy license in Canada, yet do not usually source the medicines sold to US residents from a real, licensed Canadian pharmacy. Note that our finding that 65% of prescription drug-related search results are illicit is not inconsistent with the commonly reported statistic that 97% of all Internet pharmacies are illicit: the former measures search engine results, while the latter measures all existing websites.

This report first outlines the state of Internet pharmacy regulation in the US, followed by an analysis of the online health threats to US residents, and the role of third-party facilitators. Finally, this report notes the important role that emerging initiatives such as .Pharmacy can play in reducing the incidence of illegal online drug sales in the United States.

July 2016

# ONLINE PHARMACY REGULATION IN THE US

## → Are Internet Pharmacies Permitted?

The short answer to this question is: Yes, as long as they adhere to all federal laws and regulations, and the laws and regulations of any state into which they ship drugs.

Internet pharmacies are permitted in the United States, but must adhere to the same laws and regulations as brick-and-mortar pharmacies. As a general matter, drugs must be FDA-approved and pharmacies must typically be licensed in any state to which they offer to ship medicines. There are a few states where only Internet pharmacies certified under the VIPPS<sup>1</sup> Internet pharmacy program can ship drugs (North Carolina, Kentucky, Indiana). In addition, Internet pharmacies selling controlled substances must be registered with the DEA and follow strict DEA Internet pharmacy regulations.<sup>2</sup>

Legitimate Internet pharmacies must be licensed in any states they offer to ship drugs into. In the US, pharmacies are licensed on the state-level, not federally. Each state has a board of pharmacy that regulates brick-and-mortar and non-resident pharmacies, including Internet pharmacies.<sup>3</sup> In addition, with the exception of over-the-counter (OTC) products, only drugs that are approved for sale by the FDA may be sold online.<sup>4,5</sup>

Prescription drug importation directly to patients is illegal as the United States Federal Food, Drug, and Cosmetic Act (the FDCA) prohibits the interstate shipment (which includes importation) of unapproved new drugs. Thus, the importation of drugs that lack FDA approval, whether for personal use or otherwise, violates the FDCA and is illegal.

## → What are some other resources regarding US Regulations?

The FDA makes information available on its <u>public website</u> about approved drugs and whether a prescription is required. Another resource for determining which drugs are FDA-approved is the <u>Orange</u> <u>Book</u>. It includes helpful patent information, so a user can quickly tell whether a generic version of a drug is approved. In addition, a description of the FDA drug approval process can be found on their websites.<sup>6</sup>

<sup>1</sup> http://www.nabp.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy

<sup>&</sup>lt;sup>2</sup> <u>http://www.deadiversion.usdoj.gov/fed\_regs/rules/2009/fr0406.pdf</u>

<sup>3</sup> http://www.nabp.net/boards-of-pharmacy

<sup>4</sup> http://www.fda.gov/Drugs/InformationOnDrugs/ucm135821.htm

<sup>&</sup>lt;sup>5</sup> Dietary supplements, which are sold as OTC products, do not need to be approved by the FDA.

<sup>&</sup>lt;sup>6</sup> http://www.fda.gov/drugs/developmentapprovalprocess/

# SEARCH SPACE METRICS

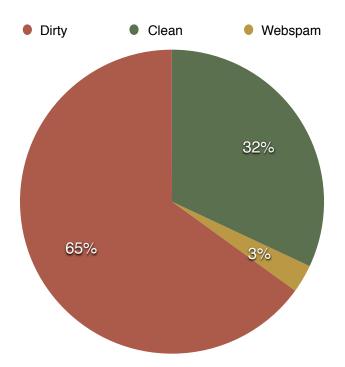
→How clean or dirty is the United States search environment for prescription drugs?

Although social media, phone sales and other media serve as vectors for the illicit sale of prescription drugs, our analysis assumes that search engines still play a central role as the platform that matches supply with online demand. As such, this analysis asks the simple question: when residents of the US use a search engine to seek to obtain prescription medicines online, to what extent are the options presented legitimate or, alternatively, illegal and potentially unsafe?

To obtain data for this analytical inquiry, in June 2016, LegitScript conducted five permutations of queries for six prescription medicines on both Google and Bing, capturing the first two pages of search results. The six products, Cialis, Pradaxa, Prevacid, Spiriva, Velcade, and Viagra, were chosen as they represent a variety of medical conditions and are well known popular products advertised and sold by Internet pharmacies.

# → Country-Specific Search Space Analysis

LegitScript's US prescription drug queries returned a total of 1,472 search results, including both organic (unpaid) and sponsored (paid advertising) results. In the United States for June 2016, we assessed the search space — what website results a patient searching for prescription medications will find — to be **32%** "**clean**" and **65%** "**dirty.**"



That is, 956 of the search results (65%) sent users to illicit Internet pharmacies,<sup>7</sup> hijacked (or hacked) websites leading to illicit Internet pharmacies, or search results that otherwise facilitate the sale and dispensing of unapproved

<sup>&</sup>lt;sup>7</sup> An Internet pharmacy is defined as a website with the primary purpose of selling medicine or pharmaceutical ingredients, including steroids or controlled substances, that are prescription-only or pharmacy-only in the patients' jurisdiction(s).

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versions of prescription medication. Among the 466 clean results, which represent 32% of the total search space, 350 (75% of the clean results) are for websites that only provide information about medications, and 116 (25% of the clean results) are for Internet pharmacies that appear to comply with applicable laws and regulations. The remaining 3% of search results are defunct "Web spam" - webpages that have been hacked with unauthorized content linking to illicit online pharmacies, but with links that have since been removed or become inactive. Had those hijacked results still led to illicit Internet pharmacies, those would have been considered dirty results, boosting the dirty ratio from 65% to 68%.

# → (So-Called) Canadian Online Pharmacies

It is important to note that many of the top dirty search results are for "so-called Canadian" Internet pharmacies, that may be registered businesses in Canada but do not always ship drugs from a Canadian pharmacy. Examples of these are canadianpharmacymeds.com and canadadrugs.com. These and other so-called Canadian pharmacies like them are businesses that may produce a Canadian pharmacy license and have a registered business address in Canada, but bi-furcate their supply chain: 1) if the customer is in Canada, the drugs are sourced from the Canadian pharmacy, but 2) if the customer is located in the US, the drugs often — in most cases, always — come from unlicensed retailers in India, Turkey or other countries. The transactions in these latter cases, which constitute most of the entities' business, are almost always illegal.

Within the data, 305 search results (21% of the total results and 40% of the dirty results) are for these so-called Canadian Internet pharmacies that do not solely provide Canadian products to US customers.

These businesses present an interesting subset of illicit Internet pharmacies: they are unquestionably illegal in general given that, 1) their primary business focus is serving customers in the US and other jurisdictions where they are not licensed, 2) they do not adhere to drug safety laws, e.g. they ship unapproved medications to US patients, and 3) they do not even source most medicines from Canada. However, solely as to serving customers within Canada, these pharmacies generally comply with Canadian laws and regulations. As such, they routinely advertise their products as safe Canadian medicines, but our actually selling substandard and unapproved products from foreign countries.

In total, the 65% of dirty results present significant patient safety risks within the United states. Many of these Internet pharmacies have been known to provide medication with incorrect amounts of active pharmaceutical ingredients, or products that are entirely counterfeit with no medical benefit.

From the 65% of illicit search results, LegitScript identified 265 unique illicit Internet pharmacies representing 55 distinct networks or groupings plus 29 unique websites unaffiliated with any known organized illicit network.

# TOP THREATS TO US RESIDENTS

Illegal Internet pharmacies rarely travel alone. Rather, the typical rogue Internet pharmacy by LegitScript's estimate, over 90% of the market — is part of a larger grouping, or "network," of anywhere from ten to 10,000 websites under common command and control.

This section highlights the networks or groupings of websites that constitute the greatest threats to residents of the United States, based on their visibility in search results.

#### **Rx-Partners**

#### Sample websites:

- safemedsrx.com
- mens-health-meds.net
- onlinebuynoprescriptionrx.com

The Rx-Partners criminal network is primarily run out of Russia and Eastern Europe, and boasts almost 4,000 active rogue Internet pharmacy websites. The network's websites sell prescription medication without requiring a prescription, and the drugs are not approved by the FDA and are illegally imported into the US from India and other countries.

Websites in the Rx-Partners network offer medicines in numerous categories, including: Antiallergic, Antibacterial, Antidepressants, Antibiotics, Hypertension, Cancer, Cholesterol, Diabetes, Erectile Dysfunction, Gastrointestinal, Mental Disorders, Muscle Relaxants, Parkinson's and Alzheimer's, Thyroid, Weight Loss, and more.

### PharmEmpire

#### Sample websites:

- medbankrx.com
- <u>rxpillsbuyonline.com</u>
- toprxpills.com

The PharmEmpire illegal online pharmacy network is relatively new, having formed at the end of 2015. Since then, LegitScript has observed a steady increase in the number of websites connected to this network. Currently, there are over 3,000 active rogue Internet pharmacies in this network, a strong showing for a relatively new network. PharmEmpire websites do not require a prescription and ship unapproved drugs worldwide and to jurisdictions where they are not permitted to do so; the drugs are unlawfully imported into the US.

The network offers products in the following categories: Allergy, Anti Fungal, Antiviral, Antibiotics, Anxiety, Arthritis, Asthma, Birth Control, Blood Pressure, Cholesterol, Depression, Diabetes, Gastrointestinal, Erectile Dysfunction, Heart Disease, Pain Relief, Sleep Aid, Weight Loss, and more.

## **Universal Drug Services (UDS)**

#### Sample websites:

- <u>northdrugstore.com</u>
- pharmacyrxworld.com
- <u>universaldrugstore.com</u>



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This is one of the so-called Canadian Internet pharmacy networks that operates with a Manitoba, Canada, pharmacy license and sells prescription drugs that are unlawfully imported from sources outside of Canada and the US and are thus considered unapproved or misbranded by the FDA to US residents.

The network offers medicines in these categories: Allergy, Alzheimer's, Antidepressants, Antipsychotics, Asthma, Blood Pressure, Cancer, Diabetes, Epilepsy, Erectile Dysfunction, Glaucoma, Parkinson's, and more.

#### Canada Health Solutions

#### Sample websites:

- canadadrugpharmacy.com
- canadadrugstop.com
- canadianpharmacymeds.com

Another so-called Canadian Internet pharmacy network unlawfully importing drugs from sources outside of Canada and the US - making them unapproved or misbranded by the FDA – and selling them to US residents. The network is

currently comprised of roughly 200 Internet pharmacy websites.

This network offers medicines in the following categories: Arthritis, Birth Control, Blood Pressure, Cancer, Diabetes, Epilepsy, Erectile Dysfunction, Cholesterol, Schizophrenia, Ulcers, and more.

#### York-Coastal Canada Pharmacy

#### Sample websites:

- doctorsolve.com
- onlinecanadianpharmacy.com
- onlinepharmaciescanada.com

Another so-called Canadian Internet pharmacy network, York-Coastal Canada Pharmacy consists of about 90 Internet pharmacy websites sourcing drugs from locations outside the US and Canada.

The network offers medicines in these categories: Acid Reflux, Acne, Arthritis, Asthma, Bronchitis, Cholesterol, Depression, Diabetes, Epilepsy, Erectile Dysfunction, Glaucoma, Pneumonia, Rheumatoid Arthritis, and more.



### → Measured a Different Way: Top-10 Illicit Internet Pharmacies by Website

As noted earlier in this report, there were 265 illicit Internet pharmacies — some of which were affiliated with a known network, while others are independent — that directly facilitate the sale of illicit medication. The following table identifies the top 10 Internet pharmacies based on their overall visibility to US patients. Each of these provide residents of the US with prescription pharmaceuticals unapproved for sale in the US and unlawfully imported into the country.

Domain Name	Network	Product Categories
canadadrugs.com	CanadaDrugs	Antibiotics, Allergy, Anti-Depressants, Asthma, Blood pressure, Cancer, Cholesterol, Diabetes, Gastrointestinal, Hair Loss, and more
canadianpharmacymeds.com	Canada Health Solutions	Arthritis, Birth Control, Blood Pressure, Cancer, Diabetes, Epilepsy, Erectile Dysfunction, Cholesterol, Schizophrenia, Ulcers, and more
daynightdrugs.com	Complete Online Pharmacy	Cholesterol, Depression, Diabetes, Erectile Dysfunction, Hair Loss, Hepatitis C, Hypertension, and more
canadianpharmacy365.net	Multi-Network Affiliation*	Allergy, Antibiotics, Arthritis, Asthma, Blood Pressure, Depression, Diabetes, Gastrointestinal, Heart Disease, Pain Relief, and more
planetdrugsdirect.com	PlanetDrugsDirect	Antibiotics, Allergy, Anti-Depressants, Asthma, Blood pressure, Cancer, Erectile Dysfunction, Hair Loss, and more
northdrugstore.com	Universal Drug Services (UDS)	Antidepressants, Antipsychotic, Asthma, Cancer, Cholesterol, Diabetes, Erectile Dysfunction, Migraines, Antibiotics, and more
viagrabestbuy.com	ViagraBestBuy	Erectile Dysfunction
canadadrugpharmacy.com	Canada Health Solutions	Arthritis, Birth Control, Blood Pressure, Cancer, Diabetes, Epilepsy, Erectile Dysfunction, Cholesterol, Schizophrenia, Ulcers, and more
buycheapcialisonline.biz	Multi-Network Affiliation*	Allergy, Antibiotics, Anxiety, Arthritis, Asthma, Birth Control, Blood Pressure, Cholesterol, Diabetes, Erectile Dysfunction, and more
hotcanadianpharmacy.com	Multi-Network Affiliation*	Antibiotics, Allergy, Anxiety, Asthma, Blood Pressure, Diabetes, Erectile Dysfunction, Herpes, Pain Relief, Sleep Aid, and more

\* Multi-Network Affiliation indicates the website in question directs patients to multiple Internet pharmacies that are connected to different networks.

# FACILITATORS

## → The effects of third-party policies

In the United States as in any other country, Internet pharmacies — whether legitimate or not need certain services to survive and thrive. Among them: 1) the ability to advertise and market their services, 2) the ability to get paid, and 3) the ability to obtain and retain a domain name or stable social media presence. The degree to which the rogue Internet pharmacy market is kept in check — or, alternatively, allowed to grow — depends in significant part on the policies that payment, shipping, domain name, e-commerce and other intermediaries implement. For each of the facilitator categories discussed, we have provided a grading to indicate the overall effort and effectiveness at keeping illicit Internet pharmacies from utilizing these various services.

#### Search Advertising: Grade = A+

For search engines available to US patients, Google holds the largest market share, with Bing at the second spot.<sup>8</sup> Both of these companies have robust policies and procedures for banning the use of their paid advertising services by illicit Internet pharmacy operators.<sup>9</sup> Within the data, there was one sponsored ad result for an illicit Internet pharmacy website (0.004% of the sponsored ad results) and the website was removed from the sponsored ad section within hours after identification.

A recent study by LegitScript on behalf of the Center for Safe Internet Pharmacies (CSIP) reviewed prescription drug related ads in the US and concluded that Google and Bing, collectively, only have an incidence of one in 600 prescription drug or pharmacy-related ads directing to illegal online pharmacies, or 0.18%.<sup>10</sup>

Social Media: Grade = C

Similarly, popular networking websites like Facebook and Twitter all have policies for identifying and removing illicit Internet pharmacy content from their <u>paid</u> advertising space. Here, the social media companies appear to block paid content. However, illicit online pharmacies are permitted to utilize free social media with little or no penalties. Moreover, policies that may, on paper, ban the use of social media by rogue Internet pharmacies are not consistently implemented: for example, <u>internationaldrugmart.com</u>, a rogue Internet pharmacy targeting the US among other jurisdictions, has a long-standing Twitter account (@idmart).

## Payment Compliance: Grade = A

According to available data, Visa and MasterCard have the most credit cards in

<sup>8</sup> http://www.statista.com/statistics/267161/market-share-of-search-engines-in-the-united-states/

In the interests of full disclosure, LegitScript conducts paid monitoring services for both Google and Bing, in which we proactively monitor their healthcare-related ads for illegal online pharmacies.

<sup>&</sup>lt;sup>10</sup> http://www.safemedsonline.org/wp-content/uploads/2016/01/The-Internet-Pharmacy-Market-in-2016.pdf



circulation, making these the most popular card brands.<sup>11</sup> Both companies have rigorous policies in place that prohibit the use of their payment networks for activity that is illegal either in the merchant's jurisdiction or in the jurisdiction of any possible cardholder.<sup>12</sup>

On the other hand, unlike Google and Bing, which have sole control over who uses their ad platforms, Visa and MasterCard rely on a network of acquiring banks to block bad merchants like rogue Internet pharmacies. While fewer rogue Internet pharmacies are offering Visa and MasterCard as payment options than before, in practice, the structure of the payment system makes it impossible for Visa and MasterCard to exercise preemptive control to block rogue Internet pharmacies. The designation of an "A" grade (instead of A+) merely reflects the intrinsic difficulty of ensuring that acquiring banks are fully aware of laws and regulations pertaining to pharmacy merchants, and accurately block bad merchants.

# US Domain Name Registrars and Registries: Grade = A

Lastly, it is important to note the overall compliance of the United States domain name registrars and registries in responding to abuse notifications regarding illicit Internet pharmacies — not only those Internet pharmacies targeting the US, but those housed at US registrars targeting other countries. For the global landscape, among the roughly 1,000 companies globally with domain name registrar accreditations, the majority have and enforce anti-abuse policies prohibiting illegal online pharmacies. Within that space, roughly 40%-45% of illicit online pharmacies are registered with just 10 domain name registrars that either do not have, or do not adequately enforce, policies prohibiting illegal prescription drug sales. In other words, nearly half of all active illegal Internet pharmacies are clustered with only about one percent of the possible registrars. This reflects the nature of illegal online pharmacy operators to choose a registrar carefully, finding those who they believe will offer protection against law enforcement or LegitScript (etc.) complaints.

Of the registrars sponsoring illegal online pharmacies, one, Key-Systems GmbH (based in Germany) is part of the Key-Systems Internet Solutions registrar group which does operate registrars based in the US. That being said, Key-Systems has been taking some intermediate steps in promoting Internet safety to protect public health. However, in order to see themselves fall out of the top problematic registrar list, Key-Systems needs to be able to process large abuse notifications effectively and consistently.

GoDaddy and eNom are the top two largest registrars in the world, and both are extremely compliant to abuse notifications. However, given the relative size of their portfolios, it is to some degree inevitable that they will always have some rogue Internet pharmacies on their

<sup>11</sup> http://www.cardhub.com/edu/market-share-by-credit-card-network/

<sup>&</sup>lt;sup>12</sup> In the interests of full disclosure, LegitScript conducts paid monitoring services for Visa, in which we proactively identify illegal online pharmacy merchants.



platforms. In fact, recent statistics list GoDaddy's portfolio at over 53 million domain names and eNom at almost 12 million.<sup>13</sup>

While the majority of US-based registrars are compliant to abuse notifications, or have little to

no Internet pharmacies in their portfolio, there are a few that remain fairly or entirely noncompliant. One in particular is GKG.net, Inc. However, this is a rare exceptions within USbased registrars.

# .PHARMACY INTEGRATION: LOOK TO THE RIGHT OF THE DOT

Of the various initiatives undertaken to address the problem of rogue internet drug outlets, one of the most promising is the .pharmacy Top-Level Domain (TLD). Launched in late 2014, this domain name suffix gives consumers around the globe an easy way to identify safe, legally operating internet pharmacies and prescription drug-related resources. The .pharmacy TLD is operated by the National Association of Boards of Pharmacy® (NABP®), which has been certifying internet pharmacies for 17 years and implementing public health solutions for over 100 years. Many of the 215 organizations currently certified through NABP's internet programs have already adopted the .pharmacy domain name.

Domain names in the .pharmacy TLD are available only to website operators that have been thoroughly vetted to ensure their compliance with pharmacy laws and practice standards, including those addressing pharmacy licensure and valid prescription requirements. As a global program, an important component of .pharmacy is ensuring that organizations are licensed and following the laws in the jurisdictions where they are based and where they conduct business. While NABP is spearheading the .pharmacy initiative, a global coalition of pharmacy community stakeholders is providing guidance to the program.<sup>14</sup>

At present, the .pharmacy domain is utilized in the US, as well as in other countries, and, as it becomes more widely adopted, will create a safe online environment for consumers. Among 175 known domain names ending in .pharmacy, 143 are registered to businesses in the US. These numbers are expected to rise as NABP begins to streamline its online certification programs into the .Pharmacy TLD Program and as community awareness of the .pharmacy TLD grows. Legitimate pharmacies should consider moving to a .pharmacy domain name to distinguish themselves from the large number of illicit online

<sup>13</sup> http://www.domainstate.com/top-registrars.html

<sup>14</sup> http://www.nabp.net/programs/pharmacy/pharmacy-and-nabp and http://www.safe.pharmacy/



pharmacies, and thereby better protect patients. It is a solution that is currently underutilized and has significant potential to grow the legitimate internet pharmacy market and protect the public health.

# CONCLUSION

No country is immune from the threat posed by illegal, unregulated prescription drug sales via the Internet. The United States is no exception: illegal Internet pharmacies seek to respond to (or create) demand, compromising almost two-thirds of the US search result space for prescription drugs. That is, **US residents who search for a prescription drug on the Internet have a two-in-three chance of selecting a website that operates illegally and unsafely.** While legitimate online pharmacies exist, and online drug sales are permitted, the two-thirds of search results considered illicit in the prescription drug market are generally operated from Canada, Russia, and Eastern Europe. These engage in risky behavior, typically selling prescription drugs without a prescription and always importing unapproved drugs into the US in violation of state and federal rule. Products sold by Internet pharmacies frequently are sourced from countries such as India, Turkey, and China and do not have regulatory approval in the country of origin or the country of destination, or are entirely counterfeit with little to none of the required ingredients.

But there are signs of hope in the US market. Most third-party facilitators, such as online advertising services and payment providers, have strict policies in place designed to hobble rogue Internet pharmacies. However, as the US market is a large focus for the illicit Internet pharmacy operators, US patient safety would greatly increase if third-party facilitators in other countries, especially domain name registrars, would show more consistency in taking action against illegal Internet pharmacies.

Additionally, among the most important ways to disrupt the rogue Internet pharmacy market in the United States is to reduce demand, thereby reducing the flow of revenue to the illicit businesses. With public education being a key component of demand reduction, legitimate pharmacies can play a role in boosting their own business and educating Internet users about how to tell the difference between legitimate and illicit online pharmacies by obtaining a .Pharmacy domain name. Pharmacy trade groups as well as regulatory authorities in the US should continue to make information about this program more available to legitimate, licensed pharmacies, while recognizing that the mere existence of a pharmacy license in the US will not permit the acquisition of a .Pharmacy domain name if the entity is violating other countries' laws.

LegitScript appreciates the opportunity to have conducted this research for the Alliance for Safe Online Pharmacies (Global).



## Appendix A: Internet Pharmacy Laws in the United States

Internet pharmacies are permitted in the United States, but must adhere to the same laws and regulations as brick-and-mortar pharmacies. As a general matter, drugs must be FDA-approved, pharmacies must typically be licensed in any state they offer to ship to, and with rare exceptions, only prescriptions dispensed by a medical practitioner who has physically examined the patient are lawful. See below for more detail.

#### Does the US permit the sale of medicine over the Internet?

<u>General rule</u>: Yes, as long as they adhere to all federal laws and regulations, and the laws and regulations of any state into which they ship drugs.

<u>Exceptions</u>: There are a few states where only Internet pharmacies certified under the VIPPS Internet pharmacy program can ship drugs (North Carolina, Kentucky, Indiana). A list of VIPPS accredited pharmacies can be found on the NABP website: <u>http://www.nabp.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy</u>. In addition, Internet pharmacies selling controlled substances must be registered with the DEA (see <u>http://www.deadiversion.usdoj.gov/fed\_regs/rules/2009/fr0406.pdf</u>) and follow strict DEA Internet pharmacy regulations.

#### Are pharmacies required to have a pharmacy license where they offer to ship drugs to?

<u>General rule</u>: Yes. If an online pharmacy offers to ship drugs to residents of a particular state, it must be licensed in that state. In the US, pharmacies are licensed on the state-level, not federally. Each state has a board of pharmacy that regulates brick-and-mortar and non-resident pharmacies, including Internet pharmacies.

<u>Exceptions</u>: Currently, Massachusetts provides reciprocity for out-of-state licenses. This may change soon, however. Also, some states permit a very small amount of drugs shipped into that state without a license there (New York, Alaska). Out-of-country pharmacy licenses are virtually never recognized or considered valid.

#### Do drugs need to be approved by a central authority for sale?

<u>General rule</u>: With the minor exceptions of OTC drugs, yes. Only drugs that are approved for sale by the FDA may be sold. A description of the FDA-approval process can be found here: <u>http://www.fda.gov/drugs/developmentapprovalprocess/</u>.

#### Is personal drug importation from outside of the US permitted?

<u>General rule</u>: No. The United States Federal Food, Drug, and Cosmetic Act (the FDCA) prohibits the interstate shipment (which includes importation) of unapproved new drugs. Thus, the importation of drugs that lack FDA approval, whether for personal use or otherwise, violates the FDCA and is illegal.

<u>Exceptions</u>: Practically speaking, none. Illegal Internet pharmacies will likely argue that it's permissible to import 90 days worth of prescription drugs from outside of the US. That's untrue, and it remains illegal.

#### Where can I get more information?

For additional information about a specific state board of pharmacy, see <a href="http://www.nabp.net/boards-of-pharmacy">http://www.nabp.net/boards-of-pharmacy</a>. All FDA-approved drugs are included in the Drugs@FDA database at: <a href="http://www.fda.gov/Drugs/InformationOnDrugs/ucm135821.htm">http://www.fda.gov/Drugs/InformationOnDrugs/ucm135821.htm</a>. Another resource for determining which drugs are FDA-approved is the Orange Book: <a href="http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm">http://www.fda.gov/scripts/cder/ob/default.cfm</a>. It includes helpful patent information, so you can quickly tell whether a generic version of a drug is approved.