



Online Pharmacy Guide for Acquirers

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Visa Inc.



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About this Guide

This document is a manual for acquirers who have boarded, or are considering boarding, an Internet pharmacy or Internet pharmacy referral merchant.

Visa Inc. partnered with LegitScript (www.legitscript.com) to create this publication. LegitScript is a compliance firm that focuses on healthcare product merchants, including Internet pharmacy and dietary supplement (also referred to as nutraceutical) merchants. LegitScript maintains a master database of Internet pharmacies that is widely used by regulatory authorities, search engines, domain name registrars, and credit card networks (including Visa Inc.). Visa Inc. works closely with LegitScript to identify instances of non-compliance with the *Visa International Operating Regulations*, and to analyze merchant compliance with applicable laws and regulations.

Visa Inc. encourages acquirers to utilize LegitScript monitoring and analysis to ensure that Internet pharmacy and nutraceutical merchants are compliant with the *Visa International Operating Regulations* with regard to Internet pharmacy-related requirements and applicable laws and regulations.

The following resources are included in the appendices:

- Model Internet Pharmacy Policy for Acquirers
- Legitimate Internet Pharmacy Verification Resources
- Where to Verify Pharmacy Licensure
- Country Summaries: Legal Requirements in Major Internet Pharmacy Target Markets

1. The Problem of Illegal Online Drug Sellers

As access to the Internet has exploded, so has the demand for healthcare products sold online. The global market for prescription medicines alone is estimated to have reached \$962 *billion* in 2012, with annualized growth through 2017 forecast at over 5%.¹

Set to surpass \$1 trillion annually, the size and growth of this market presents a real opportunity for acquirers. Unfortunately, alongside the legitimate market is a dangerous underground market of rogue Internet pharmacies which use healthcare product websites that fail to comply with basic pharmacy licensure, drug safety, and patient safety laws and regulations. The exact size of this market is anyone's guess, but rough estimates range from \$75 billion to \$430 billion. This estimate is *in addition to* the \$962 billion legal-drug market.²

The ratio of legal-to-illegal merchants has an inverse relationship in the offline and online markets. Offline "brick-and-mortar" pharmacies, the physical pharmacy that patients walk into to fill a prescription, usually operate legally and safely. As in any industry, illegal transactions and criminal activity do occur, but tend to be the exception and not the rule. By contrast, 97% of Internet pharmacy websites operate illegally, with only 3% estimated to be in compliance with applicable laws.³ Other complications occur when a pharmacy that is operating legally in the brick-and-mortar world potentially operates illegally in how it fills online orders, underscoring the fact that having a physical presence and pharmacy license are not necessarily proof of legitimacy.

Beyond Fraud and Intellectual Property to Public Health

These dynamics raise the stakes for acquirers who are considering boarding a healthcare product merchant. Risk management specialists may be used to viewing risk chiefly from the perspective of fraud, chargebacks, or intellectual property violations. But when it comes to Internet pharmacy merchants, the absence of an intellectual property violation or chargeback does not establish its legitimacy. It is entirely possible for an Internet pharmacy to sell falsified or unapproved medicines and/or sell prescription drugs without a prescription or valid pharmacy license, but violate no intellectual property rights. They may even provide superior customer service in the process.

Additionally, numerous fatalities, overdoses, and other adverse medical events have been linked to illicit online pharmacies, even those that can produce a valid pharmacy license. The combination of deadly results and financial liability have led to patient deaths, as well as to third-party facilitators being held criminally and civilly accountable.

Consider the following:

¹ http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/Press%20Room/Total_World_Pharma_Market_Topline_metrics_2012-17_regions.pdf

² See, e.g., <http://www.usatoday.com/money/industries/health/drugs/story/2011-10-09/cnbc-drugs/50690880/1>, <http://www.cfr.org/global-health/ensuring-safety-integrity-worlds-drug-vaccine-medicines-supply/p28256>

³ <http://www.nabp.net/programs/consumer-protection/buying-medicine-online>

- In a three-month period in 2011, a woman in Japan, 2 men in Ireland, and a paramedic in London all died from drugs acquired from unrelated Internet pharmacies.⁴
- “Licensed” Canadian Internet pharmacies have recently been tied to the sale of counterfeit cancer medications that contain no active ingredients, thus misleading cancer patients into believing that they are being treated, when in fact their cancer worsened.⁵
- An estimated 100,000 people die each year from counterfeit drugs. This number does not include deaths due to overdoses or other medical events from Internet pharmacy sales.⁶
- In 2011, Google paid a \$500 million fine to the U.S. Department of Justice for accepting advertisements from rogue Internet pharmacies.⁷
- In 2013, shipping company United Parcel Service (UPS) forfeited \$40 million to settle a criminal probe of its dealings with non-compliant pharmacy merchants.⁸

As shown by the examples above, boarding illicit online pharmacy merchants may not just be a violation of the *Visa International Operating Regulations* but can lead to significant health risks for cardholders and civil or criminal liability on the part of the acquirer, even if the acquirer was unaware of the illicit nature of the merchant’s business.⁹

Acquirer Obligations and the *Visa International Operating Regulations*

However, legitimate, fully compliant Internet pharmacy merchants do exist. And, as e-commerce becomes more interconnected acquirers will need the tools to distinguish between legitimate innovators seeking to provide better healthcare services to patients, and those who seek profits at the risk of patient safety. Where compliant, these businesses help patients by expanding access to life-saving medicines, reducing costs, and improving convenience. If operating legally at both the merchant’s point-of-sale and in the cardholder’s jurisdiction, these merchants can be legitimately boarded by acquirers.¹⁰

⁴ <http://sankei.jp.msn.com/life/news/110707/bdy11070720570002-n1.htm>, <http://www.examiner.ie/ireland/internet-drugs-linked-to-deaths-158146.html>, <http://www.dailymail.co.uk/news/article-1388795/Paramedic-Lorna-Lambden-died-overdosing-sleeping-tablets.html>

⁵ <http://www.cbsnews.com/news/fake-avastin-shipper-tied-to-canadadrugscom/>

⁶ <http://www.pharmaphorum.com/articles/partnerships-and-progress-on-counterfeit-medicines>

⁷ http://www.washingtonpost.com/blogs/post-tech/post/google-settles-with-justice-department-over-pharmacy-ads/2011/08/24/gIQAH9tPbJ_blog.html

⁸ <http://www.reuters.com/article/2013/03/29/net-us-ups-pharmacies-settlement-idUSBRE92S0DX20130329>

⁹ Some criminal statutes pertaining to the sale or marketing of unapproved drugs are “strict liability” — that is, it need not be proven that the facilitator knew that they were profiting from criminal activity. The current head of the FDA has stated her intention that more corporations and corporate executives be held civilly and criminally liable under this theory, commonly referred to as the Park Doctrine. See, e.g., <http://www.policymed.com/2011/11/the-park-doctrine-and-fdca-violations-holding-corporate-executives-accountable.html>.

¹⁰ Note that *Visa International Operating Regulations* disallow PSPs from providing payment services to Internet pharmacies and Internet pharmacy referral sites (ID#: 0026436).

TIP
1

Rogue Internet pharmacies are typically engaged in one or more of the four primary types of illicit behavior listed here.

1. The sale of prescription-only medicines without requiring a valid prescription as defined in the patient's jurisdiction.
 2. The sale of drugs that are considered "unapproved" in the patient's jurisdiction, or that lack market authorization, including drugs unlawfully imported into the cardholder's jurisdiction.
 3. The failure to obtain and maintain a valid pharmacy license where required.
 4. Conducting various types of fraud, or providing misleading statements as to the nature of the drugs or pharmacy business.
-

As with any high-risk market, evaluating risk and compliance can be complex, especially if the illicit merchants appear to be legitimate to acquirers. **The purpose of this document is to provide acquirers and Independent Sales Organizations (ISOs) with an overview of what it means for Internet pharmacies to be legitimate. It also provides some tools to better evaluate whether a pharmacy merchant should be boarded, and will assist in untangling what may seem to be a complex web of differing laws and regulations in multiple countries.** This document is also intended to help clarify the rules of the *Visa International Operating Regulations* regarding this merchant type, and to help prepare acquirers to respond to some of the various arguments or confusing tactics that less-than-compliant merchants may utilize.

2. Definitions: When is a Merchant an Internet Pharmacy?

What does it mean for a merchant to be an Internet pharmacy? Simply knowing that the merchant operates as a pharmacy is not enough. Some jurisdictions license brick-and-mortar pharmacies but restrict, or ban, Internet-based prescription drug sales making the evaluation of the pharmacy merchant's Internet activities critical. To start, you must understand the definitions of Internet pharmacy and of prescription-only (or pharmacy-only) medicine.

Internet Pharmacy

Visa Inc. uses the following definition in determining whether a merchant is an Internet pharmacy:

A merchant is an Internet pharmacy if it sells, dispenses or markets, or facilitates the selling, dispensing or marketing of, a prescription or pharmacy-only medicine in response to orders placed over the Internet.

Merchants that facilitate the sale of prescription or pharmacy-only drugs, but do not directly ship the drugs themselves, sometimes claim that they are exempt from having to comply with regulatory requirements because they are not a pharmacy, but merely an affiliate marketer. For example, a merchant may state that they only operate the website and are not personally responsible for shipping the drugs. Or, they may argue that they are not licensed as pharmacies, therefore they cannot be called an Internet pharmacy. These arguments should be rejected. Any facilitation of prescription drug or pharmacy-only drug orders conducted over the Internet should cause you to view the merchant as an Internet pharmacy.

TIP **2**

The difference between a brick-and-mortar pharmacy and Internet pharmacy can be blurry since a merchant can easily be both. Consider the situation where a cardholder purchases drugs over the Internet. The drugs must come from somewhere, and the source may be a licensed pharmacy.

This leads to the question of whether a particular healthcare product is a prescription-only or pharmacy-only drug, and how those terms are defined.

Prescription Drugs, Pharmacy-Only Drugs, and Over-the-Counter Drugs

Generally, drugs can be thought of as falling into one of three categories: prescription-only, pharmacy-only, and over-the-counter.¹¹ To briefly define these drug categories:

- | | |
|--|--|
| 1 Prescription-only healthcare products | These are medicines, treatments, medical devices, or other healthcare products that the relevant healthcare authorities (e.g., the U.S. Food and Drug Administration in the United States) have determined require medical supervision to be used safely and effectively. Medical supervision, in this context, means that the product should be used only following, and in accordance with, a licensed medical practitioner's order (i.e., a prescription). This means that the prescribing practitioner should have physically examined the patient and not merely reviewed an online questionnaire, although very rare exceptions do occur and are discussed later in this document. |
| 2 Pharmacy-only healthcare products | Not all jurisdictions have this category of medicines. For those that do, pharmacy-only drugs do not necessarily require a prescription but can be sold only at, and by, a licensed pharmacy. This may be for a variety of reasons such as necessary consultation with a licensed pharmacist or that the product could be one that is subject to misuse, such as pseudoephedrine which is an ingredient used to cook methamphetamine. |
| 3 Over-the-counter healthcare products | These are medicines, treatments, medical devices, or other healthcare products that the relevant healthcare authorities have determined are safe when used according to the instructions on the label. They do not require the same level of medical supervision as prescription-only drugs. |

Merchants selling healthcare products in either of the first two categories -- prescription-only or pharmacy-only -- should be thought of as pharmacies, and if selling such product via the Internet, as Internet pharmacies. Also, there are some jurisdictions where a pharmacy license or some other registration is required to sell over-the-counter medicines over the Internet. In such jurisdictions, these merchants should also be considered to be pharmacy merchants. At present, this is a minority rule.

How can one tell in which category a drug falls?

The attached appendix provides a list of resources that can be used to investigate whether a particular drug in a given country requires a prescription and/or may be sold only by a pharmacy. Most countries have a database of some sort that is published or maintained by the country's drug safety agency, such as the FDA.

TIP 3 Rogue Internet pharmacy merchants will sometimes argue that if a drug doesn't require a prescription in the country of origin (where the drug is shipped from), then it can be sold without a prescription anywhere the cardholder is located, even if the drug requires a prescription in the cardholder's country. This argument is incorrect. If a drug requires a prescription in the cardholder's country, then it must be treated as a prescription medicine, irrespective of whether or not it requires a prescription in the country of origin.

¹¹ These are not the only categories of drugs that exist, but for the purposes of any Internet pharmacy compliance discussion, these three are the most important to understand, and are the most common by far.

Prescription Drugs — More Than Just Controlled Substances

Acquirers should also be aware that controlled substance prescription medicines are just a subset of all prescription drugs. In other words, the fact that an Internet pharmacy merchant selling prescription drugs is not selling any controlled substances does not necessarily change the risk or compliance analysis at all.

Controlled substances include medicines with abuse potential, meaning medicines that may lead to a dependence or an overdose. Internationally, a global list of controlled substances is maintained by the United Nations Office of Drugs and Crime pursuant to the 1961 Single Convention on Narcotic Drugs. Most countries are signatories and may add other drugs to their controlled substances list beyond those identified pursuant to treaty.¹² Accordingly, there is a significant degree of uniformity across jurisdictions as to what medicines are also controlled substances, but also some disparities.

There is a wide-spread misperception that as long as a drug is not a controlled substance, it can be legally sold without a prescription, or based on an Internet questionnaire reviewed by an “online doctor” (without requiring a patient to see a doctor in person). In fact, this is hardly ever the case.¹³ For example:

- Common erectile dysfunction drugs like Viagra, Cialis, and Levitra are not scheduled as controlled substances. However, in most jurisdictions they require a prescription based on a doctor’s exam. Selling the drugs without a prescription is a criminal offense in those jurisdictions.
- Most cancer and HIV medications are not controlled substances but require a prescription from a licensed practitioner who has examined the patient in-person.
- Conversely, controlled substances are not necessarily prescription medicines. Drugs such as LSD and PCP cannot be sold at all, with or without a prescription.

TIP 4

Internet pharmacy merchants may claim that because they are not selling controlled substances, it is permissible for doctors to prescribe drugs to a patient they have never examined in person, via an Internet questionnaire. In fact, this is rarely permissible.

Controlled substances that can legally be sold almost always require a prescription based on an in-person examination, and additional restrictions frequently apply. The fundamental requirements that apply to Internet pharmacies that are outlined in the next section — the need for a valid prescription, pharmacy license requirements, bans against selling unapproved drugs, and prohibitions against imported drugs — all apply irrespective of whether the prescription drug is also a controlled substance.

¹² http://www.unodc.org/pdf/convention_1961_en.pdf

¹³ There are countries such as Turkey, where most non-controlled substances do not require a prescription, but in the countries that Internet pharmacies most commonly target — the U.S., Canada, China, Japan, EU nations — most non-controlled substances nevertheless require a prescription.

3. Core Principles of Internet Pharmacy Legitimacy

Around the world, there is a remarkable degree of uniformity regarding the laws and regulations pertaining to Internet pharmacies and online drug sales. There are four general rules for acquirers to remember that are mostly applicable across the globe. Of course, there are exceptions to these general principles. By and large, the first three general principles discussed in this section hold true. The fourth one is always true, both as a matter of law, and as per the *Visa International Operating Regulations*.

Though not a comprehensive list of all laws and regulations, acquirers should keep the following 4 general principles in mind:

1. Websites that allow customers to acquire a prescription drug, whether or not it is a controlled substance, based solely on an online form or questionnaire are usually illegal.
2. Pharmacies usually must be licensed in any jurisdiction where they offer to ship or dispense drugs.
3. It is usually illegal to import drugs from one country directly to a patient in another country.
4. Internet pharmacies must comply with the three principles above as they exist, not only in the jurisdiction where the merchant is located, but in any jurisdiction where the merchant offers to ship drugs.

Below is additional detail about these core principles, along with a discussion of some prominent exceptions to each rule. (Please see Appendix D for additional detail in specific jurisdictions.)

Rule #1: Prescription Requirement Based on In-Person Examination

General Rule: Any prescription medicine can be dispensed only based on a valid prescription. With some exceptions, this means that a prescriber must have a legitimate relationship with the patient that is based upon a prior in-person examination. As a general rule, merely allowing a customer to fill out an online form in lieu of receiving a physical examination from the prescribing practitioner is not considered legitimate.

Exceptions: In the United Kingdom, it is permissible in some circumstances for an Internet pharmacy to fill prescriptions based solely on an online consultation. The online consultation is not currently understood to permit the shipment of drugs prescribed in the matter to other EU member nations and should be limited to cardholders located in the UK.

In the United States, Utah also permits this practice in a very limited set of circumstances. However, the prescribing physician and patient must also be in Utah. Other states have taken regulatory action against pharmacies in Utah for shipping prescription drugs to patients in their state after reviewing only an online questionnaire.

**TIP
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Internet pharmacy merchants may claim that it is permissible for doctors to prescribe drugs to a patient after reviewing only an Internet questionnaire. By and large, this is a regulatory or legal violation. In the rare jurisdictions where this is permitted, the merchant pharmacy and cardholder (and typically, the prescriber) should all be in that jurisdiction.

**TIP
6**

Internet pharmacy merchants may claim that prescribing drugs to a patient after reviewing only an Internet questionnaire constitutes valid telemedicine. By and large, websites whose business practice focuses on providing online questionnaires for prescription drugs and dispensing medicines in response to such questionnaires are not considered to be engaged in the practice of valid telemedicine.

Rule #2: Pharmacy Licensure

General Rule: If offering to ship drugs into a particular jurisdiction (including, in the U.S., a particular state), a dispensing pharmacy must usually be licensed in that jurisdiction.

Exceptions: Some jurisdictions have reciprocity with other jurisdictions. For example, 2 states in the U.S. — Pennsylvania and Massachusetts¹⁴ — grant automatic reciprocity to any pharmacy licensed in another state. Some other states, such as New York and Alaska, require only licensure above a certain number of shipments. However, any online pharmacy merchant should be presumed to exceed these *de minimus* numbers if the drop-down menu includes those jurisdictions.

**TIP
7**

A pharmacy license granted in a jurisdiction other than the cardholder's is typically not considered valid in the cardholder's jurisdiction.

In the EU, pharmacy licensure in the EU member state is generally required. This usually means that the pharmacy is also domiciled in that EU member state, although exceptions do exist (e.g., Germany).

There are three central reasons that merely being able to produce a pharmacy license does not conclusively establish legitimacy:

1. There is no assurance that the merchant is actually dispensing drugs from that pharmacy.
2. If the customer is not in the same jurisdiction as the licensed pharmacy, the pharmacy regulator loses jurisdiction to respond to complaints and regulate transactions.
3. If the drug transaction does not take place within a single closed jurisdictional system, the drug safety authority, such as the U.S. Food and Drug Administration or UK Medicines and Healthcare products Regulatory Agency, effectively loses jurisdiction to ensure drug authenticity and safety.

¹⁴Massachusetts will likely join other states in requiring in-state licensure soon, however.

Rule #3: Drug Importation

General Rule: Prescription drugs imported from a supplier (including a pharmacy) in one country directly to a patient in another country are virtually always considered unapproved for sale. Thus, Internet pharmacies shipping drugs to patients from another country usually operate illegally.

Exceptions: Very few, although the laws in the EU are in flux on this point.

In Japan, there is an extremely narrow and tightly written exception permitting limited importation into Japan. Acquirers should not conclude that this means that prescription drug importation is permitted. The exception bans the marketing or promotion of unapproved drugs, essentially making any website that lists those products automatically non-compliant.¹⁵ If an Internet pharmacy is shipping prescription drugs into Japan, the default status is that the website is not legally compliant.

Additionally, as of 25 October 2013, the Cross Border Healthcare Directive 2011/24/EU (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF>) came into force throughout the EU. This Directive clarifies the rights of patients to access and obtain reimbursement for legitimate healthcare treatment in another EU member state, and may open up some avenues for Internet pharmacy merchants to dispense drugs to patients in other EU member states. However, the Directive explicitly states that individual EU member nations' regulations pertaining to Internet pharmacies are not superseded by the Directive (see paragraph (11)). Consequently, as of this writing, it does not appear that the directive supersedes individual member nations' requirements for pharmacy licensure or prohibitions on Internet pharmacies.

Within the EU, there are also some very specific exceptions. For example, Germany has approved some pharmacies in a limited set of other countries, such as Iceland, and these pharmacies are permitted to ship to residents of Germany.

TIP 8

There is a widespread misperception that it is lawful to import up to a 90-day supply of non-controlled prescription drugs into the U.S. or other countries. This is false, especially as it applies to Internet pharmacies. In the U.S. there is enforcement discretion for Customs officials to permit up to 90 days worth of illegal drug importation based on extremely narrow circumstances, such as the drug to be unavailable in the U.S., among other requirements. Any Internet pharmacy that makes drugs available to be shipped from one country to cardholders in another country is usually operating illegally.

Another exception is that this rule does not necessarily pertain to business-to-business transactions when the supplier is a legitimate pharmaceutical manufacturer and the purchaser is a licensed drug wholesaler. Importation in these cases is also restricted, and merely being able to provide a wholesaler license in one country does not establish permission to import drugs into another country.

¹⁵ A website that does not list any drugs on the website but provides a phone number or physical address where patients can call to check availability would potentially comply with the requirements. A recent review was conducted of several hundred Japanese-language Internet pharmacy websites by LegitScript, resulting in a finding that under 1% of Internet pharmacies importing prescription drugs into Japan actually complied with the narrow exception.

Despite the existence of some exceptions, the general rule is that drug importation directly to patients is considered illegal, and any exceptions tend to be very narrow. It is highly unlikely that a merchant is legally compliant when their drop-down menu of possible shipping locations includes jurisdictions in which it is neither domiciled nor licensed.

Rule #4: Dual Jurisdictional Compliance

General Rule: If the pharmacy merchant is in a different country than the cardholder, the merchant must comply with the laws and regulations in the cardholder's country as if it were physically located in that country.

Exceptions: None.

TIP 9 Pharmacy merchants sometimes state that because they are located outside of the cardholder's country, they need not comply with the laws and regulations of that country because they are exempt from that country's jurisdiction. That argument is contrary to most countries' laws and regulations and to the *Visa International Operating Regulations* (ID#: 0000385).

These 4 general principles are not comprehensive. As a basic rule, if an online pharmacy is in violation of any of these general principles, it should typically be seen as a rogue Internet pharmacy, unless it clearly falls within an exception to the rule.

4. Acquirer Requirements and Best Practices

Although no 2 merchants are exactly alike, the following standard policies and practices can help acquirers and ISOs manage risk relating to Internet pharmacies. You can also refer to the following document located in the Appendices:

- Model Internet Pharmacy Policy for Acquirers and ISOs

Visa Inc. Requirement: High Brand-Risk Acquirer License

Visa Inc. requires that any acquirer register with Visa Inc. to receive a High Brand-Risk Acquirer license prior to boarding a card not present / Internet pharmacy merchant. Information about this process can be found in the *Visa Global Brand Protection Program Guide for Acquirers*.

Failure to register with Visa Inc. may result in fines and penalties assessed under the *Visa International Operating Regulations* (ID#: 0026379, 0026380). Additionally, acquirers may be subject to the imposition of risk conditions which may include: the requirement of an onsite operational audit, at the acquirer's expense, to identify program gaps, prohibitions from acquiring certain merchant types or agent segments, termination of existing merchants or agents, or removal of the acquirer's Visa Inc. acceptance privileges.

Acquirers should also be aware that agents and merchants knowingly engaging in or facilitating illegal activity, including but not limited to the unlawful sale of healthcare products, may be subject to civil or criminal penalties from law enforcement authorities.

Model Policy

A model Internet pharmacy policy is attached to this document. Whether you use it verbatim or not, acquirers should maintain a clear policy for boarding and maintaining Internet pharmacy merchants. Your policy should not only make your boarding requirements simple, but should also clearly state your requirements for continuing the relationship. At a minimum, your policy should incorporate the following requirements:

- A prohibition against selling regulated healthcare products in a way that violates the laws and regulations of either the merchant's or any potential cardholders' jurisdiction.
- A clear definition of what activities will cause a merchant to be viewed as operating as an Internet pharmacy merchant.
- For specific jurisdictions, that the merchant maintain a valid certification with one or more third-party Internet pharmacy certification authorities recognized by Visa Inc.
- That any domain name used to facilitate the sale of prescription medicines be registered accurately, non-anonymously, and to the merchant.
- That the merchant disclose, on the website, contact and location information for all dispensing pharmacies and other suppliers, a way for patients to contact a pharmacist, jurisdictions where the merchant offers to ship drugs, and the merchant identifier.
- That the merchant provide at the time of boarding, and at set intervals thereafter, the documentation listed in "Underwriting an Internet Pharmacy" below.

- The merchant inform the acquirer about any actual or potential disciplinary action within 48 hours of learning about such action.

Underwriting an Internet Pharmacy

In underwriting an Internet pharmacy merchant, there are certain documents you should always collect and require the merchant to re-submit at regular intervals. These include all pharmacy licenses and internal policies pertaining to drug supply and dispensing procedures.

Government Credentialing

What to Request: Pharmacy licenses in each jurisdiction where the merchant offers to ship prescription drugs to. Or, information showing that the jurisdiction explicitly recognizes pharmacy licenses in the merchant's jurisdiction. You should also request the pharmacist license for all pharmacists and any physician or other medical practitioner employed by or contracted with the business.

Frequency: Annually.

Every jurisdiction requires governmental credentialing of pharmacies in some way. Verifying active pharmacy licenses, as well as the licenses of pharmacists in charge of day-to-day operations, should be a first step in the underwriting process. Some jurisdictions will require formal copies of licensure to be made by the accrediting board, rather than from the pharmacy. In any case, license numbers are typically required to be displayed, and generally are easily verified, with the accrediting body.

Additionally, the sale of certain products such as controlled substances, pseudophedrine, isotretinoin, etc., require additional accreditation depending upon the jurisdiction. For example, in the U.S., the previous items would need DEA registration, Combat Methamphetamine Certification, and iPledge certification, respectively. Insurance companies often request information such as DEA numbers and NPI numbers, so this is documentation that the pharmacy should have readily available, if applicable.

Exception: Be careful when businesses present wholesaler licenses. These licenses are typically easier to obtain for a business, but do not generally permit the sale of drugs to patients. Instead, these licenses allow the sale of drugs between commercial businesses. Often, an illegal pharmacy will represent itself as legitimate by suggesting its wholesaler license permits the sale of drugs to patients. This is not a true statement.

Some jurisdictions require that a pharmacy be owned or operated by a licensed pharmacist (e.g., Korea or North Dakota). In these jurisdictions, more scrutiny should be placed on the pharmacist in charge. These jurisdictions often require that the pharmacist in question work or supervise only in a small number of practice locations at a time.

Policy Documents

General Rule: Real pharmacies have policy documents on a wide variety of topics, however the presence of these policy documents does not establish legitimacy. The underwriting process should require that the documents be provided to the acquirer.

Sufficient policy documents are not merely boilerplate language on a website, but instead include specific procedures for different types of events. These documents may pertain to consent agreements with governing authorities, applicable privacy protection laws, adverse medical event reporting, shipping procedures for heat sensitive medications, and document retention plans. These policy documents are the tools pharmacies use for compliance with the vast number of applicable regulations.

As an acquirer, it may be unmanageable to become an expert in every area of pharmacy law across all jurisdictions in order to proofread these documents. Instead, get a feel for how exhaustive these documents are. The more thorough the policies are, the more likely the pharmacy is complying with its local laws. Feel free to question any portion of the policies. A legitimate pharmacy should anticipate most, if not all, of the questions you may ask regarding its policies. For detailed review, you may wish to contract with a pharmacy practice expert and/or law firm with expertise in the jurisdiction.

Exception: None. Pharmacies in any jurisdiction should have and maintain policy documents, whether or not explicitly required by regulation. If they do not have such documents, they should develop them.

Inventory Sourcing

General Rule: Most countries have what is known as a “closed source drug system” or a “closed-chain drug supply.” This means that drugs must be approved by the jurisdiction the pharmacy is selling or shipping to. Some jurisdictions have a slight variation of this practice making it acceptable for drugs sourced from specific countries to be shipped directly to the pharmacy instead of the patient. Pharmacies typically source drugs from a few wholesalers, or middle men, between manufacturers and pharmacies. Pharmacies should thoroughly vet these wholesalers and have records documenting licensure or applicable accreditation of any wholesaler with which it does business. It should be noted for greater scrutiny anytime a wholesaler is located in a country other than the country of the pharmacy.

Accordingly, as part of the underwriting process you should request information about the pharmacy merchant’s source of, and supply chain for, the drugs it receives.

Exception: Occasionally, a pharmacy will source its drugs from manufacturers, but this is extremely rare. Anytime this occurs, increased scrutiny should occur.

Prescription Processing

General Rule: Prescriptions from prescribers may be received only through specific means. Most jurisdictions allow practitioners to deliver prescriptions to a pharmacy by fax, telephone, or electronically. Patients may mail or hand deliver a physical prescription, written by the prescriber, to the pharmacy. This is an important distinction. It is generally not permitted for a patient to call, fax, email, or scan in their own prescription. At no time should a patient have both a physical prescription and the drugs that were prescribed.

Accordingly, you should request information about the pharmacy's prescription processing procedures.

Exception: At times you will see pharmacies that allow a patient to send the prescription electronically, but then request the prescriber's information. The only time that this is acceptable is if the pharmacist contacts the prescriber and receives a new prescription. The pharmacist then fills the new prescription that was received from the prescriber, and not from the patient submitted copy. While this practice may be technically legal, it is generally frowned upon by regulators as it allows the patient the possibility of filling their physical copy of the prescription at a second pharmacy. This practice should always be subject to heightened scrutiny.

Domain Name / Licensure Disclosure Requirement

As part of the underwriting process, you should require disclosure of all domain names registered by, or otherwise controlled by, the merchant. If the merchant is, or is connected to, an affiliate marketing program, you should require disclosure of all domain names that are part of the program. You should ask for the merchant to disclose any and all websites that are somehow connected to their business, and require them to explain the nature of the connection. Domain names should be disclosed even if there is no active content (that is, if the domain name has been registered but is simply an empty page), since the domain name registration information may provide more insight into the merchant's existing business as well as any new lines of business that the merchant may be contemplating (e.g., if the domain name itself contains a particular healthcare product).

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Require the merchant to submit all domain names associated in any way with their business. Require that the domain names be registered accurately and non-anonymously, and for online pharmacies, that there be a logical connection to the dispensing pharmacy or pharmacy's parent corporation.

Additionally, you should require that all domain names be accurately and non-anonymously registered. If the domain name is used as an online pharmacy the registration must have some logical connection to the dispensing pharmacy or corporation.

To explain this, domain name registration information — commonly referred to as “Whois” information — typically contains fields such as the registrant's name and (if applicable) business, address, phone number, email address, and other fields. However, many domain name registrars offer privacy services, in which the Whois information exists behind a privacy wall. Use of that privacy wall is at the discretion of the registrant, and disclosing the Whois information is a straightforward process. Non-anonymous registration is the default status for Whois records in most cases.

There are several important reasons to require that the Whois registration be accurate, non-anonymous, and have some logical connection to the dispensing pharmacy or parent corporation.

1. Registration of a domain name facilitating prescription drug sales by someone other than the pharmacy, pharmacist-in-charge, or pharmacy business owner indicates the possible existence of an affiliate pharmacy program. You need to know who is actually responsible for the website, the processing of orders, and the information received via the website.
2. A common “bait and switch” tactic used by illicit online pharmacy operators is to provide acquirers with a valid pharmacy license, but route prescription drug orders elsewhere. In other words, the pharmacy license exists, but is completely irrelevant to the drug supply chain as the drugs come from somewhere else. The likelihood of this is reduced if the pharmacy is the actual domain name registrant.
3. Transparent, non-anonymous domain name registration provides a degree of accountability. Rogue Internet pharmacy operators frequently utilize anonymous or falsified Whois information.

Ongoing Monitoring: What to Look For and Pitfalls

Ongoing monitoring of Internet pharmacy merchants requires a continuing focus on compliance with applicable regulatory requirements, continued transparency, specialized knowledge, and a focus on pharmacy best practices.

As with any merchant, there is no substitute for eyes-on, in-depth understanding of what your merchant is doing. The following best practices will help alert you to potentially problematic developments or changes in the merchant’s practice that require your attention. These can be divided into 2 categories: pharmacy practice monitoring and technical (website) analytics.

Pharmacy Practice Monitoring

1. **Pharmacy licensure/Policy documentation.** Pharmacy licensure — typically in all jurisdictions where a merchant offers to ship drugs to, absent some sort of reciprocity — is an ongoing requirement in virtually every jurisdiction worldwide. Licenses are typically renewed every one or 2 years. As a best practice, you should monitor or request monitoring of all applicable pharmacy license databases for licensure status. See Appendix C for a list of selected pharmacy licensure verification resources.

Requiring that the merchant disclose the pharmacy license is only the first step in this process. Rogue Internet pharmacies have frequently forged pharmacy licenses, and you should directly obtain the pharmacy license from, or confirm it with, the regulatory authority.

Typically, legitimate Internet pharmacies will not have an associated medical practitioner (e.g., a physician) because online prescribing is illegal in most jurisdictions without a prior in-person examination. However, in the few jurisdictions where it is lawful, you should give the prescribing practitioner the same degree of scrutiny as the dispensing pharmacist or pharmacy.

2. **Monitor the disciplinary record.** The role of regulatory agencies for pharmacies, pharmacists, and other medical practitioners is to impose discipline in appropriate cases. Ideally, your merchant will not have any disciplinary history. But if they have, you should know about it. Depending upon the country, this information is usually available at online pharmacy licensure verification websites operated by pharmacy regulators (see Appendix C). However, some jurisdictions do not release full (or any) disciplinary history without a waiver from the pharmacy and/or pharmacists. Accordingly, you should

require the merchant to disclose the existence of any past discipline and, if necessary, agree to sign a waiver permitting the applicable regulatory authorities to release information to you about the discipline and antecedent violation.

In addition to requiring the merchant to disclose the existence of any past discipline, you should monitor the regulatory agency's disciplinary rosters, which are often — but not always or not in full part — public. A quarterly review of each jurisdiction in which the merchant pharmacy is required to maintain licensure is optimal.

3. Monitor the content. Any change in the content of the website should trigger a re-review, but pay special attention to the following types of content modifications.

- **Prescription requirement.** Any language in the document, or any change in the process of ordering, suggesting a change to whether a prescription is required, or if the prescription is based solely on an online consultation, which is typically not legal.
- **Listed products (drugs).** What products is the merchant offering? Monitor to determine if a merchant previously offering only over-the-counter drugs or dietary supplements adds prescription medicines to their product roster. Moreover, you should be aware of whether the product is approved for sale in the cardholders' jurisdictions.

In the same vein, you should monitor for whether drugs offered by the merchant have been subject to regulatory action (e.g., withdrawal from the market for safety reasons). In such cases, the merchant often should no longer offer the drugs.

- **Shipping Destinations.** This is a particularly critical data element to monitor. Some pharmacy merchants acquire accounts based on a pharmacy license and legal compliance in a single jurisdiction, but subsequently proceed to ship to multiple destinations where they lack licensure and are otherwise legally non-compliant. It is critical to monitor the list of locations where the pharmacy offers to ship drugs to, since this will trigger a requirement that the merchant be licensed and legally compliant in that jurisdiction. This is ideally reviewed on a monthly basis at a minimum.
- **Address/phone/other contact information.** Any legitimate pharmacy merchant should always disclose their location and a way for patients to contact the pharmacist. Any change to the content or accessibility of this information should be monitored.

Technical Analytics

1. Monitor Whois/DNS changes. Any modification to the technical information about an Internet pharmacy website may be innocuous, but could also be indicative of a change in control or operations of the business. Among the technical data points that you should monitor are:

- Whois record
- Registrar
- IP address
- Name Servers
- Mail server (if any)
- Start of Authority (SOA) record

A change in any of the fields above is not necessarily indicative of a problem. For example, IP addresses, in particular, may be dynamic (as opposed to static) as a matter of course. However, as the acquirer, you should be aware of any changes to these fields, and follow up with analysis aimed at determining whether the change portends any modification to the pharmacy business operations.

2. Monitor all websites under shared control / Whois. As the acquirer, you should maintain full awareness about any website that reasonably appears to be under the shared control of the merchant. You can generally presume that any other domain name sharing the same Whois information, in particular the email address, is operated by the same merchant. Websites using the same other fields, such as IP address, name servers, or mail server may or may not be connected.

A Word About Nutraceuticals

Like prescription and over-the-counter drugs, laws and regulations pertaining to nutraceuticals (also called dietary supplements) vary significantly around the world. This document is not intended to provide a comprehensive overview regarding nutraceutical-related compliance and risk. However, there are instances in which websites seemingly selling only nutraceuticals will not comply with drug safety laws and regulations.

Broadly speaking, there are 2 instances in which nutraceuticals tend to trigger additional regulatory scrutiny: first, if the product is tainted with an active pharmaceutical ingredient; or second, if the product is marketed in a way that implies it is safe or effective to cure, treat, or prevent a medical condition. In the first scenario, a product marketed as a nutraceutical, but contains the same active ingredients as a prescription drug should simply be viewed as a prescription drug, a drug that, if marketed truthfully and accurately, would be subject to requiring a valid prescription, drug approval, and pharmacy licensure. Of course, in such cases, the nutraceuticals are being marketed deceptively with undeclared ingredients and would not qualify for a valid prescription or drug approval, and therefore would violate the *Visa International Operating Regulations* (ID#: 0001303, 026363). In the second situation, either drug safety or consumer protection regulatory authorities in most countries prohibit products from being marketed with language implying that they cure, treat, or prevent a medical condition, unless that product has been approved for that purpose by the relevant drug safety authority.

LegitScript maintains a searchable list of problematic healthcare products, including supplements, classified according to risk levels at legitscript.com. The LegitScript database includes information on whether healthcare products have been found to contain active pharmaceutical ingredients, have been identified as unsafe, or are misleadingly marketed. LegitScript has released an application programming interface (API) for acquirers and other third parties.

5. Addressing Grey Areas: Salvageable or Not?

Rogue Internet pharmacies engage in activity that is not merely technically illegal. Rather, such websites have been tied to serious harm, overdose, addiction, and even death. On the other hand, there are infrequent cases of Internet pharmacies that are generally legal, but engaged in minor, fixable, regulatory violations. As an acquirer, you need to know when to engage the merchant and recommend remedial action, and when you should simply not do business with the merchant at all.

Although even minor regulatory violations should never be endorsed or permitted, as a practical matter, the most attention should be given to websites engaged in intentional or knowing violation of applicable pharmacy licensure and drug safety laws. The following tables are meant to demarcate behavior that should result in termination of the relationship from behavior that is generally considered fixable.

In the table below, any one of the behaviors below should be considered sufficiently egregious so as to warrant termination of the business relationship.

Behavior Warranting Termination	Exception
Failure to require a valid prescription based on prior in-person exam for prescription drugs. This includes a prescription issued solely based on an online consultation or filling out an online form.	Very few jurisdictions permit online consultations in lieu of an in-person exam. An exception can be made if online consultations are permitted in the patient's jurisdiction where the Internet pharmacy targets customers.
Sale of unapproved or falsified drugs.	Some compounded drugs fall outside of the scope of drug approval requirements. A small number of drugs that have not been reformulated in the U.S. since before the 1960s have either been grandfathered in to legal compliance or are tolerated by the FDA, despite not being reviewed by the FDA.
Unlawful importation of drugs.	As noted in section 3. Core Principles of Internet Pharmacy Legitimacy, Rule#3 Drug Importation, there are very narrow exceptions to prescription drug importation bans that exist in most countries.
Failure to maintain pharmacy licenses in jurisdictions where the Internet pharmacy is targeting customers.	There are a limited number of jurisdictions that recognize, or have reciprocity with, another jurisdiction for pharmacy licensure. An exception may be made for unintentional behavior. For example, a dispensing pharmacy is licensed nearly everywhere required and a license appears to have inadvertently lapsed.
Use of website for phishing, spam, or other malicious behavior.	None.

By contrast, there are a few types of behavior that constitute regulatory violations, Internet pharmacies should be encouraged to fix this behavior. However, these may not warrant terminating the business relationship, standing alone.

Fixable Behavior	Exception
Failure to maintain and post legally required privacy policies (e.g., under HIPAA) and security protocols.	Suspension may be warranted if the problem is chronic and is known to put patients' private health information at risk.
Failure to provide the full contact information on the website for the dispensing pharmacy.	This is a legal requirement in some jurisdictions, and providing full contact information for the pharmacy is highly encouraged.

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Any one of the following activities is sufficiently illegal and dangerous that it serves as a basis for terminating your relationship with a merchant.

- The sale of prescription-only medicines without a valid prescription.
 - Failure to maintain valid pharmacy licenses in required jurisdictions.
 - Sale of unapproved or illegally imported drugs.
 - Spam, phishing, or botnets.
-

6. Resisting Obfuscation Tactics

Because of the large profits associated with illicit medicine sales online, rogue Internet pharmacy merchants are highly motivated to falsely appear legitimate to acquirers. This section describes some obfuscation techniques that you should be aware of.

Due to the high levels of obfuscation and illicit activity tied to affiliate marketing networks, this section first describes and discusses Internet pharmacy affiliate marketing networks.

Internet Pharmacy Affiliate Marketing Networks

Affiliate marketing networks play a central role in the underground online pharmacy market. Internet pharmacy monitoring service LegitScript, which assisted in the writing of this report, estimates that over 95% of all Internet pharmacy websites are part of an affiliate marketing program, and estimates that there are over 100 affiliate pharmacy marketing programs in existence.

Affiliate marketing programs are networks in which a central business recruits website operators to create and market their own websites (typically using a prepared template), and routes orders through the network to a supplier. The supplier often is not a pharmacy, but rather contracts with suppliers. A merchant associated with a rogue Internet pharmacy may be the affiliate marketer, the pharmacy or other drug supplier, or the network business owner.

Affiliate marketing networks are not *per se* illegal when marketing prescription drugs. But, the fundamental structure of an Internet pharmacy affiliate marketing network is highly incompatible with pharmacy compliance for two fundamental reasons:

- A central tenet of pharmacy legitimacy pertains to the transparency of operations afforded by the regulatory oversight provided by a pharmacy licensing scheme. By contrast, affiliate marketers virtually never disclose, and may not even know, where the drugs are coming from, who dispenses the drugs, or who runs the network.
- The structure of an affiliate marketing network affords merchants various alleyways in which to conceal their activities. For example, several affiliate marketing networks have an online pharmacy branch and a dietary supplement branch. The network, or key affiliates, create merchant accounts for the latter, which is less regulated, but illegally process orders for prescription drugs.

Acquirers should be aware that a single affiliate marketing network may have dozens of merchant accounts, as well as multiple payment portals. For example, one rogue Internet pharmacy network monitored by LegitScript has over 6,000 affiliated Internet pharmacy websites as of this writing, and nearly 20 dedicated payment portals linked to multiple merchant accounts.

Geo-targeting

One obfuscation tactic utilized by rogue Internet pharmacy operators is called geo-targeting, which refers to showing different Internet users different content depending on the Internet user's IP address, browser, or some other indication.

To explain how this works, when an Internet user visits a website, the website can automatically determine a variety of information about the visitor, including the visitor's IP address, type of browser, and operating system. This affords merchants the ability to analyze whether the acquirer is visiting their website and modify the content based on the acquirer's location.

Several rogue Internet pharmacy networks have been known to geo-target by either displaying seemingly legitimate content or operating legitimately (for example, properly requiring a prescription) if the Internet pharmacy is being accessed from an IP address that the merchant believes to belong to the acquirer, a search engine advertising program, a regulatory authority, or an Internet monitoring service such as LegitScript. But for the rest of the Internet, the illicit content will be displayed or a prescription will not be required. Below are two real-life examples provided by LegitScript.

Example 1: A merchant who was able to produce a Canadian pharmacy license, and who was physically located in Canada, marketed his business online as a legitimate Canadian Internet pharmacy. However, the real business model was to illegally ship drugs, diverted from locations such as India and Turkey, to U.S. residents. This merchant made sure that no Canada-based cardholders could actually order drugs from the website in order to evade regulatory scrutiny since direct drug importation to Canadian residents is illegal. To do this, the Canadian Internet pharmacy operator did not display drug-related content if the website visitor was from a Canadian IP address, but if the visitor was from a U.S. IP address, the drugs were fully available.

Example 2: An Internet pharmacy website either does not accept orders, or displays only dietary supplements, if accessed from an IP address that the merchant believes belongs to a credit card network or acquirer. For the rest of the Internet, the prescription drugs are openly displayed and sold without a prescription.

The remedy to geo-targeting is to ensure that the merchant's website is being accessed from a variety of locations, for example, using proxy IP addresses. Alternatively, consider using TOR (available at www.torproject.org), which is a free browser software that enables online anonymity. Any variation in content when viewed from multiple IP addresses should be closely scrutinized.

The Bait and Switch

The "bait and switch" refers to merchants that initially offer only dietary supplements, or some other innocuous product, but add other products such as prescription drugs after being acquired.

A more subtle but equally problematic version of this involves merchants who list only non-prescription products on their website, but after the cardholder places an order they contact the cardholder to offer prescription drugs or other regulated healthcare products in attempting to bypass any scrutiny or monitoring by the acquirer.

The remedy to the bait and switch is simple—monitoring must be ongoing and involve full awareness of the products offered by the merchant. The bait and switch most commonly hides behind dietary supplement sales, which are being used as a front. Since some supplements are marketed or used in relation to a specific medical condition, customers form a ready pool of targets for the real business which is that of the Internet pharmacy offering prescription drugs for the same condition. Monitoring for this type of behavior thus requires research into a supplement merchant's entire range of business interests and

websites. Any current or historical connection to prescription drug sales should result in heightened scrutiny, possibly including test shopping.

Irrelevant or “International” Pharmacy Licenses

Another obfuscation tactic involves providing real, yet irrelevant, pharmacy licenses.

The principle behind this tactic is simple: merely because a merchant can provide a pharmacy license does not mean that the drugs are really sourced from there. This is a common tactic utilized by “licensed” Canadian Internet pharmacies. The merchant can easily produce a pharmacist’s and pharmacy license in a Canadian province, thus seemingly establishing a legitimate pharmacy. However, LegitScript notes it is rare that when a “Canadian” pharmacy is shipping to the U.S. or outside of Canada that the drugs really come from the Canadian pharmacy. Rather, the drugs are actually sourced from elsewhere, primarily locations such as China, India, Turkey, and Singapore. In this regard, the merchant’s production of the pharmacy license in Canada is irrelevant. It may be true that the merchant is a Canadian pharmacy, but it is meaningless because the drugs are not actually sourced from the Canadian pharmacy.

In this case, the best remedy is to ensure overall legal compliance and active monitoring of the website. The likelihood of a pharmacy producing an irrelevant pharmacy license is reduced, although not eliminated, if the merchant is shipping drugs only to jurisdictions where the merchant can produce a valid pharmacy license. Ultimately, nothing can substitute for a rigorous test-buy program in which the origin of the drugs can be documented.

Yet another claim that illicit pharmacy merchants sometimes make is that they have an “international” pharmacy license, or that they have some regulatory permission to ship worldwide. This is categorically false. **There is no such thing as an “international” pharmacy license.** Acquirers should note the following:

- A pharmacy license is valid only in the jurisdiction in which it is issued. However, some other jurisdictions may explicitly recognize, or have reciprocity with, the original jurisdiction.
- A pharmacy license in one jurisdiction cannot serve to override the regulatory requirements in another jurisdiction for pharmacy licensure and drug approval, even if it is described as “international.”
- An export license is only “half” of the equation. For example, an Indian merchant that has an Indian license to export drugs must also establish that they have permission to import the drugs into the cardholder’s country. And still, these licenses would not be sufficient in most jurisdictions to ship drugs to actual patients.

False Representations About Customer Base

In a similar vein, some Internet pharmacy merchants may assure acquirers that they ship prescription drugs only into jurisdictions where they are authorized to do so, and that they do not ship drugs to customers in certain countries where they are not licensed or otherwise authorized to ship drugs. As noted earlier in this document, pharmacy licensure, and sometimes a physical presence, are usually required in any jurisdiction where an Internet pharmacy offers to ship prescription drugs.

There are two straightforward ways to address this. First, acquirers should check merchant sales batches to validate the countries where a merchant’s cardholders are located. A significant number of sales to cardholders registered in an unauthorized country indicates that the merchant is shipping drugs there illegally. Second, if a pharmacy is not authorized to sell to a particular jurisdiction there is no need to list

that location in the drop-down “shipping” menu available to customers. Merchants should be required to restrict the shipping drop-down menu only to those locations where the merchant is authorized to practice pharmacy and ship drugs.

Fake FAQs/Prescription Requirement

Yet another obfuscation tactic simply involves inserting language into a merchant's terms and conditions that falsely suggests that the merchant is legally compliant.

To cite a real-life example, numerous Internet pharmacy merchants currently include language in their websites' FAQs stating that a prescription is required from a physician who has physically examined the patient, yet the websites routinely and consistently dispense prescription drugs without requiring any such prescription.

Consequently, language in the FAQs should not be viewed as substitute for understanding the merchant's actual activities and pharmacy practices.

Red Flags: A Short List

What are some red flags that an Internet pharmacy merchant may not be legally compliant? In some cases below, the behavior is most likely an indicator of illegal activity, while in other cases it merely bears increased scrutiny.

- Online questionnaire or language indicating “no prior prescription is required.”
- Focus on lifestyle drugs or controlled substances, or products such as tramadol or fioricet, which are non-controlled substances with potential abuse-inducing effects.
- Lack of any over-the-counter products.
- Use of a server in a country outside of merchant's jurisdiction (especially Russia, Eastern Europe, or China, which tend to be problematic).
- Use of high-risk registrar, such as the LegitScript “rogue domain name registrar” list, maintained at <http://blog.legitscript.com>.¹⁶
- Lack of a privacy policy or use of SSL/HTTPS privacy protection.

¹⁶ The red flag pertaining to domain name registrars deserves a short explanation. Domain name registrars generally suspend and lock (shut down) rogue Internet pharmacy websites. However rogue Internet pharmacies tend to congregate at a small number of domain name registrars that they believe will allow them to continue operating. Internet pharmacy monitoring service LegitScript maintains a monthly list of “high-risk” registrars that take no action against rogue online pharmacies.

7. Frequently Asked Questions

Below are questions acquirers may have when determining whether to board a pharmacy merchant.

Q: The merchant has provided me with a valid pharmacy license. So what's the problem?

Receiving a pharmacy license is a great start! But as a general rule, a pharmacy license only authorizes merchant pharmacies to dispense prescription drugs, or to “practice pharmacy,” in the jurisdiction where they are licensed. There are exceptions to this, but the rule holds true in most jurisdictions. You should require the merchant to provide pharmacy licenses for any country or state in their “drop-down” list where they offer to ship prescription drugs, or request information as to why the merchant believes that they fall under one of the exceptions.

Moreover, remember that merely being able to produce a pharmacy license doesn't mean that's really where the drugs are coming from. One way to evaluate the likelihood that the pharmacy whose license you've received is actually dispensing the drugs is to check and see if the drugs sold by the merchant are actually approved for sale in the jurisdiction where the pharmacy license was issued.

Q. The merchant does ship drugs into the U.S. (or another country), but only a 90-day supply or less. That's okay, right?

No, almost certainly not. There's a widespread misperception that as long as the prescription drugs are not controlled substances, it is legal for patients to import up to 90 days' worth of drugs from another country.

This misperception exists for a couple of reasons. The first reason is that many merchants have made this argument to the public, and to acquirers, over the years. Second is that some countries, such as the United States, have what is called “enforcement discretion” for customs officials to allow entry of up to a 90-day supply of very specific drugs in an **extremely** limited range of circumstances. But this enforcement discretion does not alter the fundamentally illegal nature of the imported drugs. To LegitScript's knowledge, there are no Internet pharmacies that actually fall under this exception which requires, among other things, that the drugs not be marketed to U.S. residents (including over the Internet), that the drugs have been specifically recommended by a physician, and that the medical conditions have no available treatment whatsoever in the United States. Thus, the importation of any drug for which a treatment already exists in the U.S., especially if it is the same drug, is a criminal offense. And by virtue of promoting the drugs on a website, Internet pharmacies basically disqualify themselves from this exception.

Even in the very limited number of countries, such as Japan, that permit a limited degree of prescription drug importation, virtually no Internet pharmacies meet the requirements of the exception that prohibits any advertising or promotion of unapproved drugs to Japanese residents. This prevents any website displaying unapproved drug names or images from being in compliance.

If the importation exists solely within the EU (that is, the pharmacy is dispensing solely from one EU nation into another one), it remains unlikely that the transaction is legal except in some specific cases. For example, Germany permits a few pharmacies domiciled in other jurisdictions to import drugs.

Q. But the merchant says that the FDA routinely allows drug shipments to enter the United States or other countries without objection.

Not exactly. The customs agency of any country, particularly larger ones, can only do so much. It is certainly true that U.S. Customs has been unable to block most shipments due to the volume of shipments entering the U.S. — a dynamic that is true in many other countries. But this is a function of the challenge involved in monitoring millions of packages a day, not a desire to permit those shipments.

Q. The merchant does fill prescriptions based solely on an online questionnaire, but says that it's valid telemedicine.

Highly unlikely. In nearly all jurisdictions worldwide, it's unlawful to fill prescriptions when there is no personal interaction between a physician or other prescriber and the patient. Merely labeling the business as "tele-health" or "telemedicine" doesn't make it legitimate telemedicine, which does not include websites where patients can simply fill out an online form and get drugs.

There are very limited exceptions to this, most prominently in Utah and the United Kingdom. Even in these cases, to be fully compliant the pharmacy and prescribing practitioner should both be licensed in the jurisdiction in question and comply with the narrow range of the exception.

Q. The merchant's website doesn't list any controlled substances, so the risk is lower, correct?

Not necessarily. The reason that any medicine is designated as prescription-only is because it requires medical supervision to be used safely, irrespective of whether the drug is a controlled substance or not. Indeed, most rogue Internet pharmacies do not sell controlled substances, but this does not reduce their legal responsibility to comply with prescription requirements, drug importation restrictions, or pharmacy licensure requirements.

Q. What about compounding pharmacies – are they legitimate?

The rules regarding compounding are complex and vary by country, and within some countries, vary by local jurisdiction. In general, compounding is a legitimate, long-standing pharmacy practice where a pharmacy, under specific conditions, produces the final, dispensed drug product. Any mixing of 2 or more ingredients is typically considered compounding. There are many good reasons to compound a drug, varying from personalizing medication to producing formulations that are not commercially available.

In most respects, compounding pharmacies generally have to play by the same basic rules. They have to be licensed as a pharmacy in the jurisdictions where they are practicing pharmacy and they have to utilize appropriate sourcing for ingredients. And, for prescription medicines, or compounds including prescription ingredients, they must require a valid prescription.

Acquirers should also note that there is not necessarily a clear distinction between a compounding pharmacy and a non-compounding pharmacy. Some pharmacies specialize in compounding, and it constitutes most of their business, while other pharmacies may only occasionally (or never) compound drugs. In most jurisdictions compounding is regulated as a component of practicing pharmacy.

One important exception applies to compounding pharmacies located in the U.S. and some other countries: legitimately compounded drugs are not considered FDA-approved, but do not typically need to be. In the U.S., the FDA's position is that the state pharmacy boards have general jurisdiction over the practice of compounding. However, some offenses, such as the adulteration or misbranding of compounded drugs, may still trigger FDA scrutiny.

Compounding questions are typically best approached on a case-by-case basis. As a general rule, however, pharmacy licensure and prescription requirement regulations apply equally to compounding pharmacies, but the drugs dispensed by compounding pharmacies do not require approval by the FDA.

Appendices

Appendix A: Model Terms and Conditions

Model Internet Pharmacy Policy

Definitions:

- a. An "Internet Pharmacy" means a website, merchant, business, or individual that sells or facilitates the sale of any regulated healthcare product (including drugs, medical devices, active pharmaceutical ingredients, or other regulated substances) that requires a prescription or may only be sold or dispensed by a pharmacy according to applicable laws.
- b. "Applicable Laws" means the laws and regulations of a) the jurisdiction where the online pharmacy dispenses drugs from and b) the jurisdiction where the online pharmacy offers to dispense or ship drugs to.

Abuse policy. Merchants may not facilitate the sale of drugs in violation of Applicable Laws. This expressly includes, but is not limited to:

- The sale of prescription drugs without a prescription based on a prior in-person examination, except where such is expressly permitted by Applicable Laws,
- Selling unapproved drugs (e.g., falsified medicines, counterfeit drugs, or drugs unapproved for sale),
- Importing drugs into a country where such is restricted or not permitted,
- Dispensing drugs to patients in a jurisdiction where the merchant lacks a valid pharmacy license, absent reciprocity or other such approval.

Third-party certification. You must maintain a valid certification with one of the following Internet pharmacy certification authorities:

Program	Website	Jurisdiction	Focus
LegitScript	www.legitscript.com	International	Endorsed by NABP and recognized by other drug safety regulators.
NABP VIPPS	www.nabp.net/programs/accreditation/vipps/	U.S. and Canada	"Gold standard" for Internet pharmacies targeting U.S. or Canada.
NABP Vet-VIPPS	http://www.nabp.net/programs/accreditation/vet-vipps	U.S. and Canada	"Gold standard" for animal Internet pharmacies targeting U.S. or Canada.
NABP e-Advertiser	http://www.nabp.net/programs/accreditation/e-advertiser-approval-program	U.S. and Canada	"Gold standard" for Internet pharmacies with limited offerings targeting U.S. or Canada.

Program	Website	Jurisdiction	Focus
Deutsches Institut für Medizinische Dokumentation und Information (DIMDI)	http://www.dimdi.de/static/de/amg/var/apotheken/index.htm	Germany	Internet pharmacies targeting German citizens. (DIMDI registration is required for German Internet pharmacies).
BIG Register	https://www.bigregister.nl//zoeken/zoekenopnaame/nspecialisme/	The Netherlands	Pharmacists selling to Dutch citizens (BIG registration is required for Dutch Internet pharmacies).
Pharmaceutical Society of New Zealand	http://www.psnz.org.nz/public/home/internet_accreditation/Accredited_Internet_Pharmacies.aspx	New Zealand	Internet pharmacies targeting New Zealand citizens. None accredited as of this writing.
Health Regional Authority	Varied	France	OTC Internet pharmacies targeting French citizens.

Sole Responsibility. It is your sole responsibility to be familiar with, and ensure that your website complies with, Applicable Laws. You agree that marketing regulated healthcare products to a jurisdiction, despite not being appropriately licensed to dispense or sell such products there, or selling healthcare products online in a way that does not comply with Applicable Laws, is a violation of this agreement.

Transparency Requirements. You agree that any Internet pharmacy domain name you register or represent will be accurately and non-anonymously registered. Furthermore, you warrant that you will maintain and publicly post on any Internet pharmacy website you operate the following documents:

- The name, location, and license information for any and all pharmacies or wholesalers you use to supply customers with drugs or other regulated healthcare products.
- A telephone number for such pharmacies for patients to contact in the event of an adverse reaction or pharmacist consultation.
- A list of the jurisdictions to which you offer to ship regulated healthcare products. This list must be identical to a) any drop-down menu from which customers can select a shipping destination and b) the countries that you actually ship drugs to.
- Your merchant identifier.

Appendix B: Legitimate Internet Pharmacy Verification Resources

There are several Internet pharmacy approval programs that are legitimate. There are also others, not listed here, that are funded by or affiliated with (and endorse) illegal online pharmacies. Below are recommended Internet pharmacy verification services.

Acquirers should note that new regulations require EU member nations to provide lists of authorized Internet pharmacies. As of this writing, lists are not up-to-date for many countries, and many countries that do provide such a list have not yet authorized any Internet pharmacies. Consequently, the links below are likely to increase in number.

Program	Website	Jurisdiction	Focus
LegitScript	www.legitscript.com	Global	Free for Internet pharmacies. Endorsed by NABP.
NABP VIPPS	www.nabp.net/programs/accreditation/vipps/	U.S. and Canada	"Gold standard" for Internet pharmacies targeting U.S. or Canada.
NABP Vet-VIPPS	http://www.nabp.net/programs/accreditation/vet-vipps	U.S. and Canada	"Gold standard" for animal Internet pharmacies targeting U.S. or Canada.
NABP e-Advertiser	http://www.nabp.net/programs/accreditation/e-advertiser-approval-program	U.S. and Canada	"Gold standard" for Internet pharmacies with limited offerings targeting U.S. or Canada.
Deutsches Institut für Medizinische Dokumentation und Information (DIMDI)	http://www.dimdi.de/static/de/amg/var/apotheken/index.htm	Germany	Internet pharmacies targeting German citizens (DIMDI registration is required).
BIG Register	https://www.bigregister.nl//zoeken/zoe-kenopnaamenspecialisme/	The Netherlands	Pharmacists or other healthcare providers targeting Dutch citizens (BIG registration is required).
Pharmaceutical Society of New Zealand	http://www.psnz.org.nz/public/home/internet-accreditation/Accredited_Internet_Pharmacies.aspx	New Zealand	Internet pharmacies targeting New Zealand citizens. None accredited as of this writing.
Regional Health Authorities (list maintained by the National Council of the Order of Pharmacists)	http://www.ordre.pharmacien.fr/e-commerce/search	France	Internet pharmacies targeting French citizens.

Although the United Kingdom also has a required Internet pharmacy registration service, acquirers should be aware that the registration is largely voluntary, and the seal of approval does not necessarily denote legal compliance. Moreover, registration does not guarantee compliance in jurisdictions outside of the United Kingdom. As such, we decline to list the UK's Internet pharmacy registration program in the list above.

Although France is included in the list above, there is currently no centralized program or website, and no Internet pharmacies selling prescription drugs have been approved.¹⁷

As of this writing, Internet pharmacies are banned by many countries. Here is the current status, as of early 2014, of several key countries where Internet pharmacies most commonly target customers.

Country	Internet Prescription Drug Sales
United States	Permitted
Australia	Permitted
Brazil	Permitted
Canada	Permitted
China	Not permitted
Croatia	Not permitted
Estonia	Not permitted
Finland	Permitted
France	Not permitted
Germany	Permitted
Greece	Permitted
Indonesia	Law unclear, but probably permitted
Ireland	Not permitted
Israel	Permitted
Italy	Not permitted
Japan	Not permitted

¹⁷ Internet pharmacies must "obtain the authorisation of the Director of the relevant Health Regional Authority (i.e., "les Agences Régionales de Santé") and inform the National Order of Pharmacists." (<http://www.allenoverly.com/publications/en-gb/Pages/France-issues-good-dispensing-practices-for-online-sale-of-medicines.aspx>) Information about legitimate OTC drug sellers is available at <http://www.ordre.pharmacien.fr/ecommerce/search>.

Country	Internet Prescription Drug Sales
Jordan	Not permitted
Korea	Not permitted
Morocco	Not permitted
Netherlands	Permitted
New Zealand	Not permitted
Norway	Permitted
Poland	Permitted
Russia	Not permitted
Spain	Not permitted
Thailand	Not permitted
Turkey	Not permitted
United Kingdom	Permitted

Appendix C: Where to Verify Pharmacy Licensure Status

The tables below provide resources for verification of pharmacy licenses. Note that the presence of a pharmacy license, standing alone, is not enough to establish legitimacy.

U.S. State	Verification URL
Alabama	https://albopharm.glsuite.us/GLSuiteWebUAT/Clients/ALBOPharm/Public/LicenseVerification/Search.aspx
Alaska	http://www.commerce.state.ak.us/occ/OccSearch/main.cfm
Arizona	https://az.gov/app/pharmacy/search.xhtml
Arkansas	http://www.ark.org/asbp/roster/index.php
California	http://www2.dca.ca.gov/pls/wllpub/wllqryna\$lcev2.startup?p_qte_code=PHX&p_qte_pgm_code=7200
Colorado	https://www.colorado.gov/dora/licensing/Lookup/LicenseLookup.aspx
Connecticut	https://www.elicense.ct.gov/Lookup/LicenseLookup.aspx
Delaware	https://dpronline.delaware.gov/mylicense%20weblookup/Search.aspx?facility=Y
District of Columbia	http://app.hpla.doh.dc.gov/weblookup/
Florida	http://ww2.doh.state.fl.us/IRM00PRAES/PRASLIST.ASP
Georgia	http://verify.sos.ga.gov/websites/verification/
Hawaii	https://pvl.ehawaii.gov/pvlsearch/
Idaho	https://idbop.glsuite.us/GLSuiteWeb/Clients/IDBOP/Public/Verification/Search.aspx
Illinois	https://www.idfpr.com/licenselookup/licenselookup.asp
Indiana	https://mylicense.in.gov/EVerification/Search.aspx
Iowa	http://www.iowa.gov/ibpe/verification.html (Must download list.)
Kansas	https://www.accesskansas.org/pharmacy_verification/index.html
Kentucky	https://secure.kentucky.gov/pharmacy/licenselookup/
Louisiana	https://secure.pharmacy.la.gov/Lookup/LicenseLookup.aspx
Maine	http://pfr.informe.org/almsonline/almsequery/welcome.aspx?AspxAutoDetectCookieSupport=1
Maryland	http://dhmh.maryland.gov/pharmacy/SitePages/verifications.aspx

U.S. State	Verification URL
Massachusetts	http://license.reg.state.ma.us/public/_dhplnewsystem.asp
Michigan	http://w3.lara.state.mi.us/free/
Minnesota	https://www.hlb.state.mn.us/mnbop/glsuiteweb/homeframe.aspx
Mississippi	http://msphrweb.starsystemlive.com/star/portal/msphr/page/LicenseLookup/portal.aspx
Missouri	https://renew.pr.mo.gov/licensee-search.asp
Montana	http://bsd.dli.mt.gov/license/bsd_boards/pha_board/board_page.asp
Nebraska	http://www.nebraska.gov/LISSearch/search.cgi
Nevada	http://bop.nv.gov
New Hampshire	http://www.nh.gov/pharmacy/licensing/verification.htm (Must download list.)
New Jersey	https://newjersey.mylicense.com/verification/Search.aspx
New Mexico	http://www.rld.state.nm.us/boards/Look_Up_A_License.aspx
New York	http://www.op.nysed.gov/opsearches.htm#rx
North Carolina	http://www.ncbop.org/ncbop_verification.htm
North Dakota	https://www.nodakpharmacy.com/verify.asp
Ohio	https://license.ohio.gov/lookup/default.asp?division=96
Oklahoma	http://www.ok.gov/OSBP/License_Verification/index.html
Oregon	https://obop.oregon.gov/licenseelookup/
Pennsylvania	http://www.licensepa.state.pa.us/
Rhode Island	https://healthri.mylicense.com/Verification/Search.aspx?facility=Y
South Carolina	https://verify.llronline.com/LicLookup/LookupMain.aspx?AspxAutoDetectCookieSupport=1
South Dakota	http://doh.sd.gov/boards/pharmacy/verification.aspx
Tennessee	http://health.state.tn.us/HCF/Facilities_Listings/facilities.htm
Texas	http://www.tsbp.state.tx.us/dbsearch/default.asp
Utah	https://secure.utah.gov/llv/search/index.html;jsessionid=6324fa94955af11800823a969522
Vermont	https://secure.vtprofessionals.org/Lookup/LicenseLookup.aspx

U.S. State	Verification URL
Virginia	https://secure01.virginiainteractive.org/dhp/cgi-bin/search_publicdb.cgi
Washington	https://fortress.wa.gov/doh/providercredentialsearch/
West Virginia	http://www.state.wv.us/pharmacy/index.cfm?fuseaction=Home.main
Wisconsin	http://online.drl.wi.gov/licenselookup/licenselookup.aspx
Wyoming	http://pharmacyboard.state.wy.us/OLV.aspx

Jurisdiction	Verification URL
Australia	The registration and regulation of pharmacy premises are the responsibility of regulatory agencies in individual states/territories. Although there is no central verification source available online, a list of state/territory regulatory agencies can be found here: http://www.pharmacyboard.gov.au/documents/default.aspx?record=WD11%2f4819&dbid=AP&chksum=19dJU0RzmsFVnhRveFFYA%3d%3d
Brazil	http://portal.anvisa.gov.br/wps/content/Anvisa+Portal/Anvisa/Servicos/Consulta+a+Banco+de+Dados/Autorizacao+de+Funcionamento+de+Farmacias+e+Drogarias
Canada	http://napra.ca/pages/Licensing_Registration/Authorities.aspx?id=1971 (go to appropriate college of pharmacy, and then follow that website's links to either a pharmacy directory or searchable database).
China (mainland)	http://app1.sfda.gov.cn/datasearch/face3/dir.html (Approved OTC Internet pharmacies can be found under this link: “其他” / “互联网药品交易服务”)
France	OTC medicines may be sold online by authorized pharmacies. The list of authorized online pharmacies can be found here: http://www.ordre.pharmacien.fr/e-commerce/search
Germany	http://www.dimdi.de/static/de/amg/var/apotheken/index.htm
Indonesia	There is no official source available online, but a partial list can be found here: http://www.gpfarmasi.org/index.php?option=com_content&view=article&id=54&Itemid=68
Ireland	http://public.thepsi.ie/
Israel	http://www.old.health.gov.il/units/pharmacy/store_hm.asp
Italy	There is no official source available online.
Japan	Brick-and-mortar pharmacies are licensed through the prefectures where they are located; however, there are no official verification sources available online.

Jurisdiction	Verification URL
Korea	There is no official source available online.
Netherlands	http://www.igz.nl/onderwerpen/curatieve-gezondheidszorg/apotheken/apotheekregister/ (list of licensed pharmacies) and https://www.bigregister.nl//zoeken/zoekenopnaamenspecialisme/ (searchable database for licensed health professionals, including pharmacists)
New Zealand	http://www.psnz.org.nz/public/home/internet_accreditation/Accredited_Internet_Pharmacies.aspx
Russia	http://www.roszdravnadzor.ru/rl/search
Spain	There is no official source available online.
Thailand	There is no official source available online.
Turkey	There is no official source available online.
United Kingdom	http://www.pharmacyregulation.org/registers/pharmacy

Appendix D: Country Summaries

Overview: 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 U.S. permit the sale of medicine over the Internet?

General rule: 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.

What are the exceptions? 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: <http://www.nabp.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy>. In addition, Internet pharmacies selling controlled substances must be registered with the DEA at (http://www.deadiversion.usdoj.gov/fed_regs/rules/2009/fr0406.pdf)

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: Yes. If an online pharmacy offers to ship drugs to residents of a particular state, it must be licensed in that state.

What are the exceptions? Currently, Pennsylvania and Massachusetts provide 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.

Where do I look? In the U.S., pharmacies are licensed on the state-level, not federally. Each state has a board of pharmacy which regulates brick-and-mortar and non-resident pharmacies, including Internet pharmacies. You can check each state board of pharmacy's license list, also available at <http://www.fda.gov/besafex>.

Where can I get more information? For additional information about a specific state board of pharmacy, see: <http://www.nabp.net/boards-of-pharmacy>.

Do drugs need to be approved for sale?

General rule: With minor exceptions, 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: <http://www.fda.gov/drugs/developmentapprovalprocess/>.

What are the exceptions? OTC drugs may be sold so long as they comply with an OTC monograph. While OTC monographs are pending, OTC drugs under consideration are given the benefit of the doubt. There are additional exceptions for drugs that were sold before 1938 and between 1938 through 1962. Drugs sold before 1938 are considered "grandfathered" drugs and do not need to be approved for safety and efficacy. Drugs sold after 1938 but before 1962 often fall into an area colloquially referred to as "DESI drugs." These drugs are typically considered unapproved and unlawful, but are tolerated by the FDA for numerous reasons. This tolerance is shown by the FDA's use of enforcement discretion.

Do drugs need to be approved for sale?

[continued]

Where can I get more information? All FDA-approved drugs are included in the Drugs@FDA database at: <http://www.fda.gov/Drugs/InformationOnDrugs/ucm135821.htm>. This database does not include any drugs that meet one of the above exceptions.

Another resource for determining which drugs are FDA-approved is the Orange Book: <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. It includes helpful patent information, so you can quickly tell whether a generic version of a drug is approved.

Is personal drug importation from outside of the U.S. permitted?

General rule: 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.

What are the exceptions? 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 U.S. That's untrue, and it remains illegal.

There is "enforcement discretion" practiced in extremely narrow cases. The conduct is still illegal but customs agents are authorized to overlook it. However the exception virtually never applies to Internet pharmacies. Generally referred to as the Personal Importation Policy, information is found in Chapter 9-2 Coverage of Personal Importations:

(<http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf>) Possible exceptions include: (1) the drug is unapproved and intended for use for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; (2) there is no known commercialization or promotion of the drug to persons residing in the U.S. by those involved in the distribution of the product; (3) the product is considered not to represent an unreasonable risk; (4) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than a 3-month supply), and provides the name and address of the doctor licensed in the U.S. responsible for his/her treatment with the product, or provides evidence that the product is for the continuation of treatment begun in a foreign country.

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm082690.htm>; see also <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194904.htm>

According to the FDA, "[t]his FDA guidance is not, however, a license for individuals to import unapproved (and therefore illegal) drugs for personal use into the U.S. Even if all of the factors noted in the guidance are present, the drug remains illegal and FDA may determine that such drugs should be refused entry or seized. The guidance does not create any legally enforceable rights for the public; nor does it operate to bind FDA or the public. Most importantly, this policy is not intended to allow importation of foreign versions of drugs that are approved in the U.S."

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm082690.htm>

Where can I get more information? FDA Import Program details may be found here: <http://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm>. Additional information may be found here: <http://www.fda.gov/Drugs/DrugSafety/ucm170594.htm>.

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

General rule: Internet pharmacy customers must be physically examined by the prescribing practitioner in order for the prescription to be considered valid and legal. Only filling out an online form is not legally compliant.

What are the exceptions? Only one state, Utah, permits online consultations in lieu of a physical exam, and only for a small number of drugs. In this case, the patient, physician, and pharmacy must all be in Utah for the exception to apply.

Additionally, some states have telemedicine provisions. The Federation of State Medical Boards lists individual state licensure requirements for the practice of telemedicine here:

http://www.fsmb.org/pdf/grpol_telemedicine_licensure.pdf. Also, most states require an in-person physical exam prior to the prescribing of medication. For a state-by-state overview of Internet prescribing language by state medical boards, see:

<http://www.fsmb.org/pdf/InternetPrescribing-law&policylanguage.pdf>.

Additional U.S. Resources

- Find a Board of Pharmacy: <http://www.nabp.net/boards-of-pharmacy>
- Confirm FDA drug approval: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

U.S. State	Verification URL
Alabama	https://albopharm.glsuite.us/GLSuiteWebUAT/Clients/ALBOPharm/Public/LicenseVerification/Search.aspx
Alaska	http://www.commerce.state.ak.us/occ/OccSearch/main.cfm
Arizona	https://az.gov/app/pharmacy/search.xhtml
Arkansas	http://www.ark.org/asbp/roster/index.php
California	http://www2.dca.ca.gov/pls/wllpub/wllqryna\$lcev2.startup?p_qte_code=PHX&p_qte_pgm_code=7200
Colorado	https://www.colorado.gov/dora/licensing/Lookup/LicenseLookup.aspx
Connecticut	https://www.elicense.ct.gov/Lookup/LicenseLookup.aspx
Delaware	https://dpronline.delaware.gov/mylicense%20weblookup/Search.aspx?facility=Y
District of Columbia	http://app.hpla.doh.dc.gov/weblookup/
Florida	http://ww2.doh.state.fl.us/IRM00PRAES/PRASLIST.ASP
Georgia	http://verify.sos.ga.gov/websites/verification/
Hawaii	https://pvl.hawaii.gov/pvlsearch/
Idaho	https://idbop.glsuite.us/GLSuiteWeb/Clients/IDBOP/Public/Verification/Search.aspx
Illinois	https://www.idfpr.com/licenselookup/licenselookup.asp

U.S. State	Verification URL
Indiana	https://mylicense.in.gov/EVerification/Search.aspx
Iowa	http://www.iowa.gov/ibpe/verification.html (Must download list.)
Kansas	https://www.accesskansas.org/pharmacy_verification/index.html
Kentucky	https://secure.kentucky.gov/pharmacy/licenselookup/
Louisiana	https://secure.pharmacy.la.gov/Lookup/LicenseLookup.aspx
Maine	http://pfr.informe.org/almsonline/almquery/welcome.aspx?AspxAutoDetectCookieSupport=1
Maryland	http://dhmh.maryland.gov/pharmacy/SitePages/verifications.aspx
Massachusetts	http://license.reg.state.ma.us/public/_dhpnewsystem.asp
Michigan	http://w3.lara.state.mi.us/free/
Minnesota	https://www.hlb.state.mn.us/mnbop/glsuiteweb/homeframe.aspx
Mississippi	http://msphrweb.starsystemlive.com/star/portal/msphr/page/LicenseLookup/portal.aspx
Missouri	https://renew.pr.mo.gov/licensee-search.asp
Montana	http://bsd.dli.mt.gov/license/bsd_boards/pha_board/board_page.asp
Nebraska	http://www.nebraska.gov/LISSearch/search.cgi
Nevada	https://pharmacy.bop.nv.gov/datamart/selectSearchType.do?from=loginPage
New Hampshire	http://www.nh.gov/pharmacy/licensing/verification.htm (Must download list.)
New Jersey	https://newjersey.mylicense.com/verification/Search.aspx
New Mexico	http://www.rld.state.nm.us/boards/Look_Up_A_License.aspx
New York	http://www.op.nysed.gov/opsearches.htm#rx
North Carolina	http://www.ncbop.org/ncbop_verification.htm
North Dakota	https://www.nodakpharmacy.com/verify.asp
Ohio	https://license.ohio.gov/lookup/default.asp?division=96
Oklahoma	http://www.ok.gov/OSBP/License_Verification/index.html
Oregon	https://obop.oregon.gov/licenseelookup/
Pennsylvania	http://www.licensepa.state.pa.us/
Rhode Island	https://healthri.mylicense.com/Verification/Search.aspx?facility=Y

U.S. State	Verification URL
South Carolina	https://verify.llronline.com/LicLookup/LookupMain.aspx?AspxAutoDetectCookieSupport=1
South Dakota	http://doh.sd.gov/boards/pharmacy/verification.aspx
Tennessee	http://health.state.tn.us/HCF/Facilities_Listings/facilities.htm
Texas	http://www.tsbp.state.tx.us/dbsearch/default.asp
Utah	https://secure.utah.gov/llv/search/index.html;jsessionid=6324fa94955af11800823a969522
Vermont	https://secure.vtprofessionals.org/Lookup/LicenseLookup.aspx
Virginia	https://secure01.virginiainteractive.org/dhp/cgi-bin/search_publicdb.cgi
Washington	https://fortress.wa.gov/doh/providercredentialsearch/
West Virginia	http://www.state.wv.us/pharmacy/index.cfm?fuseaction=Home.main
Wisconsin	http://online.dr1.wi.gov/licenselookup/licenselookup.aspx
Wyoming	http://pharmacyboard.state.wy.us/OLV.aspx

Overview: Internet Pharmacy Laws in Australia

Internet pharmacies are **permitted** in Australia, where the Internet pharmacy is the website component of a registered Australian brick-and-mortar pharmacy operated by licensed Australian pharmacists. That said, Australia has a “personal importation” loophole that allows individuals to import a 3-month supply of prescription medicine, assuming certain conditions are met (including the holding of a valid prescription from an Australian-registered medical practitioner). As a general matter, drugs must be approved by the Therapeutic Goods Administration (TGA). Physicians must personally examine patients before prescribing medication. See below for more detail.



Does Australia permit the sale of medicine over the Internet?

General rule: Yes, with limitations. Australia-based brick-and-mortar pharmacies may sell medicine over the Internet, as long as they adhere to all national laws and regulations, and the laws and regulations of any applicable Australian state or territory.

Requirements for Australian Internet pharmacies: Australia does not allow pharmacies to accept faxed or emailed prescriptions. For mail-order pharmacies, the original prescription must be mailed and received prior to the dispensing of medication. Only valid prescriptions written by registered Australian physicians can be dispensed. See “Pharmacy Guidelines for Dispensing of Medicines” for details, at:

<http://www.pharmacyboard.gov.au/documents/default.aspx?record=WD10%2f2951&dbid=AP&checksum=WMyYdhKfX3%2bWGPiGUCsMw%3d%3d> (page 2); see also

http://www.public.health.wa.gov.au/cproot/3565/2/Prescribing_S4_S8_080825.pdf According to the Therapeutic Goods Administration (TGA), “[t]he site you are purchasing from should provide an Australian street address and telephone number.”

<http://www.tga.gov.au/consumers/information-online-internet.htm#UqIks2RDtnc>.

What about international pharmacies? Although Australian law clearly regulates Australia-based online pharmacies, there is a sizeable legal loophole available to international pharmacies in the form of Australia’s “Personal Importation Scheme.” The scheme permits individual importation of prescription medicines, provided the individual importing the medicine holds a valid prescription from an Australian physician, and meets certain other requirements. (See “Are Drugs Required to Be Approved?” on the next page for details.)

<http://www.tga.gov.au/consumers/personal-importation-scheme.htm#UqJAs2RDt5W>.

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: Pharmacies must be registered in the state/territory where they are located. Pharmacists must be licensed nationally. Whether pharmacies registered in one Australian state/territory can ship drugs to other Australian states/territories depends on individual state/territory pharmacy regulations.

Additional information: Australian pharmacy law has both a national and state/territorial component. As of 2010, pharmacists are licensed nationally by the Pharmacy Board of Australia, working in partnership with the Australian Health Practitioner Regulation Agency (AHPRA). See <http://www.pharmacyboard.gov.au/About.aspx> and <http://www.ahpra.gov.au/>.

Are you required to have a pharmacy license where you offer to ship drugs to? [continued]

The registration and regulation of pharmacy premises are the responsibility of pharmacy approval authorities in individual states/territories. A list of these agencies can be found here: <http://www.pharmacyboard.gov.au/documents/default.aspx?record=WD11%2f4819&dbid=AP&chksum=19dJU0RzsmsFVnhRveFFYA%3d%3d>.

State/territory law specifies whether a pharmacy must be registered in a state/territory to ship drugs into that state/territory. In the state of Victoria, for example, the "Victorian Pharmacy Authority Guidelines 2013" suggest that pharmacies must have a Victorian Pharmacy Authority registration, as follows: "The practice of pharmacy must be carried out in premises that are registered by the Authority." See http://www.pharmacy.vic.gov.au/cms_files/VPA%20Guidelines%202013.pdf (Section 3.2.1).

Are drugs required to be approved for sale?

General rule: Yes. *The Therapeutic Goods Act 1989* requires that all medicines imported into Australia must be included in the Australian Register of Therapeutic Goods (ARTG). The law may be found here: <http://www.comlaw.gov.au/Series/C2004A03952>. In order for a medicine to be included in the ARTG, a sponsoring company is required to file an application with the TGA. The application requires data that supports the quality, safety, and efficacy of the product for its intended use, completed forms, and the payment of fees. See here for details: <http://www.tga.gov.au/industry/pm-basics-regulation.htm#UqIVh2RDt5U>.

ARTG database: The ARTG database is searchable and updated nightly. It can be found here: <http://search-au.funnelback.com/s/search.html?collection=tga-artg>.

What categories of medicines are sold in Australia? Australia classifies medicines into "Schedules" according to the level of regulatory control of availability required to protect public health. The Schedules are published annually in the Standard for the Uniform Scheduling of Medicines and Poisons, and are also known by their legal title, the "Poisons Standard." Individual Australian states or territories may adopt these standards without variation, or may make changes. The relevant schedules follow:

- Schedule 2 – Pharmacy Medicine (must be purchased in a pharmacy)
- Schedule 3 – Pharmacist Only Medicine (must be dispensed under pharmacist-guidance and approval)
- Schedule 4 – Prescription Only Medicine or Prescription Animal Remedy
- Schedule 5 – Caution
- Schedule 8 – Controlled Drug
- Schedule 9 – Prohibited Substance

Please note, OTC medicines can be supplied as: (a) Schedule 2 (pharmacy medicine), (b) Schedule 3 (pharmacist only medicine), or (c) general sales medicines, which are not included in any of the Schedules to the Poisons Standard.

Where can I get more information? The TGA provides links to the most recent version of the SUSMP, here: <http://www.tga.gov.au/industry/scheduling-poisons-standard.htm#susmp>. They update this website regularly, adding amendments to the current year's SUSMP. To find the Poisons Standard for a specific territory or state, you must go to the health authority website for that territory/state. For example, the New South Wales Poisons Standard (which they refer to as the "Poisons List" and which is based on the SUSMP, with a small number of variations) can be found here: <http://www0.health.nsw.gov.au/PublicHealth/Pharmaceutical/legislation.asp>.

Is personal drug importation from outside of Australia permitted?

General rule: Yes, with limitations. Australia has a “personal importation scheme” that allows a 3-month supply for personal use. If a medicine is prescription-only or a controlled drug (Schedules 4 and 8) under Australia’s Poisons Standard, the importer **must have a prescription from an Australian-registered medical practitioner.**

<http://www.tga.gov.au/consumers/personal-importation-scheme.htm#UqIJZWRDtnC>. There is also a **list of drug substances that require specific import authorizations.** That list can be found here: <http://www.health.gov.au/internet/main/publishing.nsf/Content/ocs-treaties-compliance-prohibited-impexp-precursor.htm>.

Additional information about the limitations of the Personal Importation Scheme: The Personal Importation Scheme permits Australians to import a **3-month supply** (at the maximum dose recommended by the manufacturer) of unapproved therapeutic goods into Australia without any approval required by the TGA provided that:

- the goods are for the individual’s own treatment or the treatment of immediate family; and
- the individual does not supply (sell or give) the medicine to any other person; and
- where possible, the individual keeps the medicines or medical devices in their original packaging with any dispensing labels intact; and
- the goods are not restricted under Australian Customs controls or quarantine rules and the goods do not contain a controlled substance as provided in the “List of drug substances requiring import and or export authorisations,” here: <http://www.health.gov.au/internet/main/publishing.nsf/Content/ocs-treaties-compliance-prohibited-impexp-precursor.htm>; and
- the goods are not injections that contain material of human or animal origin (except insulin); and
- the total quantity of the goods imported within a 12 month period does not exceed 15 months supply of the goods (for medicines, at the maximum dose recommended by the manufacturer); and
- if the goods are medicines in Schedule 4 or 8 of the SUSMP (also known as the Poisons Standard) a prescription from an Australian-registered medical practitioner is held for the medicines.

For additional details, see here: <http://www.tga.gov.au/consumers/personal-importation-scheme.htm#UqIJZWRDtnC>.

Additional customs information: The list of drug substances requiring import and or export authorisations includes substances that are commonly found in other countries’ dietary supplements, for example, DHEA, norandrostenedione, and yohimbine. Products found containing these ingredients will be seized by Australian customs.

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

General rule: Patients must be physically examined by an Australian physician. According to TGA, "[p]rescriptions obtained following an 'online consultation,' or questionnaire, are not acceptable." <http://www.tga.gov.au/consumers/information-online-internet.htm#UqIGlmRDtnc>

Additional Australian Resources

- Australian Register of Therapeutic Goods Database:
<http://search-au.funnelback.com/s/search.html?collection=tga-artg>

Overview: Internet Pharmacy Laws in Brazil

Internet pharmacies are **permitted** in Brazil, where the Internet pharmacy is the website component of a licensed Brazilian brick-and-mortar pharmacy. As a general matter, drugs must be approved by ANVISA, the National Health Surveillance Agency in Brazil. Physicians must personally examine patients before prescribing medication. See below for more detail.



Does Brazil permit the sale of medicine over the Internet?

General rule: Yes, as long as they adhere to Brazilian law RDC 44/2009, which is enforced by ANVISA (Agência Nacional de Vigilância Sanitária), the National Health Surveillance Agency in Brazil. RDC 44/2009 may be found here: http://anvisa.gov.br/divulga/noticias/2009/pdf/180809_rdc_44.pdf. This law permits Internet sales of prescription drugs by appropriately licensed Brazilian brick-and-mortar pharmacies that are open to the public, with a pharmacist present during all hours of the brick-and-mortar pharmacy's operation. A valid prescription is required. Controlled substances may not be sold online.

Additional requirements for Internet pharmacies: RDC 44/2009 sets out additional requirements for Internet pharmacies. An Internet pharmacy's website must use the domain "com.br" and its homepage must contain the following information: (1) Corporate name and trade name of the pharmacy or drugstore responsible for dispensing, CNPJ, address and telephone number of the brick-and-mortar location; name and registration number on the Board of the Pharmacist; (2) Name and registration number of the Council's Responsible Pharmacist Technician; (3) License or Permit information; (4) Authorization of company (AFE) issued by ANVISA; (5) Special permit (AE) to pharmacies, where applicable; (6) Direct link to information about the name and board registration number of the pharmacist at the time of the consultation; and (7) Alert messages and health recommendations determined by ANVISA.

Are you required to have a pharmacy license in Brazil to ship drugs to Brazil?

General rule: Yes. Pharmacies must be licensed in Brazil in order to ship medicines into Brazil. Article 53, Section 2 of RDC 44/2009 specifies that "[i]t is unlawful to sell medicines on Internet websites that are not owned by actual [brick and mortar] pharmacies or drugstores that are authorized and licensed by health regulatory agencies."

How do I find out if an Internet pharmacy is licensed by ANVISA? An Internet pharmacy must post its ANVISA permit number on its website. To determine whether a pharmacy is licensed, ANVISA provides a link to a searchable database:

<http://portal.anvisa.gov.br/wps/content/Anvisa+Portal/Anvisa/Servicos/Consulta+a+Banco+de+Dados/Autorizacao+de+Funcionamento+de+Farmacias+e+Drogarias>.

Do drugs need to be approved for sale?

General rule: Yes. Drugs must be approved by ANVISA. Federal Law No. 6,360 of September 23, 1976 is Brazil's primary pharmaceutical products law.

http://portal.anvisa.gov.br/wps/wcm/connect/605bd1004745968f9e68de3fbc4c6735/lei_6360.pdf?MOD=AJPERES

What categories of medicines are sold in Brazil? There are 2 categories of medicines in Brazil: prescription-only and OTC. See RDC 138/2003, http://www.abimip.org.br/site/images/RDC-138-03_GITE.pdf.

Where can I get more information? Brazil has a partially complete database of drugs, which includes both prescription and OTC products. ANVISA states that this database, the "Bulgaria Eletrônico," will be complete by the end of 2014. It can be found here:

<http://portal.anvisa.gov.br/wps/content/Anvisa+Portal/Anvisa/Inicio/Medicamentos/Assunto+de+Interesse/Bulas+e+Rotulos+de+medicamentos/Como+acessar+o+Bulario+Eletronico+-+Cidadao+-+Profissionais>

Is personal drug importation from outside of Brazil permitted?

General rule: Yes, where there is a valid prescription for individual use, limited in quantity/frequency. The Brazilian tax board website notes, regarding “postal imports” of “prescription drugs sent to individuals,” “[d]uring customs clearance procedures the Ministry of Health will enforce the presentation of a valid prescription.”
<http://www.receita.fazenda.gov.br/principal/ingles/faq.htm#Postal>. On its website, ANVISA confirms this requirement, stating that personal importation of medicines requires a prescription and “should not be characterized in frequency and quantity.”
<http://portal.anvisa.gov.br/wps/content/Anvisa+Portal/Anvisa/Setor+Regulado/O+que+voce+precisa/Importacao/Importacao+pele+consumidor+pessoa+fisica+consumo+proprio>

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

General rule: Physicians must personally examine patients prior to dispensing medication. See here for details: http://www.portalmédico.org.br/resolucoes/CFM/2011/1974_2011.htm
According to Resolution CFM N. 1974/2011, it is prohibited for a physician to: “(n) give consultations, diagnose or prescribe through any means of mass communication or distance; (j) provide advice to patients and families as a replacement for a medical consultation in person.” (“(n) Consultar, diagnosticar ou prescrever por qualquer meio de comunicação de massa ou a distância; (j) oferecer consultoria a pacientes e familiares como substituição da consulta médica presencial”).

Additional Brazilian Resources

- Determine whether an Internet pharmacy is licensed with ANVISA:
<http://portal.anvisa.gov.br/wps/content/Anvisa+Portal/Anvisa/Servicos/Consulta+a+Banco+de+Dados/Autorizacao+de+Funcionamento+de+Farmacias+e+Drogarias>
- Confirm ANVISA drug approval:
<http://portal.anvisa.gov.br/wps/content/Anvisa+Portal/Anvisa/Inicio/Medicamentos/Assunto+de+Interesse/Bulas+e+Rotulos+de+medicamentos/Como+acessar+o+Bulario+Eletronico+-+Cidadao+-+Profissionais>

Overview: Internet Pharmacy Laws in Canada



Internet pharmacies are **permitted** in Canada, but must adhere to the same laws and regulations as brick-and-mortar pharmacies. As a general matter, drugs must be Health Canada-approved. Pharmacies must be licensed in the province where they are located, and must comply with the laws of the jurisdictions where they ship medicine. Patients must be physically examined by a Canadian physician prior to receiving a prescription. See below for more detail.

Does Canada permit the sale of medicine over the Internet?

General rule: Yes, a licensed brick-and-mortar pharmacy with a legitimate street address and a pharmacy license number (or accreditation) may sell medicine over the Internet in Canada. See: http://napra.ca/pages/Practice_Resources/QuestionsandAnswersConsumers.aspx?id=3177 (“To date, only “brick and mortar” pharmacies are licensed to operate in Canada. A licensed pharmacy selling drugs over the Internet must be the website of an actual physical pharmacy with a legitimate street address. A legitimate website will clearly display the fact that the pharmacy is licensed or accredited by the province or territory in which they operate and will provide their street address and pharmacy license number.”)

Additional requirements: Prescription drugs cannot be dispensed from a Canadian pharmacy unless a doctor licensed to practice in Canada has written the prescription. http://napra.ca/pages/Practice_Resources/QuestionsandAnswersConsumers.aspx?id=3177#Answer1 (“pharmacists in Canada are not legally allowed to fill prescriptions from physicians that are not licensed to practice medicine in Canada.”)

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: Pharmacies must be licensed in the Canadian province in which they are physically located, and must comply with the laws of the jurisdictions into which they ship. To determine whether a pharmacy is appropriately licensed, one must search the provincial or territorial pharmacy regulatory authority’s website. These websites have searchable databases of registered pharmacies. A complete list of the provincial and territorial pharmacy regulatory bodies in Canada may be found here: http://napra.ca/pages/Licensing_Registration/Authorities.aspx?id=1971

Do drugs need to be approved for sale?

General rule: Yes, drugs must be approved by the Therapeutic Products Directorate of Health Canada, under Canada’s Food and Drugs Act and Regulations: <http://www.hc-sc.gc.ca/fn-an/legislation/acts-lois/index-eng.php>. Before drug products are authorized for sale in Canada, Health Canada reviews them to assess their safety, efficacy and quality. For details, see here: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/reviewfs_examenfd-eng.php

What categories of medicines are sold in Canada? Drug products fall into one of 2 categories: prescription and non-prescription. <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/index-eng.php>

Where can I get more information? To determine whether a drug is approved for sale in Canada, look at the Health Canada Drug Product Database, here: <http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp>. The NAPRA (National Association of Pharmacy Regulatory Authorities) searchable national drug schedule database is also useful: <http://napra.ca/pages/Schedules/Search.aspx>

Is personal drug importation

General rule: No. Health products containing prescription drugs, which are listed in Schedule F of the Food and Drug Regulations

from outside of Canada permitted? (http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-365.html), must come directly from a pharmacy located in Canada (please see section 5.2.2 of the Canadian Health Products Import and Export Policy, here: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/pol-0060_biu-uif-eng.php).

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form? Per the policies of the Federation of Medical Regulatory Authorities of Canada and Health Canada, physicians should only prescribe (including telephone prescribing, internet prescribing, countersigning of prescriptions and electronic prescribing) in the context of an established patient-physician relationship. See <http://www.fmrac.ca/policy/prescribing.html> and <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/internet-eng.php>.

Additional Canadian Resources

- Find a licensed pharmacy: http://napra.ca/pages/Licensing_Registration/Authorities.aspx?id=1971 (go to appropriate college of pharmacy, and then follow that website's links to either a pharmacy directory or searchable database).
- Confirm Health Canada drug approval: <http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp>

Overview: Internet Pharmacy Laws in China

Internet pharmacies are **not permitted** to sell prescription drugs but are permitted to sell OTC products online in China. Pharmacies must be certified by the China Food and Drug Administration (CFDA). All drugs, both prescription and OTC, must be approved by the CFDA. Patients must be physically examined by a physician in order to receive prescription medication. See below for more detail.



IMPORTANT NOTICE REGARDING CHINA/HONG KONG INTERNET PHARMACY LAWS.

Hong Kong and mainland China operate under the “one China, two systems” philosophy. This means mainland China and Hong Kong have different laws and different government systems. This summary outlines the regulations of Mainland China.

Does China permit the sale of medicine over the Internet?

General rule: No. Not for prescription drugs.
Exception: OTC products approved by the China Food and Drug Administration (CFDA) are allowed to be sold online.

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: Yes. Pharmacies must be certified by CFDA. The CFDA requires that any pharmacy dispensing to patients in China must be licensed in China for their Drug Retailing License (see <http://www.sda.gov.cn/WS01/CL0064/23396.html>, Chapter III). In order to apply for a license, a company must apply at its local FDA location, therefore requiring that the entity have a domestic location in China.

Online OTC pharmacies must obtain an Internet drug information service qualification, an Internet and drug transaction service qualification certificate, and a telecommunications business license (ICP). See <http://www.sfda.gov.cn/WS01/CL0060/9432.html> (Article 17). Certified online OTC pharmacies are required to display their registration license in a noticeable place on the website.

Where can I get more information? To see Internet OTC pharmacies certified by CFDA, see <http://app1.sfda.gov.cn/datasearch/face3/dir.html>, under “其他” / “互联网药品交易服务”. Websites that provide medical information only (but do not sell products) also need to be certified by the CFDA and can be found in the CFDA searchable database (<http://app1.sfda.gov.cn/datasearch/face3/dir.html>), under “其他” / “互联网药品信息服务”.

Do drugs need to be approved for sale?

General rule: Yes. All prescription and OTC drugs must be approved by CFDA (see <http://www.sda.gov.cn/WS01/CL0053/24529.html> Chapter II).

What categories of medicines are sold in China? There are 2 kinds of prescription drugs in China: (1) prescription-only drugs or (2) drugs that are either OTC or prescription. The classification depends on the dosage and whether it is for short term or long-term use. There are also 2 kinds of OTC drugs in China: (1) Red OTC Logo drugs, which can only be sold by pharmacies or retailers that have the Drug Retailing License or (2) Green OTC Logo drugs, which can be sold in general stores.

Where can I get more information? CFDA has a searchable database of every Chinese government-approved drug and dietary supplement both by product or manufacturer name. If a drug is found under the approved drug list, but not in the OTC category, then it is assumed to

be a prescription drug. See <http://app1.sfda.gov.cn/datasearch/face3/dir.html>.

Is personal drug importation from outside of China permitted?

General rule: Practically speaking, no. Importation of prescription drugs is strictly regulated in China. Importation of drugs must go through a rigorous approval process. See <http://www.sda.gov.cn/WS01/CL0053/24529.html> Chapter VI.

Drugs that are imported without permission are treated as “counterfeit drugs” under the Drug Administration Law (<http://www.sda.gov.cn/WS01/CL0064/23396.html> Article 48). Individuals may be allowed to import a small amount of drugs for their personal use (see <http://www.sda.gov.cn/WS01/CL0064/23396.html> Chapter V).

However, the relevant provisions of the General Administration of Customs place restrictions on the amount of drugs allowed for personal importation. Additionally, importation for personal use generally refers to a situation in which the patients personally carry the drugs when traveling across the border. It does not cover the situation where an overseas pharmacy sells directly to patients in China.

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

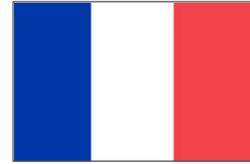
General rule: Patients must be physically examined to buy prescription drugs. The Ministry of Health Order No. 66 on Internet Healthcare Information Services states that “online diagnose and treatment activities are not permitted” (“不得从事网上诊断和治疗活动”). See http://www.gov.cn/flfg/2009-06/23/content_1347818.htm Chapter III.

Additional Chinese Resources:

- Confirm CFDA drug approval: <http://app1.sfda.gov.cn/datasearch/face3/dir.html>
- Alternate drug database: www.Yaoliwang.com (a CFDA-certified Internet Drug Information Service website)
- Confirm CFDA pharmacy approval: <http://app1.sfda.gov.cn/datasearch/face3/dir.html> (Approved OTC Internet pharmacies can be found under this link: “其他” / “互联网药品交易服务”)

Overview: Internet Pharmacy Laws in France

Internet pharmacies selling prescription drugs are **not permitted** in France. Only the online sale of OTC drugs are allowed, and the practice is heavily regulated. As a general matter, drugs must be ANSM or EMA-approved. Currently, only prescriptions dispensed by a medical practitioner who has physically examined the patient are lawful, however, EU law in this area is in flux. See below for more detail.



Does France permit the sale of medicine over the Internet?

General rule: No. The sale of prescription drugs over the Internet is prohibited in France. See: <http://www.sante.gouv.fr/dispensation-des-medicaments-par-internet-questions-reponses.13562.html>.

Where can I get more information? While France does not allow for the sale of prescription medication online, it does allow for the sale of OTC medicines online. Internet drug sales of non-prescription drugs are heavily regulated. See: <http://www.sante.gouv.fr/vente-en-ligne-de-medicaments.html>. The list of authorized online pharmacies that are allowed to sell OTC medicines can be found here: <http://www.ordre.pharmacien.fr/ecommerce/search>.

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: Yes, but Internet pharmacies are not permitted to ship drugs to France.

Exception: Companies shipping prescription medication into France for importation purposes must be licensed with L'Agence nationale de sécurité du médicament et des produits de santé (ANSM). In order to ship prescription medications into France, the drugs must be approved for the France market and the company shipping the drugs must be registered with ANSM. See: <http://www.legifrance.gouv.fr/affichCode.do?idSectionTA=LEGISCTA000006190669&cidTexte=LEGITEXT000006072665>

Do drugs need to be approved for sale?

General rule: Yes, drugs must be approved by either the European Medicines Agency (EMA) or ANSM.

The process: For drugs that are only seeking authorization in France, applications for approval must be sent to ANSM, which evaluates the drugs according to scientific criteria of quality, safety, and efficiency. See: [http://ansm.sante.fr/Activites/Autorisations-de-Mise-sur-le-Marche-AMM/Definition-et-modalite-des-AMM/\(offset\)/0](http://ansm.sante.fr/Activites/Autorisations-de-Mise-sur-le-Marche-AMM/Definition-et-modalite-des-AMM/(offset)/0). ANSM continues to monitor the drug after it is placed onto the market and controls advertising to the public and health professionals.

What categories of medicines are sold in France? Drugs are classified as either prescription or non-prescription (referred to as Direct Access medications). For more information on Direct Access medications, see: [http://ansm.sante.fr/Dossiers/Medicaments-en-acces-direct/Medicaments-en-acces-direct/\(offset\)/0](http://ansm.sante.fr/Dossiers/Medicaments-en-acces-direct/Medicaments-en-acces-direct/(offset)/0).

Where can I get more information? A searchable database for all drugs currently marketed (including 2 years of historic data) can be found at: <http://base-donnees-publique.medicaments.gouv.fr/index.php>. All drugs that have obtained authorization for placing into the market (whether marketed or not) can be found at: <http://ansm.sante.fr/Services/Repertoire-des-medicaments>. Further, lists of certain drugs that may be sold without a prescription can be found at: [http://ansm.sante.fr/Dossiers/Medicaments-en-acces-direct/Medicaments-en-acces-direct/\(offset\)/0](http://ansm.sante.fr/Dossiers/Medicaments-en-acces-direct/Medicaments-en-acces-direct/(offset)/0).

EMA drug database: In addition, the EMA has a separate database of approved prescription drugs that should also be considered as approved in France. This database can be viewed here: <http://www.ema.europa.eu/ema/>.

Is personal drug importation from outside of France permitted?

General rule: No, for purposes of Internet pharmacies.

What are the exceptions? The drug importation laws are focused on personal importation (bringing the drugs into France physically) and regulations differ depending on whether the person is coming in from the Schengen Area or other countries. See:

http://ansm.sante.fr/var/ansm_site/storage/original/application/940e29473178cf015010cbe2d85995a2.pdf. Up to 3 months of prescription medicines can be personally imported. See: http://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=282CC62578554D5036A42159EA88FC22.tpdjo06v_2?idArticle=LEGIARTI000006914856&cidTexte=LEGITEXT000006072665&dateTexte=20111101. More than 3 months of medication is permissible if accompanied by a prescription specifying that a longer treatment period is necessary. See: http://www.legifrance.gouv.fr/affichCode.do;jsessionid=5882F92BB2FA0325CA283A465E159E17.tpdjo06v_2?idSectionTA=LEGISCTA000018776640&cidTexte=LEGITEXT000006072665&dateTexte=20131125. Also, a prescription is always mandatory for medical drugs with narcotic and psychotropic ingredients.

If medicines are going to be sent into France by mail, there needs to be documentation that the company has obtained a license from ANSM to import the medications. Similarly, a certified copy of the marketing license would be required. See:

<http://www.douane.gouv.fr/page.asp?id=106>.

Where can I get more information? The various forms and procedures for companies to import and export drugs can be found here:

<http://ansm.sante.fr/Mediatheque/Publications/Formulaires-et-demarches-Stupefiants-et-psychotropes> and [http://ansm.sante.fr/Declarer-un-effet-indesirable/Pharmacodependance-Addictovigilance/Reglementation/\(offset\)/6](http://ansm.sante.fr/Declarer-un-effet-indesirable/Pharmacodependance-Addictovigilance/Reglementation/(offset)/6)

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

General rule: No prescription medicines are allowed to be sold online, regardless of the relationship between the patient and the physician.

Where can I get more information? This is an area to monitor on since as of 25 October 2013, the Cross Border Healthcare Directive 2011/24/EU came into effect throughout the EU. For the full text of this Directive, see:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF>. This Directive clarifies the rights of patients to access and obtain reimbursement for safe, good quality healthcare treatment in another EU member state. Cross-border prescriptions fall under this Directive enabling any EU resident to receive a cross-border prescription and get it dispensed in another EU country. Arguments have been made that this covers prescriptions dispensed from legal UK online pharmacies, which only require a form to be filled out. While this aspect has yet to be fully tested for legality in all EU states, this Directive would not change the fact that prescription medications are forbidden to be sold online in France. This Directive covers only the prescription itself being valid when given by a UK doctor online.

Additional French Resources

- Confirm ANSM drug approval: <http://ansm.sante.fr/Services/Repertoire-des-medicaments>

Overview: Internet Pharmacy Laws in Germany

Internet pharmacies are **permitted** in Germany, where the Internet pharmacy has been approved by DIMDI, the German Institute of Medical Documentation and Information. As a general matter, drugs must be approved by the European Medicines Agency (EMA) or the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM). Currently, only prescriptions dispensed by a medical practitioner who has physically examined the patient are lawful. However, EU law in this area is in flux. See below for more detail.



Does Germany permit the sale of medicine over the Internet?

General rule: Yes, if the pharmacy has been licensed as a pharmacy in Germany or, for non-German pharmacies, is listed with the Deutsches Institut für Medizinische Dokumentation und Information (DIMDI), the German Institute of Medical Documentation and Information.

What are the guidelines? The pharmacy must ask for a prescription and should have a clickable DIMDI icon somewhere on their site. Clicking on the icon will take the user to a DIMDI page, which details that website's specific information.

Where can I get more information? DIMDI publishes a downloadable list of all approved pharmaceutical websites in Germany: <https://versandapotheken.dimdi.de/pdfs/var-name.pdf>. This list includes every pharmacy-related website that is approved to sell and ship to Germany, from the simple brick-and-mortar pharmacies with no products to the fully legitimate online pharmacies. This list is updated every working day and can also be downloaded from the links on the DIMDI website: <http://www.dimdi.de/static/de/amg/var/apotheken/index.htm>.

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: Yes. Pharmacies must be registered with DIMDI. See: <http://www.dimdi.de/static/de/amg/var/index.htm>. You do not have to be domiciled in Germany in order to get approved by DIMDI, but the pharmacy must have a shipping permit for Germany and comply with German regulations.

Where do I look? All pharmacies registered to ship medicines within and into Germany can be found here: <http://www.dimdi.de/static/de/amg/var/apotheken/index.htm>. This list of registered pharmacies is updated every business day.

Do drugs need to be approved for sale?

General rule: Yes, drugs must be approved by either the European Medicines Agency (EMA) or the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM).

The process: BfArM is the agency that provides authorization of finished medicinal products on the basis of the German Medicines Act. http://www.bfarm.de/DE/Arzneimittel/zul/_node.html. Companies must prove the efficacy, safety, and pharmaceutical quality of the drug prior to receiving authorization. Marketing authorizations are good for 5 years and must be renewed with BfArM to remain valid.

Where can I get more information? There is a drug database searchable by members of the public available here: <http://www.pharmnet-bund.de/dynamic/de/am-info-system/index.html>. To enter, click on "Recherche für medizinische Laien" ("Research for layperson") then click "akzeptieren" ("accept").

Is there an EU database of approved drugs? The European Medicines Agency has a separate database of approved prescription drugs that should also be considered as approved in Germany. <http://www.ema.europa.eu/ema/>.

Is personal drug importation from outside of Germany permitted?

General rule: Yes, with restrictions: http://www.dimdi.de/static/de/amg/fag/var/fag_0005.html

What are the guidelines? German citizens may order prescription drugs from a select list of approved foreign countries as long as the pharmacy in question has a shipping permit for Germany and complies with German law. Currently, German citizens may order from mail-order pharmacies in (1) Iceland; (2) the UK; (3) the Netherlands (must be a brick-and-mortar pharmacy); (4) Sweden (only prescription drugs); and (5) Czech Republic (only non-prescription drugs).

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

General rule: Yes. A physical exam is required.

What are the guidelines? While telemedicine is widely regarded as a useful way for patients to receive care when they are unable to see a doctor in person, it is not intended to be a replacement for a physical examination. See here: <http://www.bundesaerztekammer.de/page.asp?his=0.2.23.8260.8265.8432.8433&all=true>. The German Medical Association has outlined guidelines for telemedicine, which clearly state that it is not to be a replacement for an ongoing doctor-patient relationship. <http://www.bundesaerztekammer.de/page.asp?his=1.100.1143%23ll>.

Where can I get more information? The law in this area is changing. As of 25 October 2013, the Cross Border Healthcare Directive 2011/24/EU came into force throughout the EU. See here: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF>. This Directive clarifies the rights of patients to access and obtain reimbursement for safe, good quality healthcare treatment in another EU member state. Cross-border prescriptions fall under this Directive enabling any EU resident to receive a cross-border prescription and get it dispensed in another EU country. Arguments have been made that this covers prescriptions dispensed from legal UK online pharmacies, which only require a form to be filled out. This has yet to be fully tested for legality in all EU states. However, Stiftung Warentest, a testing agency in Germany, has advised against using UK pharmacies that only require an online questionnaire, rather than a face-to-face physical examination by a physician. <http://www.test.de/DrEd-Riskanter-Besuch-beim-Online-Arzt-4420335-0/>.

Additional German Resources

- Confirm DIMDI pharmacy licensure: <https://versandapotheken.dimdi.de/pdfs/var-name.pdf>
- Confirm BfArM drug approval: <http://www.pharmnet-bund.de/dynamic/de/am-info-system/index.html>

Overview: Internet Pharmacy Laws in Indonesia

Internet pharmacies are likely **permitted** in Indonesia, but must adhere to the same laws and regulations as brick-and-mortar pharmacies. As a general rule, drugs must be approved by BPOM, the Indonesian National Agency of Drug and Food Control. There is no evidence that Indonesian law allows online questionnaires to substitute for physical examinations by a physician. See below for more detail.



Does Indonesia permit the sale of medicine over the Internet?

General rule: Indonesian law is unclear regarding the legal status of Internet pharmacies. We note that Apotek Kimia Farma, a major brick-and-mortar pharmacy licensed in Indonesia, accepts online orders and refill requests of prescription drugs (but requires a prescription).

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: Yes. All Indonesian pharmacies must be licensed by the Indonesian Ministry of Health. Licensure requirements may be found here:

<http://henriprihantono.blogdetik.com/files/2009/01/cara-ijin-apotik-2002.pdf>.

Where can I get more information? Indonesia does not provide much licensure information online. A (most-likely incomplete) list of licensed pharmacies that are also members of the Indonesian Pharmaceutical Association may be found here:

http://www.gpfarmasi.org/index.php?option=com_content&view=article&id=54&Itemid=68.

However, we found no requirement that pharmacies be members of the Indonesian Pharmaceutical Association.

Do drugs need to be approved for sale?

General rule: To be sold in Indonesia, drugs must be registered with the Badan Pengawas Obat dan Makanan (Indonesian National Agency of Drug and Food Control, known as "BPOM" and sometimes as "POM").

What categories of medicines are sold in Indonesia? Indonesia has several categories of drugs: (1) Strong drugs (2) OWA drugs (short of "Obat Wajib Apotek," which means "Pharmacy Mandatory Drug" in Indonesian); (3) Limited free drugs; and (4) Free drugs. Strong drugs are the equivalent of prescription-only. OWA drugs must be dispensed by a licensed pharmacist. Limited free drugs and free drugs are both equivalent to OTC medicines in the U.S.

Where can I get more information? To determine whether a drug may be legally sold in Indonesia, BPOM provides a searchable drug database: <http://www.pom.go.id/webreg/>.

Is personal drug importation from outside of Indonesia permitted?

General rule: No, with rare exceptions.

Exceptions: There are legal exceptions which allow for "special lane drug importation," but this type of importation is limited to (a) drugs for clinical trials; (b) donated drugs; or (c) drugs for specific therapeutic use (requested by a physician). See:

http://jdih.pom.go.id/produk/KEPUTUSAN%20KEPALA%20BPOM/SK%20Ka%20BPOM_No.%20HK.00.05.3.00914_tentang%20Pemasukan%20Obat_2002%20.PDF

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

General rule: Unclear. We are not aware of any laws or regulations in Indonesia addressing the practice of telemedicine.

Additional Indonesian Resources

- Confirm BPOM drug approval: <http://www.pom.go.id/webreg/>
- Find a licensed pharmacy: There is no official source available online, but a partial list can be found here: http://www.gpfarmasi.org/index.php?option=com_content&view=article&id=54&Itemid=68

Overview: Internet Pharmacy Laws in Ireland



Internet pharmacies are not permitted in Ireland under any circumstances. All pharmacies operating in Ireland must be licensed by the Pharmaceutical Society of Ireland. Medicinal products marketed in Ireland must be authorized by the Irish Medicines Board. Currently, only prescriptions dispensed by a medical practitioner who has physically examined the patient are lawful, however, EU law in this area is in flux. See below for more detail.

Does Ireland permit the sale of medicine over the Internet?

General rule: No. Supply of prescription medicines via the Internet is illegal and in contravention of Irish legislation. See: <http://www.imb.ie/EN/News/Medicines-via-the-Internet.aspx?page=1&year=0&categoryid>.

Are you required to have a pharmacy license in Ireland to ship drugs to Ireland?

General rule: Prescription medicines cannot be shipped in Ireland. Pharmacies must be licensed in Ireland to dispense medicine in Ireland. <http://www.imb.ie/EN/News/Medicines-via-the-Internet.aspx?page=1&year=0&categoryid>.

Where can I get more information? The Pharmaceutical Society of Ireland licenses all pharmacies in Ireland. Their searchable database can be found here: <http://public.thepsi.ie/>.

Do drugs need to be approved for sale?

General rule: Yes, medicinal products marketed in Ireland must be authorized by the Irish Medicines Board (IMB). If a drug is approved using the “national procedure,” the drug may only be marketed in Ireland and not in any other Member State. See: <http://www.imb.ie/EN/Medicines.aspx>.

What categories of medicines are sold in Ireland? Ireland has 3 categories of medicines: (1) Prescription-only medicine (POM); (2) Pharmacy-only (P) and (3) General sale (equivalent to OTC in the U.S.). <http://www.imb.ie/EN/Medicines/Human-Medicines/Licensing/Legal-Supply-Status-and-Reclassification.aspx>

EU Procedure: The European Medicines Agency (EMA) is responsible for the scientific evaluation of applications via the “centralized procedure.” A marketing authorization granted under the centralized procedure is valid for the entire Community market, which means the medicinal product may be put on the market in all Member States. Additional information about the various methods of approving drugs can be found here: <http://www.imb.ie/EN/Medicines.aspx>.

Where can I get more information? To determine the approval and prescription status of a specific medicine, review the IMB’s Human Medicines Products List: <http://www.imb.ie/EN/Medicines/HumanMedicines/HumanMedicinesListing.aspx>.

Is personal drug importation from outside of Ireland permitted?

General rule: Practically speaking, no.

Exceptions: With permission, under very limited circumstances (i.e., clinical trials and in accordance with the specifications of a practitioner for use by his individual patients). <http://www.imb.ie/EN/Human-Medicines/Human-Medicines/Access-to-Unauthorised-Medicines.aspx>

Do these exceptions apply to sales from Internet pharmacies? Ireland makes it clear that their Revenue and Customs Officers monitor all importations into Ireland. According to the IMB, "This includes the regular monitoring of small packets sent through the mail or via courier companies. The IMB cooperates with the Revenue and Customs Service in relation to illegally supplied mail ordered medicines. These products will be detained on detection and will not be supplied to the purchaser. The Internet supplier will not likely refund the purchaser as it takes no responsibility for such detentions and the consumer is out of pocket with no recourse to compensation." <http://www.imb.ie/EN/News/Medicines-via-the-Internet.aspx?page=1&year=0&categoryid>

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

General rule: Since prescription medicine may not be purchased over the Internet under any circumstances, this question is moot.

A possible change in the law: The law in this area is changing. As of 25 October 2013, the Cross Border Healthcare Directive 2011/24/EU came into force throughout the EU. See here: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF>. This Directive clarifies the rights of patients to access and obtain reimbursement for safe, good quality healthcare treatment in another EU member state. Cross-border prescriptions fall under this Directive enabling any EU resident to receive a cross-border prescription and get it dispensed in another EU country. Arguments have been made that this covers prescriptions dispensed from legal UK online pharmacies, which only require a form to be filled out. This has yet to be fully tested for legality in all EU states.

Additional Irish Resources

- Find a PSI licensed pharmacy: <http://public.thepsi.ie/>
- Confirm IMB drug approval: <http://www.imb.ie/EN/Medicines/HumanMedicines/HumanMedicinesListing.aspx>

Overview: Internet Pharmacy Laws in Italy

Internet pharmacies are **not permitted** in Italy. Medicinal products marketed in Italy must be authorized by the Agenzia Italiana de Farmaco (AIFA). Personal drug importation is permitted, with restrictions. Currently, only prescriptions dispensed by a medical practitioner who has physically examined the patient are lawful, however, EU law in this area is in flux. See below for more detail.



Does Italy permit the sale of medicine over the Internet?

General rule: No. Online pharmacies or “E-pharmacies” are prohibited under Italian law. <http://www.agenziafarmaco.gov.it/en/content/counterfeiting-medicines-phenomenon-and-data>. In the English version of AIFA’s website, AIFA states that they cannot prevent Italians from buying from foreign online pharmacies. However, the Italian version of the site is slightly different, saying that Italian legislation does not prevent users from purchasing products from dangerous and unauthorized pharmacies. <http://www.agenziafarmaco.gov.it/it/content/farmacie-online-e-indagini-di-intelligence>. Our interpretation of these 2 slightly different versions of Italian legal explanation is that Italy, like most countries, focuses on prosecuting illegal pharmacies and not end-users.

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: Pharmacies must be licensed by local authorities to operate within Italy. <http://www.federfarma.it/Farmaci-e-farmacie/Farmacie-e-farmacisti-in-Italia/La-presenza-delle-farmacie-sul-territorio/Legge-8-novembre-1991,-n--362-Art--1.aspx>. They must apply for an additional license every 3 years in order to distribute controlled substances. Italian law requires pharmacies to also register nationally as part of a wider prescription medication-tracking program. <http://www.trovanorme.salute.gov.it/dettaglioAtto?sessionId=2mHOP2eo4J8w8qLqBMq4nA?id=1550>.

Do drugs need to be approved for sale?

General rule: Yes, medicinal products marketed in Italy must be authorized by the Agenzia Italiana del Farmaco (AIFA). If a drug is approved using the “national procedure,” the drug may only be marketed in Italy and not in any other Member State. <http://www.agenziafarmaco.gov.it/en/content/registration>.

What categories of medicines are sold in Italy? Italy classifies substances into 2 categories: OTC (“senza obbligo di ricetta”, “da banco”, or “SOP”) and “prescription” (“con obbligo di ricetta”). Prescription-only medications fall into several categories:

- Ricetta Ripetibile (Repeatable Prescription): These types of medications may be refilled up to 10 times before a new prescription (and examination) would be required.
- Ricetta Non Ripetibile (Non-Repeatable Prescription): These more dangerous types of medications may only be prescribed for 30 days at a time.
- Ricetta Limitativa (Limited Prescription): These most dangerous types of medication are either only permitted for hospital use, or can only be prescribed by a specialist.

Do drugs need to be approved for sale?
[continued]

EU Procedure: The European Medicines Agency (EMA) is responsible for the scientific evaluation of applications via the “centralized procedure.” A marketing authorization granted under the centralized procedure is valid for the entire Community market, which means the medicinal product may be put on the market in all Member States.

Where can I find additional information? Additional information about the various methods of approving drugs in Italy can be found here:

<http://www.agenziafarmaco.gov.it/en/content/registration>.

The Italian database of AIFA-approved drugs can be found here:

<https://farmaci.agenziafarmaco.gov.it/aifa/pages/home.jsp>.

Is personal drug importation from outside of Italy permitted?

General rule: Yes, but with restrictions. Per Italian Ministerial Decree of August 29, 1997, the Procedure for the Parallel Importation of Human Medicine, parallel importation from another EU member state is authorized with proper paperwork and licensing. Finally, importation of medication not yet registered in Italy may be permitted by doctor or hospital request.

<http://www.impactitalia.gov.it/binary/impa/cont/parallelimport.pdf>. “Importazione di medicinali dall'estero” provides details on the legal methods of importation.

<http://www.agenziafarmaco.gov.it/sites/default/files/guidaoperativamedicinali2010.pdf>; see also

http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=3639&area=farmaci&menu=strumenti

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

General rule: Since Internet pharmacies are prohibited under Italian law, this question is moot. See: <http://www.agenziafarmaco.gov.it/it/content/farmacie-online-e-indagini-di-intelligence>.

However, multiple decisions passed down by the Italian Supreme Court declare that prescriptions must be issued immediately after a face-to-face examination.

<http://www.iusinaction.com/italiano-medici-di-base-e-certificati-via-telefono-lo-stop-della-cassazione/?lang=it>.

A possible change in the law: The law in this area is changing. As of 25 October 2013, the Cross Border Healthcare Directive 2011/24/EU came into force throughout the EU. See here:

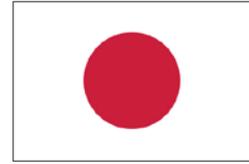
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF>. This Directive clarifies the rights of patients to access and obtain reimbursement for safe, good quality healthcare treatment in another EU member state. Cross-border prescriptions fall under this Directive enabling any EU resident to receive a cross-border prescription and get it dispensed in another EU country. Arguments have been made that this covers prescriptions dispensed from legal UK online pharmacies, which only require a form to be filled out. This has yet to be fully tested for legality in all EU states.

Additional Italian Resources

- Confirm AIFA drug approval: <https://farmaci.agenziafarmaco.gov.it/aifa/pages/home.jsp>

Overview: Internet Pharmacy Laws in Japan

Internet pharmacies are **not permitted** in Japan. Only the sale of certain OTC drugs is permitted online. As a general matter, drugs must be PMDA-approved and brick-and-mortar pharmacies must be licensed in their respective jurisdiction. See below for more detail. Please note that the Japanese Ministry of Health is releasing new regulations in 2014. LegitScript will provide updated information on its website (legitscript.com) regarding the new regulations, which are expected to expand the ability of licensed pharmacies in Japan to sell OTC medicines online, but not to change the illegal nature of Internet-based prescription drug sales.



Does Japan permit the sale of medicine over the Internet?

General rule: Japan does not permit the sale of prescription medication online.

Exceptions: The Ordinance for Enforcement of the Pharmaceutical Affairs Act (http://www.mhlw.go.jp/bunya/iyakuhin/ippanyou/pdf/shikoutuuti_kaitei110331.pdf) allows the online sale of Class 3 OTC and quasi drugs. However, in response to a recent Supreme Court decision, OTC drugs are currently sold widely online regardless of their "class" listing. <http://law.e-gov.go.jp/htmldata/S36/S36F03601000001.html>.

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: Internet pharmacies that sell prescription medications are not permitted in Japan. Brick-and-mortar pharmacies are licensed through the jurisdiction where they are located (Pharmaceutical Affairs Law Article 4. See:

<http://law.e-gov.go.jp/htmldata/S35/S35HO145.html>).

Do drugs need to be approved for sale?

General rule: Yes. Drugs are approved by the Pharmaceuticals and Medical Devices Agency (PMDA). See: <http://www.pmda.go.jp/>. This agency separates drugs into 3 categories of human medicines: Ethical Drugs, OTC Drugs, and Quasi Drugs. Ethical drugs can either be prescription or non-prescription and OTC is separated into 3 Classes. See:

<http://www.ndl.go.jp/jp/data/publication/issue/pdf/0727.pdf>.

Where can I get more information? The database for ethical drugs can be found here: http://www.info.pmda.go.jp/psearch/html/menu_tenpu_base.html.

The database for OTC Drugs can be accessed here:

<http://database.japic.or.jp/ctrl/attDocsForm?targetDB=1&x=66&y=16>.

Is personal drug importation from outside of Japan permitted?

General rule: Yes, with limitations.

What are the guidelines? Japan allows citizens to import up to a one-month supply of prescription medication. This exception is very narrow and sellers are not allowed to advertise drugs that are not approved in Japan. However, drugs that are personally imported into Japan do not necessarily have to be approved. See <http://www.mhlw.go.jp/kinkyu/diet/tuuchi/0828-4.html>.

Where can I get more information? The importation rules are spelled out here: <http://www.mhlw.go.jp/kinkyu/diet/tuuchi/0828-4.html>.

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

General rule: Internet pharmacies are not allowed in Japan so there can be no lawful sale of prescription drugs based on an online questionnaire.

Where can I get more information? Although Internet pharmacies are prohibited, the practice of telemedicine is permitted in limited conditions. Doctors can consult remotely only to patients with chronic conditions who have previously established doctor-patient relationship. Please see:

<http://www.mhlw.go.jp/bunya/iryuu/johoka/dl/tushinki02.pdf>.

Additional Japanese Resources:

- Confirm PMDA drug approval for Ethical drugs:
http://www.info.pmda.go.jp/psearch/html/menu_tenpu_base.html
- For OTC drugs: <http://database.japic.or.jp/ctrl/attDocsForm?targetDB=1&x=66&y=16>

Overview: Internet Pharmacy Laws in Korea

Internet pharmacies are **not permitted** in Korea. Korean law requires that medicines may only be sold in physical pharmacy locations. As a general matter, drugs must be approved by the Ministry of Food and Drug Safety (MFDS). Korea does not permit online prescribing and prescriptions must be based on an in-person examination. See below for more detail.



Does Korea permit the sale of medicine over the Internet?

General rule: No. Internet pharmacies are not permitted in the Korean territory. The Pharmaceutical Affairs Act states: “no pharmacy founder or drug distributor shall sell drugs at a place, other than his/her physical pharmacy or shop.” (<http://www.law.go.kr/법령/약사법> Article 50, paragraph 1).

Where can I get more information? Korean internet regulations also prohibit online pharmaceutical sales. See, for example, the Act on Promotion of Information and Communication Network Utilization and Information Protection (“IT Network Act”). (http://www.law.go.kr/법령/정보통신망_이용촉진_및_정보보호_등에_관한_법률) and the Regulations Concerning Deliberation on Information and Communication (<http://www.law.go.kr/LSW/admRulInfoPWah.do?admRulSeq=2000000060868>).

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: N/A. Drugs may not be shipped in Korea.

Where can I get more information? Under Korean law, pharmacies may only be operated by pharmacists licensed by the Ministry of Health and Welfare (MOHW), the governmental agency that oversees the regulation of pharmacies and pharmacists in Korea (Article 20 and 44 of the Pharmaceutical Affairs Act: <http://www.law.go.kr/법령/약사법>). Once a pharmacist procures a pharmacist’s license, he or she can then go to the person’s residing MOHW office to register to open a pharmacy (Article 20). Korean law only allows pharmacists to open a single physical pharmacy (Article 21).

Do drugs need to be approved for sale?

General rule: Yes. All manufactured and imported drugs must obtain approval by the Ministry of Food And Drug Safety (MFDS) (<http://www.mfds.go.kr/index.jsp>) before commercialization (Article 31 and 42 of the Pharmaceutical Affairs Act). See <http://www.law.go.kr/법령/약사법>. The MFDS is the entity responsible for regulation of drugs (including re-examination and re-evaluation) of drugs (Article 32 and 33).

What categories of medicines are sold in Korea? Korea has 2 categories of drugs: (1) Prescription Drugs (전문의약품) and (2) OTC Drugs (일반의약품) (Article 2, paragraph 4, 9, and 10).

Is personal drug importation from outside of Korea permitted? **General rule:** Yes, with limitations. Personal importation of 6 bottles (or 3-month supply) of prescription medicine for personal use is allowed for both citizens and visitors with a doctor's prescription or other official documents. This does not include controlled substances, marijuana, or drugs under Abuse and Misuse Drugs - <http://www.law.go.kr/LSW/admRulInfoP.do?admRulSeq=2000000022750>
See Customs Standards here: http://www.customs.go.kr/kcshome/main/content/ContentView.do?contentId=CONTENT_ID_000001136&layoutMenuNo=12440.

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form? **General rule:** Patients must be physically examined by a physician. Article 17 of the Medical Service Act prohibits medical doctors to write prescriptions to patients when not seen "face-to-face." <http://www.law.go.kr/법령/의료법>. Also, Article 12, paragraph 1 of the Veterinarians Act indicates that "veterinarians cannot prescribe prescriptions if not seen face-to-face." www.law.go.kr/법령/수의사법

Additional Korean Resources:

Confirm MFDS drug approval. Search by:

- Product names - <http://drug.mfds.go.kr/html/search.jsp?collection=kifda>
- Active ingredients - http://drug.mfds.go.kr/html/search_detail.jsp?collection=kifdadetail
- Pill shape/color/imprint codes - http://drug.mfds.go.kr/html/search_drug_grain.jsp?collection=kifdadruggrain

(Note: searchable only in Korean characters.)

Overview: Internet Pharmacy Laws in the Netherlands

Internet pharmacies are **permitted** in the Netherlands, but the pharmacy needs to be licensed in the Netherlands. Drugs need to be approved for sale in the Dutch market by the Medicines Evaluation Board. Currently, only prescriptions dispensed by a medical practitioner who has physically examined the patient are lawful, however, EU law in this area is in flux. See below for more detail.



Does the Netherlands permit the sale of medicine over the Internet?

General rule: Yes, the Netherlands permits Internet pharmacies, provided that the pharmacies are licensed in the Netherlands. See Dutch Medicines Law, Articles 61(1)(a) and 1.1(II):

http://wetten.overheid.nl/BWBR0021505/geldigheidsdatum_24-10-2012.

Where can I find more information? A searchable database and an overview of all Dutch registered pharmacies can be found at

http://www.apotheek.nl/Alle_Apotheken/Apotheek/default.aspx?mld=10947&rid=

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: Yes. Internet pharmacies must be licensed in the Netherlands. See <http://www.igz.nl/onderwerpen/curatieve-gezondheidszorg/apotheken/apotheekregister/> (from De Inspectie voor de Gezondheidszorg (IGZ), i.e., the Health Care Inspectorate).

For more information on the IGZ's authority, see:

http://www.igz.nl/Images/Handel_in_geneesmiddelen_via_internet%5B1%5D_tcm294-290412.pdf

Do drugs need to be approved for sale?

General rule: Yes, before a medicine can be marketed in the Netherlands, it must receive an authorization from the Medicines Evaluation Board (MEB) (in Dutch, it is the CBG - College ter Beoordeling van Geneesmiddelen). <http://www.cbg-meb.nl/CBG/en/human-medicines/medicinal%20products/default.htm>; see also Dutch Medicines Law, Article 40: http://wetten.overheid.nl/BWBR0021505/geldigheidsdatum_24-10-2012

EU Procedure: To obtain a European marketing authorization, the manufacturer follows a decentralized (<http://www.cbg-meb.nl/CBG/en/human-medicines/regulatory-affairs/decentralised-and-mutual-recognition-procedures/default.htm>) or a centralized procedure (<http://www.cbg-meb.nl/CBG/en/human-medicines/regulatory-affairs/centralised-procedure/default.htm>) via the European Medicines Agency, the EMA. <http://www.ema.europa.eu/ema/>

What categories of medicines are sold in the Netherlands? Under Articles 56 through 60 of the Dutch Medicines Act, http://wetten.overheid.nl/BWBR0021505/geldigheidsdatum_24-10-2012, the Netherlands has 4 categories of drugs:

- Prescription-only (Uitsluitend recept, or UR): Can only be obtained with a valid prescription
- Pharmacy Only (Uitsluitend apotheek, or UA): Can be obtained without a prescription, but only from a pharmacy.
- Pharmacy or Drugstore only (Uitsluitend apotheek of drogist, or UAD): Can be obtained without a prescription, but only from a pharmacy OR drugstore.

Do drugs need to be approved for sale?
[continued]

- General Sales (Algemene verkoop, or AV): The Dutch version of OTC. These medications can be purchased from any store that is registered with the KvK. See: <http://www.kvk.nl/over-de-kvk/over-het-handelsregister/zoeken-in-het-handelsregister/>.

Where can I get more information? The MEB's human medicines database can be found here: <http://www.cbg-meb.nl/CBG/en/human-medicines/geneesmiddeleninformatiebank/default.htm>.

Is personal drug importation from outside of the Netherlands permitted?

General rule: Yes, under very limited circumstances, and generally with permission by Dutch authorities. See Dutch Medicines Law, Article 40(3) for details: http://wetten.overheid.nl/BWBR0021505/geldigheidsdatum_24-10-2012.

See parallel importation details here: <http://www.cbg-meb.nl/CBG/en/human-medicines/regulatory-affairs/legislation-guidelines/guidelines+parallel+import/default.htm>.

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

General rule: A physical exam is required. According to Article 67 of the Dutch Medicines Law, "It is prohibited for anyone to prescribe drugs via the Internet to a person that the prescriber has never met in person, or doesn't know, or doesn't have the medication history available from." http://wetten.overheid.nl/BWBR0021505/geldigheidsdatum_26-10-2011; see also <http://www.rijksoverheid.nl/onderwerpen/geneesmiddelen/vraag-en-antwoord/mag-een-arts-via-internet-medicijnen-voorschrijven.html>.

A possible change in the law: The law in this area is changing. As of 25 October 2013, the Cross Border Healthcare Directive 2011/24/EU came into force throughout the EU. See here: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF>. This Directive clarifies the rights of patients to access and obtain reimbursement for safe, good quality healthcare treatment in another EU member state. Cross-border prescriptions fall under this Directive, enabling any EU resident to receive a cross-border prescription and get it dispensed in another EU country. Arguments have been made that this covers prescriptions dispensed from legal UK online pharmacies, which only require a form to be filled out. This has yet to be fully tested for legality in all EU states.

Additional Dutch Resources:

- Find a registered Dutch pharmacy: http://www.apotheek.nl/Alle_Apotheken/Apotheek/default.aspx?mld=10947&rlid= or <http://www.igz.nl/onderwerpen/curatieve-gezondheidszorg/apotheken/apotheekregister/>
- Confirm MEB drug approval: <http://www.cbg-meb.nl/CBG/en/human-medicines/geneesmiddeleninformatiebank/default.htm>

Overview: Internet Pharmacy Laws in the Russian Federation



Internet pharmacies are **not permitted** in the Russian Federation under any circumstances. In fact, medicines cannot be shipped by mail or courier in the Russian Federation. Only brick-and-mortar pharmacies located in Russia can be licensed in Russia. Drugs must be registered with the Government Register of Medicinal Products. See below for more detail.

Does the Russian Federation permit the sale of medicine over the Internet?

General rule: No. Medicines fall under the legal category of products whose free distribution is prohibited.

See: http://ecology.gpntb.ru/usefullinks/oficialdoc/zakonrf/zakons_ukaz/zakons_256/.

Products that fall in this category may not be sold by distance methods, including the Internet. See here:

http://www.consultant.ru/document/cons_doc_LAW_71418/#E0A927566520794306D4A7EB72F28CE9.

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: Drugs may not be shipped by mail or courier in the Russian Federation.

Additional information about pharmacy licensure in the Russian Federation: Only brick-and-mortar pharmacies located in Russia can be licensed in Russia.

http://www.consultant.ru/document/cons_doc_LAW_124279/

Do drugs need to be approved for sale?

General rule: Yes. Generally, drugs must be approved by the Federal Service on Surveillance in Healthcare (Roszdravnadzor). <http://www.roszdravnadzor.ru/>. Please see Chapter 6 Statute 13.1 of Federal Law from 12.04.2010 N 61-FZ "On the handling of Medicines" (adopted by State Duma on 24.03.2010): <http://graph.document.kremlin.ru/page.aspx?1057229>.

What categories of medicines are sold in the Russian Federation? Russia recognizes prescription and non-prescription drugs, but all medicines (both prescription and OTC) are prohibited from being sold online.

Where can I get more information? To determine whether a drug is approved in the Russian Federation, you may search the Government Register of Medicinal Products here:

<http://grls.rosminzdrav.ru/grls.aspx>.

Is personal drug importation from outside of the Russian Federation permitted?

General rule: No. Medicines cannot be delivered to anyone by mail or by courier.

Exception: The exception rarely applies. Russia allows individuals who are travelling to the Russian Federation to physically bring medicines for personal use which are in their possession, even if these medicines are not registered with the government. However, these medicines cannot be shipped to travelers.

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

General rule: Since medicines cannot be delivered by mail or courier in the Russian Federation, this question is moot.

Additional Russian Federation Resources:

- Confirm pharmacy licensure: <http://www.roszdravnadzor.ru/rl/search>
- Confirm drug approval: <http://grls.rosminzdrav.ru/grls.aspx>

Overview: Internet Pharmacy Laws in Spain

Internet pharmacies are **not permitted** to sell prescription medicine in Spain, however, OTC products may be sold online. Drugs must be approved by the AEMPS (Agencia Espanola de Medicamentos y Productos Sanitarios). Currently, only prescriptions dispensed by a medical practitioner who has physically examined the patient are lawful. However, EU law in this area is in flux. See below for more detail.



Does Spain permit the sale of medicine over the Internet?

General rule: No. Prescription drugs may not be sold over the Internet in Spain. See: http://www.aemps.gob.es/en/publicaciones/publica/regulacion_med-PS/docs/folleto-regulacion_Med-PS.pdf (page 19).

Exception: OTC medicines may be sold online. See: http://www.aemps.gob.es/informa/notasInformativas/laAEMPS/2013/NI-AEMPS_16-2013-venta-med-ilegales.htm.

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: Yes. According to Articles 100 and 102 of La Ley General de Sanidad, all pharmacies must be properly licensed in order to dispense medication. See: <http://www.mssi.gob.es/profesionales/farmacia/legislacion/leyes/lgs.htm>.

Do drugs need to be approved for sale?

General rule: Yes, drugs must be approved by the AEMPS (Agencia Espanola de Medicamentos y Productos Sanitarios). Details regarding drug approval may be found here: http://www.aemps.gob.es/publicaciones/publica/regulacion_med-PS/docs/folleto-regulacion_Med-PS.pdf.

What categories of medicines are sold in Spain? Spain has 2 categories of drugs - prescription-only (con receta) or over-the-counter (sin receta).

Where can I get more information? Spain's searchable database for human medicines can be found here: <http://www.aemps.gob.es/cima/fichasTecnicas.do?metodo=detalleForm>. The database lists those medicines authorized in Spain, and the category (prescription/OTC) of authorized medicines.

Is personal drug importation from outside of Spain permitted?

General rule: Only under very limited circumstances. Individuals traveling to Spain are allowed to take medications for their own use, as long as the amount does not "represent a deviation in amount or destination," according to Article 74 of Ley 29/2006 (Guaranteeing the Rational Use of Medicines and Health Products). <http://www.boe.es/buscar/act.php?id=BOE-A-2006-13554>.

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

General rule: Physical exams are required. According to the Código de Ética Médica de 2011, Article 26, it is unethical to “practice [medicine] by consultation only by letter, telephone, radio, newspapers or internet.”

https://www.cgcom.es/sites/default/files/codigo_deontologia_medica.pdf. Since all licensed doctors in Spain must follow this code, and since infractions of the code are considered disciplinary offenses (Chapter I, Article 2), the practice of prescribing medication without a face-to-face consultation is illegal in Spain.

A possible change in the law: The law in this area is changing. As of 25 October 2013, the Cross Border Healthcare Directive 2011/24/EU came into force throughout the EU. See: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF>. This Directive clarifies the rights of patients to access and obtain reimbursement for safe, good quality healthcare treatment in another EU member state. Cross-border prescriptions fall under this Directive enabling any EU resident to receive a cross-border prescription and get it dispensed in another EU country. Arguments have been made that this covers prescriptions dispensed from legal UK online pharmacies, which only require a form to be filled out. This has yet to be fully tested for legality in all EU states.

Additional Spanish Resources:

- Confirm AEMPS drug approval: <http://www.aemps.gob.es/cima/fichasTécnicas.do?metodo=detalleForm>

Overview: Internet Pharmacy Laws in Thailand

Internet pharmacies are **not permitted** to sell prescription medicine in Thailand, however, OTC products may be sold online. Drugs must be approved by the Thai FDA. See below for more detail.



Does Thailand permit the sale of medicine over the Internet?

General rule: Internet sales are limited to OTC products. Specially controlled drugs (prescription) and dangerous drugs (pharmacist-dispensed) are required by law to be sold in a physical pharmacy and dispensed by a Thai-licensed pharmacist only. See Thai Drug Law, § 14, <http://faolex.fao.org/docs/texts/tha53461.doc>.

Exception: Since no license is required to sell OTC medicines in Thailand, and these medicines need not be sold in a Thai-licensed pharmacy, OTC medicines may be sold online. See Thai Drug Law, § 13(3), <http://faolex.fao.org/docs/texts/tha53461.doc>.

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: Yes. All licensed pharmacies are required to have a physical location in Thailand and a pharmacist to oversee the pharmacy's operation. See Thai Drug Law, § 14, <http://faolex.fao.org/docs/texts/tha53461.doc>.

Do drugs need to be approved for sale?

General rule: Yes, All medicinal products must be approved by the Thai FDA. See: <http://www.fda.moph.go.th>

What categories of medicines are sold in Thailand? Three main categories: (1) Specially controlled drugs (equivalent to prescription-only in the U.S.); (2) dangerous drugs (must be dispensed by a pharmacist); and (3) household medicines (equivalent to OTC medicines);

Where can I get more information? The Thai FDA drug database can be found here: <http://fdaolap.fda.moph.go.th/logistics/drgdrug/DSerch.asp>. You can look up a medicine by active ingredient, drug name, registered name (brand), manufacturer, and supplier. You are unable to browse a list of drugs and must input at least one field to search for the sought after drug.

There is an additional online database with drugs and health information created by National Electronics and Computer Technology Center (government agency): <http://yaandyou.net/>. This database includes OTC products as well.

There are also Thai FDA lists of narcotics and psychotropic drugs. For narcotics, see here: http://narcotic.fda.moph.go.th/faq/upload/Thai%20Narcotic%20Act%202013%20May_b7fe.pdf

For psychotropics, see here: http://narcotic.fda.moph.go.th/faq/upload/Thai%20Psychotropic%20Act%202013%20May_cc73.pdf.

Is personal drug importation from outside of Thailand permitted?

General rule: Yes, but it is extremely limited. Personal importation is limited to (1) medical practitioners for a particular patient or by veterinary practitioners for a particular animal, (2) non-dangerous herbal drugs or household medicines, or (3) importation “with the person into the Kingdom not exceeding the amount required for his personal use for thirty days.” See Thai Drug Act, § 13, <http://faolex.fao.org/docs/texts/tha53461.doc>. Although the last category could be a loophole, our understanding is that importation must be physically “with the person,” not “in the mail.”

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

General rule: Since prescription medicine may not be sold over the Internet in Thailand, this question is moot.

Additional Thai Resources:

- Confirm Thai FDA drug approval: <http://fdaolap.fda.moph.go.th/logistics/drgdrug/DSerch.asp>

Overview: Internet Pharmacy Laws in Turkey



Internet pharmacies are **not permitted** in Turkey. The General Directorate of Pharmaceuticals and Pharmacy, under the Turkish Ministry of Health (MOH) is in charge of the sale, distribution, approval, and regulation of all drugs in Turkey. Turkish law specifies that an in-person consultation by a physician is necessary for the issuance of a prescription. See below for more detail.

Does Turkey permit the sale of medicine over the Internet?

General rule: No. Turkish law does not permit the online sale of pharmaceutical or medicinal products. See: <http://www.resmigazete.gov.tr/eskiler/2012/05/20120531-3.htm>

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: Pharmacies cannot sell drugs online. Physical pharmacies must be approved by the Turkish Ministry of Health before dispensing prescription-only and OTC medicines. Licensure requires registration as a pharmacist in Turkey.

For details, see here: <http://www.iracm.com/wp-content/uploads/2013/01/loi-sur-les-pr%C3%A9parations-m%C3%A9dicales-et-pharmaceutiques-anglais-3753.pdf> and here: <http://www.resmigazete.gov.tr/eskiler/2012/05/20120531-3.htm>.

Do drugs need to be approved for sale?

General rule: Yes. The General Directorate of Pharmaceuticals and Pharmacy, under the Turkish Ministry of Health (MOH) is in charge of the sale, distribution, approval and regulation of all drugs (prescription and OTC) in Turkey. See generally, here: <http://www.mondaq.com/x/193666/Healthcare/Pharmaceutical+Regulations+under+Turkish+Law>.

What categories of medicines are sold in Turkey? The MOH lists 4 classes of drugs: (1) OTC (OTC), (2) Narcotic Prescription (Red), (3) Psychotropic Prescription (Green), and (4) Normal Prescription (Normal),

Where can I get more information? For a comprehensive database of all drugs regulated by the Turkish Ministry of Health, go to: <http://www.ieg.gov.tr/kubktlist.aspx> and search for your product. Registration is required. If a product match and its associated PDF come up, it is a government-regulated drug that is not permitted for online sale. Alternatively, you can use the alphabetical search function at this privately run resource: <http://www.ilacrehberi.com/ilac-listeleri/>

Is personal drug importation from outside of Turkey permitted?

General rule: No, with very rare exceptions.

Exceptions: Personal drug importation is allowed in only extremely rare circumstances (i.e. for members of the Turkish armed services, under explicit physician dictates, etc.). http://www.e-kutuphane.teb.org.tr/pdf/tebhaberler/ocak_subat00/5.pdf.

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

General rule: Since medicines cannot be sold online in Turkey, this question is moot. However, Turkish law does specify that a physical exam is necessary for a prescription. According to the MOH's Regulations on Pharmacies and Pharmacy Services, Part four: Pharmacy Services, Articles 22 (Acceptable Prescriptions), 23 (Psychotropic Drug Prescriptions) and 26 (Making Drugs, Labels and Packaging), physicians may produce a valid prescription, written on paper with prescriber's signature, contact information, and medication instructions, only after an in-person patient consult. See <http://www.mevzuat.gov.tr/Metin.Aspx?MevzuatKod=7.5.5532&MevzuatIisiki=0&sourceXmlSearch=eczane>.

Additional Turkish Resources:

- Confirm MOH drug approval: <http://www.ieg.gov.tr/kubktlist.aspx>

Overview: Internet Pharmacy Laws in the UK

Internet pharmacies are **permitted** in the UK, provided they are licensed by the General Pharmaceutical Council (GPhC) and comply with all relevant UK legislation. Only registered pharmacy premises in the UK are approved by the GPhC to operate as licensed Internet pharmacies. As a general matter, drugs must be approved by the Medicines and Healthcare products Regulatory Agency for use in the UK. The UK permits online consultations via form, provided the prescribers follow certain ethical guidelines. See below for more detail.



Does the United Kingdom permit the sale of medicine over the Internet?

General rule: Yes, if the pharmacy is registered with the General Pharmaceutical Council (GPhC). Only registered pharmacies that offer professional services via the Internet can use the Internet pharmacy logo. See: <http://www.pharmacyregulation.org/registration/internet-pharmacy>.

Are you required to have a pharmacy license where you offer to ship drugs to?

General rule: Yes. Pharmacies must be licensed by the GPhC, the independent regulator for pharmacists, pharmacy technicians, and pharmacy premises in Great Britain. The GPhC authorizes Internet pharmacies only after verification that the request has come from the operator of a registered brick-and-mortar pharmacy. See: <http://www.pharmacyregulation.org/sites/default/files/Internet%20Pharmacy%20Logo%20-%20conditions%20for%20use.pdf>.

Where can I get more information? The GPhC maintains a searchable pharmacy register, found here: <http://www.pharmacyregulation.org/registers/pharmacy>. An Internet pharmacy that is registered with the GPhC is provided a logo to post on its website. The logo carries a unique registration number for a particular pharmacy, and links to that specific pharmacy's webpage on the GPhC website. An example of the logo (without the registration number) follows:



Do drugs need to be approved for sale?

General rule: Yes, drugs must be approved by either the European Medicines Agency (EMA) and/or the Medicines and Healthcare products Regulatory Agency (MHRA).

The process: The EMA licenses drugs for a Europe-wide license. The MHRA then approves those drugs for use in the UK. Under Regulation 46 of The Human Medicines Regulations 2012 (SI 2012/1916) all medicines must have a marketing authorization (Product License) unless exempt. See: <http://www.legislation.gov.uk/uksi/2012/1916/regulation/46/made>. Pharmaceutical companies can also apply directly to the UK to license drugs for use in the UK only (this rarely happens anymore).

Do drugs need to be approved for sale?
[continued]

What categories of medicines are sold in the UK? In the UK, drugs fall into one of the following categories: (1) prescription-only (POM), (2) pharmacy-only (P) or (3) general sales list (GSL is the equivalent of OTC). POM and P medicines can only be sold or supplied at registered pharmacy premises by or under the supervision of a pharmacist. For details, see:

<http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingandsupplyingofmedicines/>.

Where can I get more information? Additional details about drug approval can be found at <http://www.mhra.gov.uk/Howweregulate/Medicines/Overviewofmedicineslegislationandguidance/index.htm>.

Drug database: To search for approved drugs, the MHRA has a webpage that provides lists of substances, here:

<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Legalstatusandclassification/Listsofsubstances/>. These lists delineate which active pharmaceutical ingredients fall into which category (POM, P or GSL).

Is personal drug importation from outside of the United Kingdom permitted?

General rule: Rarely, and with specific MHRA permission. According to the MHRA, "reasons of cost, convenience or institutional need are not acceptable."

When does the MHRA object to personal drug importation? Objections may be raised to import where: (1) the MHRA has concerns about the safety or quality of the product, (2) there is an equivalent licensed medicinal product available that will meet the needs of the individual patient, or (3) the MHRA is not satisfied that there is a special need for the supply to an individual patient. It is MHRA policy that the special need must be clinical in nature. Reasons of cost, convenience, or institutional need are not acceptable. See:

<http://www.mhra.gov.uk/Howweregulate/Medicines/Importingandexportingmedicines/Importingunlicensedmedicines/>.

Are Internet pharmacy customers required to be physically examined by a doctor in order to buy a prescription drug, or can they just fill out a form?

General rule: Online consultations, via an online form, are permitted in the UK. Prescribers must follow certain ethical guidelines, detailed in "Prescribing guidance: Remote prescribing via telephone, video-link or online."

http://www.gmc-uk.org/guidance/ethical_guidance/14326.asp.

Additional UK Resources:

- Confirm GPhC pharmacy licensure: <http://www.pharmacyregulation.org/registers/pharmacy>

Appendix E: Key Terms and definitions

API

An application programming interface (API) is a tool software components use to interact with one another. API can also refer to active pharmaceutical ingredient.

Counterfeit Medication

A counterfeit medication is a product that is manufactured by a third party in an effort to resemble that of an approved medication. The actual ingredients in the counterfeit product are typically unknown.

DEA

The United States Drug Enforcement Agency (DEA) is the U.S. Department of Justice's branch in charge of controlled substances in the U.S. Their jurisdiction includes almost anything relating to controlled substances in the U.S., including importing, exporting, prosecuting, dispensing, registering, and shipping.

Dietary Supplements

A dietary supplement is a product ingested by mouth that contains ingredients typically found in one's diet. These ingredients are generally vitamins, minerals, herbs, amino acids, extracts, or other botanicals. Most jurisdictions have specific regulations as to how these products may be advertised and where these products may be sold. Generally, they are sold over-the-counter.

Domain Name

A domain name is a set of characters that assists in directing a computer's browser to the content of a website.

Drug Wholesaler

A drug wholesaler is typically a licensed business entity that acts as a drug distribution intermediate between pharmacies and manufacturers. They do not have authorization to distribute drugs to patients.

Falsified medicines

A falsified medication is a product that is not an approved medication, but is claimed to act as if it were an approved medication.

FDA

The U.S. Food and Drug Administration (FDA) is a branch of the U.S. Health and Human Services agency and is in charge of various health related products, including drugs. The drug safety authorities in some other countries utilize the same name (FDA).

Geo-targeting

Geo-targeting is the strategy of only showing specific website content to users in specific geographical locations. This is typically achieved by filtering IP addresses based on their geographical signatures.

HIPAA

The Health Insurance Portability and Accountability Act (HIPAA) is a comprehensive law that includes a large number of healthcare privacy regulations.

Internet Pharmacy

An Internet pharmacy is a merchant that sells, dispenses or markets, or facilitates the selling, dispensing or marketing of, a prescription or pharmacy-only medicine in response to orders placed over the Internet.

IP address

An Internet Protocol (IP) address is a set of numbers that identify devices interacting with the Internet. An IP address also approximately indicates the geographical location of the device.

Jurisdiction

A jurisdiction is any sovereign geographical area that develops and enforces its own laws. In the Internet pharmacy world, jurisdictions typically include states, countries, and provinces.

Mail Server

A mail server is a computer server used to facilitate the transfer of emails. Mail servers can be domain name specific and can be an identifying piece of information for affiliated websites.

Name Server

A name server points a domain name to the content on a server (IP address). Name servers may be unique to a particular domain name or IP address, or utilized by thousands or millions of domain names and IP addresses.

NPI Number

A National Provider Identification number is a registration number most healthcare providers in the U.S. obtain in order to process insurance claims. The registration information for these numbers may be found at <https://nppes.cms.hhs.gov>.

Nutraceutical

The term nutraceutical is another name for dietary supplements. Regulatory bodies generally frown upon the term nutraceutical, as it suggests that the product has some pharmaceutical-like benefit. Dietary supplements are typically not permitted to claim pharmaceutical benefits.

Over-The-Counter Healthcare Products

Over-the-counter healthcare products are medicines, treatments, medical devices, or other healthcare products that the relevant healthcare authorities have determined are safe when used according to the instructions on the label. They do not require the same level of medical supervision as prescription-only drugs.

Pharmacy-Only Healthcare Products

Pharmacy-only healthcare products are products that can only be sold at, and by, a licensed pharmacy. This classification may not exist in every jurisdiction.

Phishing

Phishing is the attempt to gain private information by pretending to be a trusted source. This occurs most often with websites or emails that are designed to represent themselves as organizations like banks, social media networks, or ecommerce merchants.

Prescription

A prescription is an order from a practitioner authorizing the sale of a healthcare product. Prescriptions may be transmitted directly to a pharmacy by a prescriber, or written out in physical form and given to patients. Pharmacies then may dispense prescription-only healthcare products pursuant to these orders.

Prescription-Only Healthcare Product

A prescription-only healthcare product is a medicine, treatment, medical device, or other healthcare product that the relevant healthcare authorities (e.g., the U.S. Food and Drug Administration in the United States) have determined requires medical supervision to be used safely and effectively. Medical supervision, in this context, means that the product should only be used following, and in accordance with, a prescription.

Privacy/Proxy Services

A privacy or proxy service is a service offered to mask a domain names whois information.

Proxy IP address

A proxy IP address is an IP address that substitutes the normal IP address of a device. It is useful for avoiding IP address filtering, like geo-targeting.

Registrant

A registrant is a person or entity that registers a domain name.

Registrar

A registrar is a vendor of domain names.

Rogue Internet Pharmacy

A rogue Internet pharmacy is any Internet pharmacy that violates or operates out of compliance with applicable laws and regulations.

SOA

The Start of Authority (SOA) record identifies the authoritative name server for a website. An email is often associated with the authoritative server as part of the SOA record.

Spam

Spam is an unsolicited electronic communication, generally an advertisement. An exact definition is difficult to pin down, but it most closely resembles traditional junk mail one receives via traditional postage systems.

TOR

TOR is a set of software, usually built into a browser, that allows a user to access the Internet anonymously.

Unapproved Medicines

Unapproved medicines are medications that have not been approved for use by the applicable regulatory body in a jurisdiction. Counterfeit, falsified, and foreign drugs are all typically unapproved and illegal. Additionally some legal exceptions, like compounded drugs and grandfathered drugs, exist without approval.

Whois Information

Whois information is a collection of information provided by registrants when registering a domain name. This information includes information such as name servers, mail servers, and contact information for the registrant. Whois information is an excellent source for additional information regarding any e-commerce merchant.



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