



Internet Pharmacy Guide

A Complimentary Resource for Registrars, Registries and
Hosting Providers

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legitscript.com

A Letter to Registrars, Registries and Hosting Providers

This is a complimentary guide for domain name registrars, registries and hosting providers interested in implementing voluntary policies to prohibit rogue Internet pharmacies from using their services. It is intended to be a single reference point for information about the rules that govern Internet prescription drug sales in the jurisdictions most commonly targeted by Internet pharmacies, the risks posed by “rogue” Internet pharmacies, and recommended “best practices.”

There are many legitimate Internet pharmacies. Unfortunately, there are far more that are not. Connected with the latter are numerous cases of deaths, overdoses, and other adverse health effects from substandard or counterfeit drugs or prescription drugs sold without a valid prescription. Since 2008, a growing number of companies have implemented policies prohibiting rogue Internet pharmacies from using their services. The standard anti-abuse policies of registrars, hosting providers, search engine advertising programs, credit card networks, and banks prohibit using their services to illegally sell prescription drugs.

At the same time, many companies without active anti-abuse policies focused on rogue Internet pharmacies have entirely reasonable — and usually, the same — questions. What makes an Internet pharmacy legal or illegal? Under which countries’ laws? Do I need to be concerned about liability? What protections for the registrant exist? How can I ensure that the process is fair and transparent? This document contains straightforward answers to these questions and more.

Moreover, for registrars subject to ICANN’s 2013 Registrar Accreditation Agreement, new contractual provisions require registrars to “investigate” and “respond appropriately” to abuse complaints involving illegal activity. Some non-ICANN registries have similar requirements. Because objective standards developed by regulatory authorities exist that define what makes an Internet pharmacy illegal — standards that are remarkably consistent worldwide — this guide is intended to help registrars and registries investigate such claims, and to determine what is an “appropriate response.”

For companies that already take voluntary anti-abuse steps against rogue Internet pharmacies, this manual is intended to help make the process easier. For companies without such policies, we hope that this document will encourage you to consider voluntarily adopting these or similar policies and procedures.

LegitScript thanks the registrar, registry and content hosting community for its leadership in making the Internet safer and more secure. We hope that this resource is helpful to your anti-abuse efforts and are proud to reaffirm our commitment to your anti-abuse efforts worldwide.

I. Putting a Human Face on the Problem

About 3% of Internet pharmacies are legitimate. 97% fail to adhere to drug safety laws and regulations.

(Source: [National Association of Boards of Pharmacy](#).)



Lorna Lambden, above, died after taking unregulated sleeping pills bought online without a prescription.

Legitimate Internet pharmacies do exist. But those that refuse to play by the rules — rules that exist to protect patients by providing transparency and accountability to the prescription drug market — profit at the expense of human health. Among the data:

- In a three-month period in 2011, a Japanese female, two Irish men and a London paramedic all died from drugs acquired from unrelated Internet pharmacies.¹
- Licensed Canadian Internet pharmacies shipping drugs to the US — outside of the jurisdiction where they are authorized to practice pharmacy — were found to have been diverting orders to unlicensed suppliers in Turkey, Barbados and Singapore, and were tied to counterfeit cancer medication sales in the US.²
- An estimated 100,000 people die each year from counterfeit drugs, a figure that is not limited to medical events from Internet pharmacy sales.³
- Over 20,000 rogue Internet pharmacies documented by LegitScript over the past five years display what may appear to be US and Canadian pharmacy licenses, but are forgeries.

The story of Lorna Lambden, a young London woman pictured in the image to the left, is illustrative of the risk associated with unlawful Internet pharmacies. Ms. Lambden was a paramedic who, due to her irregular work schedule, had difficulty sleeping. The official inquest found that she died as a result of having used prescription sleeping medicines purchased from an Internet pharmacy. This website sold prescription drugs, without requiring an in-person examination by a physician, that were illegally imported into the UK.⁴

The laws, regulations and best practices summarized in this guide are designed to protect patients from such adverse medical events. Registrars and registries play a critically important role in this process, through the implementation of policies disallowing their services from being used by rogue Internet pharmacies.

But what sort of due diligence is required? What sort of behavior is sufficiently egregious to warrant domain name suspension? It is helpful to think of Internet pharmacies as falling into three categories: 1) those that are fully legitimate, 2) those that have minor problems that do not warrant domain name suspension, and 3) those that are classified as “rogue” and put patient safety at risk. This guide is intended to explain what types of conduct make an Internet pharmacy “rogue” and thus serious enough to warrant attention by a domain name registrar.

II. Three Basic Principles of Internet Pharmacy Legitimacy

Note: Throughout this manual, “Internet pharmacies” is intended to refer to websites that facilitate the sale of medicines that are prescription-only in the customer’s jurisdiction. Websites facilitating over-the-counter medicine sales may be considered “Internet pharmacies” in some countries, but this is not a universal rule.

This section outlines a process for registrars to tell whether an Internet pharmacy selling prescription medicine is operating legally or not.

There is a remarkable degree of consistency worldwide on the following three fundamental principles. If an Internet pharmacy is violating any one of the principles below, with rare exceptions explained herein, it is operating unlawfully.

1. **Licensure. Pharmacies need to be licensed or registered where they offer to ship drugs.** *If an entity is shipping drugs to individual patients in Country “A,” it must be licensed as a pharmacy or otherwise registered in Country “A.” Unless it is, it may not ship prescription drugs to Country “A” from Country “B” — even if licensed as a pharmacy in Country “B.”*
2. **Prescriptions. Selling prescription drugs without requiring a valid prescription is unlawful.** *Simply filling out an online form, in lieu of a prior in-person physical examination, is rarely considered an appropriate basis for a valid prescription and is usually illegal.*
3. **Shipping. Drugs must be approved for sale in the jurisdictions where they are shipped to (e.g., Country “A”).** *Prescription drugs imported directly to a patient from another country (e.g., Country “B”) are typically considered unapproved for sale.*

Underlying these three common principles is a fourth universal principle:

4. **Internet pharmacies must comply with the three principles above, not only in the jurisdiction where the merchant is located, but also in any jurisdiction where they offer to ship drugs.**

On the following pages is a short discussion about each legal principle.

1. Pharmacy Licensure Requirement

In the vast majority of countries and territories around the world, any entity shipping drugs to individual customers in a jurisdiction must be licensed, registered or otherwise recognized in the customer’s

There are three basic principles underlying Internet pharmacy legitimacy. With rare exceptions, these are consistent globally.

Internet pharmacies should comply with the laws not only where they operate from, but also anywhere that they offer to ship to.

jurisdiction. (In some but not all jurisdictions, this means that the pharmacy must also be physically domiciled there.)

Reason for the requirement. The practice of pharmacy requires special training and education. There is no “right” anywhere in the world to sell prescription drugs — rather, it is a privilege granted by official licensing agencies. The mission of these agencies is to protect patients in their jurisdiction, so those agencies need to know who is dispensing drugs to patients in that jurisdiction. Licensed entities found to be dispensing drugs in a way that is unsafe, illegal or unethical can be held accountable by those licensing agencies — but those agencies often find that foreign or unlicensed entities are physically “out of reach” and ignore regulatory directives, fines or other discipline.

There’s no “right” to sell prescription drugs, online or offline. In every country, doing so requires special training and certification.

Exceptions. Some jurisdictions have reciprocity with other jurisdictions and thus recognize those other jurisdictions’ licenses. Even so, these non-resident pharmacies will almost always be listed in some official roster.

If a pharmacy offers to ship drugs to an EU member state, that pharmacy is almost always required to be licensed in the destination jurisdiction. This nearly always means that the pharmacy is also domiciled in that EU member state, although exceptions do exist (e.g., Germany, which has registered a few other pharmacies outside of Germany but within the EU).

Is a pharmacy license enough to prove legitimacy? Standing alone, no. Being able to produce a pharmacy license or similar recognition from licensing authorities where an Internet pharmacy offers to ship drugs is an important start. However, it’s not the end of the story. There are three main reasons that merely being able to produce a pharmacy license does not conclusively establish legitimacy:

If an Internet pharmacy offers “worldwide shipping” or shipping to numerous countries, it’s not legally compliant.

1. Without further review, 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, as a practical matter, jurisdiction to respond to complaints and regulate the transaction.
3. Similarly, if the drug transaction does not take place within a single “closed jurisdictional system,” the drug safety authority, such as the US Food and Drug Administration (FDA) or UK Medicines and Healthcare Products Regulatory Agency (MHRA), effectively loses jurisdiction to ensure drug authenticity and safety.



Easy Red Flag #1: If an Internet pharmacy offers shipping to more than one country, it is rarely going to be legally compliant. If an Internet pharmacy offers “worldwide shipping” of prescription drugs, it cannot possibly be legal.



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Drugs Have to Come From Somewhere: Why a Pharmacy License Isn't Enough

True story. The Internet pharmacy airmailchemist.com could provide a real pharmacy license — from Tweens Pharmacy in the United Kingdom. So, airmailchemist.com was legit, right?

No — it was a rogue Internet pharmacy. If you were a customer outside of the UK — and thus outside of the UK authorities' ability to regulate the transaction — Tweens Pharmacy would ship you controlled substance prescription drugs without requiring a prescription via airmailchemist.com. Law enforcement has reported at least one recent death from this website. LegitScript has conducted test buys to confirm the illegality, source of the drugs and lack of a prescription requirement.

After all, when rogue Internet pharmacies sell prescription drugs without a prescription, the drugs have to come from *somewhere* — and sometimes, it's from a real, licensed pharmacy, operating outside of the jurisdiction where it has a valid license, and actually sending drugs from elsewhere or selling prescription drugs without requiring a valid prescription. Although a pharmacy license is a first, necessary step toward establishing legitimacy, standing alone, it isn't enough to establish legitimacy, particularly if it is shipping outside of the jurisdiction where the license is valid or is engaged in other illegal activity.

2. Valid Prescriptions vs. Online Questionnaires

With rare exceptions, just having a doctor review a form filled out by the patient isn't enough, and is considered the same as not requiring a prescription.

Internet pharmacies that sell prescription drugs — any drug designated as requiring a prescription in the customer's jurisdiction — without requiring a prescription operate illegally, even in the occasional cases where the drug can be sold without a prescription in the jurisdiction where the drug is shipped from. With very rare exceptions, a prescription based solely on an online consultation or filling out an online form, without requiring a prior in-person exam by the prescriber, is also considered unlawful.

Reason for the requirement. If a drug is designated as prescription-only, it is because it has been determined to require an enhanced level of medical supervision to be used safely and effectively. (If it can be used without medical supervision, it is designated as an over-the-counter drug.) The requisite level of medical supervision nearly always requires that the prescribing medical practitioner have a real relationship with the patient, which in turn requires that the prescriber have physically examined the patient prior to the prescribing (even if it was several months before).

Exceptions: Within the United Kingdom and in Utah, it is permissible in some circumstances for an Internet pharmacy to fill prescriptions based solely on an online consultation, but only to patients in those jurisdictions. The UK's online consultation scheme is not currently understood to permit the shipment of drugs prescribed solely on the basis of an online questionnaire to other EU member nations, and this service should be limited to customers in the UK. Similarly, in Utah, the prescribing physician and patient should also be in Utah, and other states have taken regulatory action against Internet pharmacies in Utah that have shipped prescription drugs in response to an online questionnaire to patients in other states.



Easy Red Flag #2: With rare exceptions in specific jurisdictions, providing online questionnaires for prescription drugs and dispensing medicines solely in response to such questionnaires is not considered legal or safe medical/pharmacy practice.

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Just Filling Out an Online Form: It's Rarely Considered a Valid Prescription

True story. A number of offshore affiliate marketing programs, such as UltraPayRx, recruit US doctors and pharmacies to prescribe and dispense drugs without requiring the doctor to physically examine the patient, often focusing on addictive pain medication such as Tramadol. These programs promise big payouts to the medical professionals for prescribing and dispensing based only on an online form.

What these programs don't disclose is that the doctors and pharmacists who agree to engage in this practice usually end up finding themselves arrested, indicted or disbarred for the practice (as did pharmacist [Charles Schultz](#) or Dr. [Elias Karkalas](#)) — or their patients dead, as in the case of [Justin Pearson](#). With rare, well-regulated exceptions, simply filling out an online form isn't a valid prescription.

3. Shipping Directly to Patients From Foreign Suppliers

Internet pharmacies may only sell prescription drugs that have been ruled safe and effective by the drug safety agency in their customers' jurisdictions, or that have some legal exemption. Most countries have a publicly accessible list of approved prescription drugs. Links to several countries' approved prescription drug lists are provided in the Appendices to this report.⁵

It is nearly always illegal to import drugs from Country "A" directly to a patient in Country "B" via the Internet.

Prescription Drug Importation. As a general rule, prescription drugs imported from a supplier (including a pharmacy) in one country directly to a patient in another country are considered "unapproved for sale." Thus, Internet pharmacies shipping prescription drugs from Country "B" into Country "A" are generally considered unapproved for sale merely by virtue of being imported.

Reason for the requirement. Drug safety authorities, such as the FDA (in the US), Ministry of Health, Labor and Welfare (in Japan) and the MHRA (in the UK), generally require a "closed supply chain" for prescription drugs, so that authenticity and quality can be monitored from the point of production to the end user. Simply put, when drugs come into a country from elsewhere, the FDA or other regulatory authority loses the ability to monitor and ensure the safety and authenticity of the drugs. (While prescription drugs may legitimately be made in foreign factories, these are inspected and allowed to be part of the supply chain, but only to a limited number of licensed distributors or wholesalers, not directly to a patient.)

Exceptions: There are a few exceptions to this general rule.

There are a very small number of exceptions to this rule, but these are tightly crafted, and Internet pharmacies overtly shipping to other countries do not meet any legal exemption.

- Japan. In Japan, there is an extremely narrow, tightly written exception permitting limited importation into Japan. Registrars should not conclude that this means that prescription drug importation is permitted in Japan, or that Internet pharmacies can import foreign drugs from outside of Japan into the country unrestricted. Indeed, the exception is narrowly written and bans the marketing or promotion of unapproved drugs, essentially making any website that lists those products automatically noncompliant. If an Internet pharmacy is shipping prescription drugs into Japan, the default status is that the website is not legally compliant. LegitScript has observed a total of two websites (under 0.1%) out of thousands shipping prescription drugs into Japan that potentially were in compliance with the importation exception.
- Germany. In the European Union, Germany has licensed some pharmacies in a limited set of other countries such as Iceland, and these pharmacies are permitted to ship prescription drugs to residents of Germany.

An Important Note About the European Union



Recent regulatory developments in the European Union have led to some confusion regarding the legality of an Internet pharmacy shipping drugs from a licensed pharmacy in one EU member state to patients in another member state. In short, the Cross-Border Healthcare Directive (2011/24/EU), which breaks down many barriers to healthcare access within the

EU, explicitly states that individual member nations' regulations pertaining to Internet pharmacies and prescription drug sales are not superseded by the Directive. So, Italy, France and Belgium — just to cite three examples — can ban online prescription drug sales (or require registration), and a pharmacy licensed in the UK cannot argue that it is entitled to ignore Italian, French and Belgian pharmacy licensure and Internet pharmacy laws. **Internet pharmacies in one EU member nation must comply with the laws and regulations in any other EU member nation where they are shipping prescription drugs to.**

The new EU Cross-Border Healthcare Directive still requires EU member nations to respect other EU member nations' laws on Internet pharmacies.

Here, a brief note about intra-EU prescription drug shipments is appropriate. The [Cross-Border Healthcare Directive 2011/24/EU](#) came into force throughout the EU in late 2013. 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 pharmacies to dispense drugs to patients from one EU member state to another in limited cases, provided that the drugs have market authorization in both countries and the pharmacy fully adheres to registration or licensing requirements in all EU countries it offers to ship drugs to. Moreover, Paragraph 11 explicitly states that individual EU member nations' regulations pertaining to Internet pharmacies are not superseded by the Directive. Consequently, no Internet pharmacy may rely on the Directive to argue that a pharmacy licensed anywhere in the EU is automatically authorized to ship prescription drugs anywhere else in the EU.

- [Australia](#). Drug importation into Australia is not specifically banned, although Internet pharmacies shipping into Australia tend to be noncompliant for other reasons. Importantly, any dispensing of a prescription drug requires a prescription issued by a medical practitioner licensed in Australia.
- [Some business-to-business transactions](#). This principle 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. (However, importation in these cases is not unrestricted, and merely being able to provide a wholesaler license in one country in no way establishes permission to import drugs into another country.)

Despite the existence of some exceptions, all of which are tightly crafted, 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 any Internet pharmacy whose drop-down menu of possible shipping locations includes jurisdictions in which the merchant is neither domiciled nor licensed is legally compliant.



Easy Red Flag #3: Rogue Internet pharmacies sometimes state that “it is legal to import up to a 90-day supply of prescription medicines for your personal use in many or all countries,” especially making this claim as to the United States. These claims are simply false.⁶



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A Secure Supply Chain: Why Prescription Drug Importation Is Generally Illegal

True story. Why shouldn't prescription drug importation be legal? After all, if it's a licensed pharmacy in another country, isn't it just as safe — and maybe more cost-effective? Unfortunately, no.

Montana Healthcare Solutions (mthcs.us, now offline) marketed itself as a safe medicines supplier, but in fact was importing counterfeit drugs to doctors and clinics outside of the FDA's approved supply chain. Simply put, the Internet pharmacy business running the operation didn't really know where the drugs came from. One of its principals, [Paul Bottomley](#), pleaded guilty to selling counterfeit cancer medicines — and despite being marketed as alternatively a “Montana” or “Canadian” company, the counterfeit drugs were traced as far back as Egypt, after which the real trail of origin ran cold.

III. Conducting an Investigation

For registrars accredited by ICANN under the 2013 Registrar Accreditation Agreement (RAA), Section 3.18.1 requires the registrar to “(t)ake reasonable and prompt steps to investigate and respond appropriately to any reports of abuse,” including reports of illegal activity. Registries and 2009 RAA registrants may have similar policy requirements or simply wish to adequately investigate allegations of rogue Internet pharmacy activity.

How can complaints regarding rogue Internet pharmacies best be investigated? LegitScript offers a free search tool on our website, legitscript.com, showing whether an Internet pharmacy has been designated as “rogue.” For registrars or registries that want to conduct their own investigation, LegitScript recommends the following steps. (If the complaint has been submitted by LegitScript, we have already conducted the due diligence described below.)

The easiest way to conduct an investigation is simply to require registrants to produce a pharmacy license for each jurisdiction they offer Rx drugs to.

Basic Investigation

LegitScript recommends that registrars take three preliminary steps upon receiving a rogue Internet pharmacy complaint.

1. Where are drugs shipped? Review the drop-down list of countries the website offers to ship drugs to. The Internet pharmacy will need to comply with the laws and regulations in these countries.
2. Does the website require a prescription in those countries? Conduct a brief review of the website to verify it requires a prescription in the countries where the drugs are shipped. Don't just rely on the FAQs: see if you can actually submit an order without having to provide a prescription.
3. Ask the registrant for a pharmacy license in those jurisdictions. Contact the registrant and request that the registrant produce a pharmacy license or other such registration in those countries.

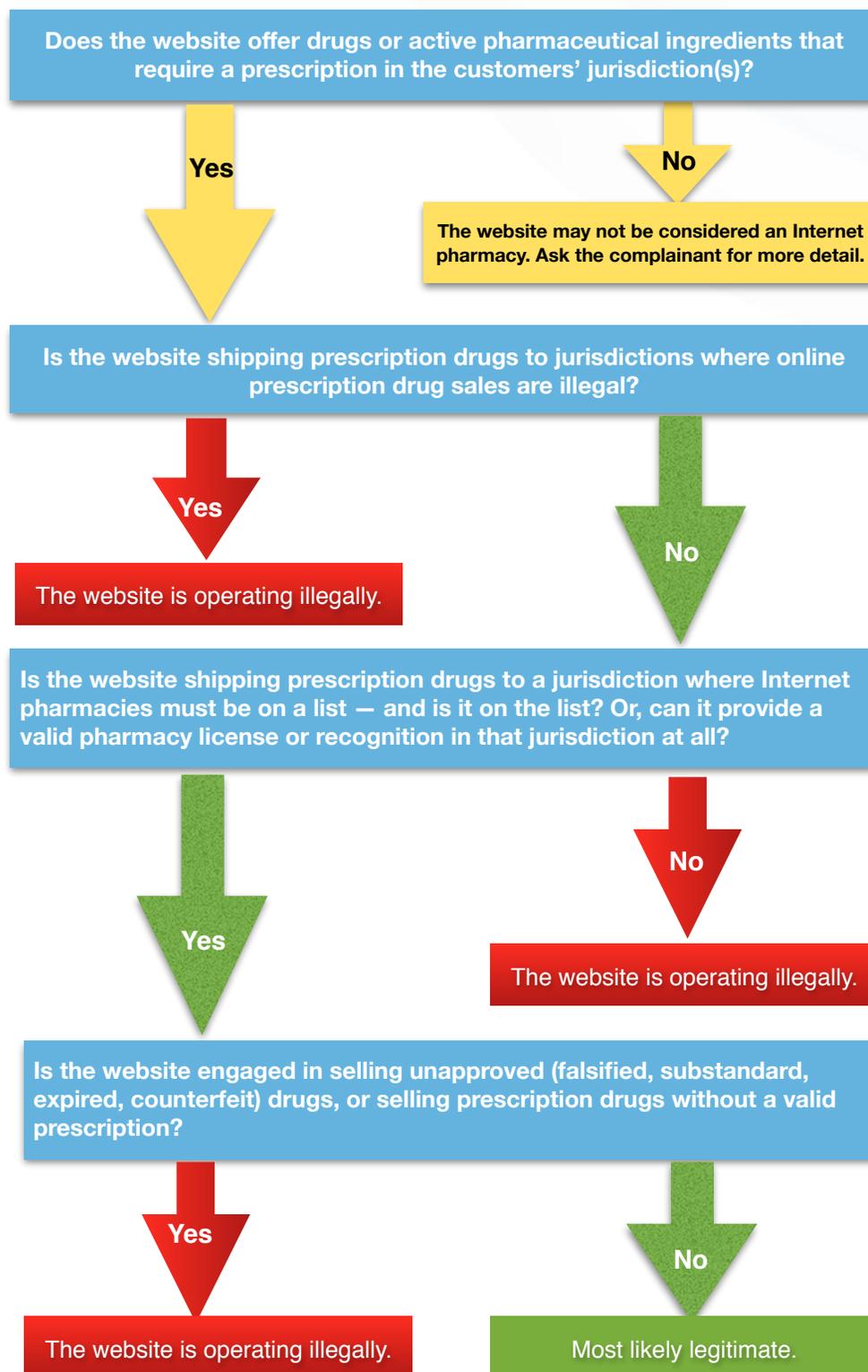
If a registrant cannot provide a pharmacy license or some other recognition in the jurisdictions it offers to ship prescription drugs to, it is not compliant with pharmacy practice requirements.



Some registrars are not comfortable verifying the authenticity of pharmacy licenses. Upon request, LegitScript is happy to verify the validity of the pharmacy license and identify the jurisdictions in where it is valid.

To explain the rationale for this approach, it is helpful to think about which party has the burden to produce information when a complaint is submitted. Certainly, the complainant should be held responsible for providing sufficient information to substantiate the complaint. In the case of Internet pharmacies, however, once the sale of prescription medicines is

established, the onus is on an Internet pharmacy operator to be able to provide a pharmacy license, or legal authorization to dispense prescription drugs. Depending upon the nature of the complaint, it may still be advisable to review other allegations of illegal activity, but requiring the registrant to produce valid pharmacy licensure **in jurisdictions where the website ships drugs to** is a straightforward and simple “shortcut” to the right result.



The graphic above is meant to “make it easy” for registrars and registries. However, the additional points below should be kept in mind.

- Determining whether the drug requires a prescription. The critical question is whether the drug requires a prescription in the customers’ jurisdictions, not in the jurisdiction where the drug is sold from. A list of drug safety authorities’ drug classification databases is provided in Appendix C.
- What if a drug isn’t listed in the drug classification database? If a drug is not listed as prescription-only in a particular jurisdiction, it might be a knockoff version unapproved for sale. For example, Kamagra, Silagra and Lovegra will not be listed as prescription-only drugs by the US or EU drug safety authorities, because the drugs are knockoffs marketed by unlicensed Indian firms and are not approved for sale outside of India. However, they contain prescription-only active pharmaceutical ingredients and are treated as prescription medicines (albeit unapproved, illegal ones).
- OTC Internet pharmacies. Although some jurisdictions consider websites only selling over-the-counter drugs to be governed as Internet pharmacies, this is a minority approach worldwide. However, it is possible that registrars will occasionally receive complaints from regulators about websites illegally selling over-the-counter drugs. Those websites are not the subject of this guide, although LegitScript is happy to answer questions on a case-by-case basis.
- Online prescription drug sales are simply illegal in some jurisdictions. These include Italy, France, Belgium and several other jurisdictions. Please see Appendix C for a more comprehensive list.
- Prescriptions must usually be the result of an in-person examination. With specific, well-known exceptions (e.g., the United Kingdom and Utah), almost all countries prohibit the dispensing of prescription drugs over the Internet solely based on an online consultation, where the patient did not have to visit a doctor.

Merely passing on the complaint to the registrant should not be seen as an investigation. Instead, request that the registrant produce pharmacy licenses where the drugs are shipped to.

Finally, what if you can’t substantiate the illegal activity? Ask the complainant for additional information. For example, in numerous cases, LegitScript is aware that rogue Internet pharmacy operators have “geo-targeted” domain name registrars, making a website look like it is selling shoes or books when accessed from the registrar’s IP address, but actively selling illegal prescription drugs to the rest of the world. Careful complainants will have documented the allegedly illegal activity with screen captures or other proof.

Notifying the registrant. The registrant should, of course, be notified about the complaint and any action you take. Many registrars elect to convey the complaint to the registrant as part of the process. However, some registrars have responded to complaints simply by passing on the

complaint to the registrant and doing nothing further, stating that it is up to the registrant to respond to the complaint.

LegitScript has expressed concern to ICANN that merely passing on a complaint to a registrant, and then conveying the registrant's response back to the complainant, should not be seen as constituting an investigation that meets the requirements of Section 3.18 of the 2013 Registrar Accreditation Agreement. After all, rogue Internet pharmacy operators can be counted on — quite reliably, in fact — to vigorously protest as to their legitimacy. Rogue Internet pharmacies are highly profitable. Individuals and businesses engaged in criminal activity generally do not voluntarily discontinue their illegal conduct merely based on a polite request, or forthrightly concede that their conduct is unlawful. Accordingly, LegitScript recommends utilizing the approach described in this section.

IV. Due Diligence, Due Process and Appeals

If a domain name is used to sell prescription drugs, the onus is on the registrant to produce a valid pharmacy license upon request.

Complainants to a registrar have an obligation to engage in due diligence before submitting a complaint to a registrar. This is for several reasons: to avoid interruption of service to an innocent registrant; to avoid causing inconvenience to a registrar; to protect the registrar (and the complainant) from liability, among others. This section describes LegitScript's process for verifying illegal conduct prior to notifying a registrar.

To put this process in context, it is important to recognize when the "burden of production" shifts from the complainant to the registrant. As explained in the previous section, any entity selling prescription drugs within (or into) a particular jurisdiction is bound to meet certain legal requirements there, the most obvious of which includes pharmacy licensure (or similar legal recognition) by the authorities in that jurisdiction. Without exception, pharmacy licensure is public information and designed for transparency: there is not a single jurisdiction in the world where licensed pharmacies have the right to conceal or not disclose their licensure information. Accordingly, if a complainant establishes that a domain name is used to sell prescription drugs illegally, the onus turns to the Internet pharmacy operator to provide a pharmacy license or similar legal authorization to dispense prescription drugs in that jurisdiction, at a minimum.

LegitScript's Process for Verifying Illegal Online Pharmacy Conduct

LegitScript invites registrars or registries with questions about our process to contact us for more detail.

Step 1

Analyst training. Before being allowed to classify websites as Internet pharmacies, or to append a "rogue" designation to an Internet pharmacy, analysts undergo a minimum of three months of training in the laws and regulations in multiple jurisdictions around the world. Analysts are provided thousands of websites to review and classify and are only "graduated" from the program upon achieving 100% accuracy on a consistent basis. This includes accurately identifying the criminal network that an Internet pharmacy is associated with, in cases where such an association exists.

Step 2

Human-level analysis (first round). LegitScript employs over 35 analysts who review and analyze websites automatically flagged as possible Internet pharmacies. Each analyst conducts three levels of verification:

At least three LegitScript analysts verify that an Internet pharmacy is engaged in serious, egregious criminal behavior before notifying a registrar.

- a. Is the website selling prescription drugs? The analyst is responsible to verify that the drugs require a prescription in the jurisdictions where sold to. If so, the website is flagged as an Internet pharmacy.
- b. Does the Internet pharmacy engage in any of three types of illegal activity? These are the sale of prescription drugs without a valid prescription; the sale of unapproved drugs; or the practice of pharmacy without licensure in the customers' jurisdictions. This is verified via direct interaction with the website. To determine drug approval status, analysts are trained to be familiar with drug approval statuses, and drug import laws, in each country, and to access official drug classification databases as needed.
- c. Rogue vs. unapproved. Usually, Internet pharmacies engaged in only one out of three types of illegal behavior are classified as "unapproved" but not "rogue." Internet pharmacies engaged in two or more types of the three illegal behaviors are classified as "rogue." (As a practical matter, almost all websites designated as "rogue" fail all three criteria.)

The analyst then uploads the website to the database, classified as an Internet pharmacy with the appropriate legitimacy status.

Step 3

Automatic identification of registrar and screen captures. LegitScript's process automatically queries the registrar and collects screen capture and source code evidence.

Step 4

Analyst #2: second-layer review of rogue Internet pharmacies with a particular registrar.
LegitScript's registrar liaison reviews all Internet pharmacies designated as "rogue" that are registered with a particular registrar. The analyst is responsible for conducting a thorough re-review of each and every website to re-verify the illegal activity. Any domain names for which the website content has changed, or for which Analyst #2 is not in agreement, are excluded from further action.

Step 5

Analyst #3: third-layer review of rogue Internet pharmacies with a particular registrar. The list of rogue Internet pharmacies reviewed by Analyst #2 is submitted to Analyst #3 for review. Analyst #3 must independently verify the illegal activity for each website and concur with the rogue designation. Any domain names for which the content has changed, or for which Analyst #3 is not in agreement, are excluded from further action.

Step 6

Senior/management-level verification. The final list is submitted to senior-level management for final review and approval before submission to the registrar for action. Any domain names for which the website

content has changed, or for which the senior-level analyst is not in agreement, are excluded from further action.

The most serious health violations are the sale of prescription drugs without a prescription, the sale of unapproved drugs, and the practice of pharmacy without required licenses.

LegitScript does not normally contact rogue Internet pharmacy registrants first to engage in a dialogue about the registrant's activity or offer any warning — indeed, LegitScript's position is that this is a counterproductive practice.

The first reason for this is that LegitScript designates an Internet pharmacy website as “rogue,” and reports it to a registrar, if the behavior is so egregious, and obviously illegal, that the criminal conduct can easily be verified on the face of the website. Put a different way, if there were any reasonable question about the website's legality, LegitScript would not designate it as rogue in the first place and it should not be reported to a registrar. (It might garner an “unapproved” designation, but we do not report these to registrars.) In other words, only “slam dunks” should be reported to registrars, and LegitScript defines those as websites for which the illegal drug activity is patently, and easily verifiable, on the face of the website itself. If there is any reasonable question whatsoever about the legality, a registrar should not receive a complaint about it.

Second, it is important to remember where the “burden of production” lies regarding allegations involving illegal online drug sales. At first, the complainant has the burden of showing that the domain name is used to sell prescription drugs illegally. However, once that is established, the onus is on the Internet pharmacy operator to produce appropriate licensure upon request, at a minimum. Furthermore, the burden is not on the complainant — or, the registrar or registry, for that matter — to warn a registrant or serve as their compliance advisor.

No matter what conduct is alleged, registrant rights should be protected via an appeals process.

Third, rogue Internet pharmacies are highly motivated to continue illegal drug sales, which are highly profitable. On the few occasions in which LegitScript has been in contact with a registrant prior to enforcement, or the registrar warns a registrant, there was a high rate of the registrant simply transferring the domain name to another registrar, or temporarily taking the website offline for a week or two or temporarily displaying other content. Ultimately, this turns into a cat-and-mouse game that puts patients at risk once the registrant feels that they are again “safe” to resume drug sales.

LegitScript's process is designed to return zero false positives, and to the best of our knowledge, LegitScript has never submitted an Internet pharmacy complaint to a registrar in error. Nevertheless, as a matter of due process, it is important to offer registrants a right to appeal — the process for which is described in the next section.

LegitScript Appeals Process

LegitScript offers a free appeals process for domain name registrants whose domain names have been suspended for operating a rogue

Internet pharmacy. This is an entirely free service at no cost to the registrant or to the registrar.

The process is simple: any Internet pharmacy operator whose domain name was suspended is invited to provide a copy of their pharmacy license to LegitScript and, as necessary, the license of the medical practitioner. (The pharmacy license alone does not establish legitimacy, but is merely a first step.) LegitScript works directly with the licensing authorities to verify pharmacy and medical practitioner licenses. Upon verification of the pharmacy and/or practitioner license in all legally required jurisdictions (typically, anywhere that the drugs were offered to be shipped to), LegitScript will thereafter re-review and work with the registrant to evaluate the nature of the registrant's conduct, such as the sale of prescription drugs without a prescription.

LegitScript places a high premium on "getting it right," and in any case where we recommend suspension of a domain name to a registrar, we already know of and have established the illegal conduct and absence of appropriate pharmacy licensure. In over 50,000 rogue Internet pharmacy suspensions originating from a LegitScript abuse notification, no registrant has actually provided the required pharmacy licensure documents.

Despite that, LegitScript is committed to continuing to provide an option for registrants to appeal our notifications. Results are conveyed to registrars upon request.

V. To Suspend...or Another Resolution?

Once a registrar has verified a violation, how should the registrar respond? Different registrars take different approaches. LegitScript offers the following recommendations for consideration, particularly as to when it is appropriate to suspend and lock a domain name.

The following tables are meant to demarcate behavior that LegitScript recommends result in termination of the relationship and suspension of the domain names, from behavior that is generally considered “fixable.” In the table below, any one of the listed behaviors should be considered sufficiently egregious as to warrant suspension of the domain name. Generally, however, LegitScript’s alerts are predicated on most or all of the first four of the five categories.

Behavior warranting termination	Exception
Failure to require a valid prescription. 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) such as the UK.
Unlawful importation of drugs.	There are very narrow exceptions to prescription drug importation bans that exist in most countries.
Failure to maintain pharmacy licenses or registration in jurisdictions where 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: if, for example, a dispensing pharmacy is licensed nearly everywhere required and a license appears to have inadvertently lapsed.
Sale of unapproved drugs.	Some compounded drugs fall outside of the scope of drug approval requirements. A small number of drugs that have not been reformulated since before the 1960s in the US have either been “grandfathered in” to legal compliance or are tolerated by the FDA, despite not being reviewed by the FDA. The same is true in other countries.
Use of website for phishing, spam or other malicious behavior.	Credible information indicating that the registrant lost control of the domain name, which was hacked or hijacked (and confirmation that the domain name has returned to the registrant’s control).

By contrast, some types of behavior that constitute regulatory violations — and, of course, Internet pharmacies should be encouraged to fix this behavior — may not warrant terminating the

business relationship or suspending the domain name, without other factors. Domain names used only for the following type of conduct are not the subject of LegitScript notifications to registrars or registries.

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 full contact information on website for dispensing pharmacy.	This is a legal requirement in some jurisdictions, and providing full contact information for the pharmacy is highly encouraged in the event of an adverse reaction.

Additionally, much of the decision whether to recommend suspension of a domain name used for the illegal sale of prescription drugs should be based on whether the illicit activity is intrinsically dangerous to human health. The most common, and easily verifiable, illegal and dangerous conduct is the facilitation of the sale of prescription-only medicines without requiring a valid prescription.

VI. What Registrants Tell You: Untangling Truth From Fiction

Registrants using a domain name to sell prescription drugs may strenuously claim that they are legitimate and operating legally, even hiring an attorney to write a letter attesting to the website's legitimacy. You may even receive what appears to be a valid pharmacy license (and indeed, it may be valid ... or, it could be forged). There are, of course, legitimate Internet pharmacies, too — so, how can you, the registrar, know when the registrant is telling the truth and is legitimate, or is not being truthful?

- Maintain a basic familiarity with what's legal and what's not. Registrars and registries can't be expected to become experts in this field. But most of these principles are fairly straightforward: you can't sell prescription drugs without a valid prescription, and you usually need a pharmacy license in jurisdictions you ship drugs to.
- Ask LegitScript. We're here to help. We have no interest in shutting down legitimate Internet pharmacies. And except when we pass on information from a government agency or INTERPOL, we are not acting on anybody's behalf. It's a public service based on public health risk. There's absolutely zero benefit to us in requesting suspension of an Internet pharmacy that's actually operating legally. We'll always tell you — for free — why we designated an Internet pharmacy as “rogue,” and walk through the applicable laws and regulations.
- Be cautious about relying on letters from attorneys. Relying upon letters from an attorney hired by the registrant to attest to the website's legitimacy is problematic for two reasons. First, attorneys usually can only attest to what's legal in their own jurisdiction, which may be where the pharmacy is physically operating from, but not the laws and regulations where the Internet pharmacy is actually shipping drugs to. Second, attorneys are being paid to issue the letter: you aren't their client, and they don't have an ethical obligation to give you, the registrar, helpful advice and look out for your interests. They are being paid to make the best argument they can for their client, the registrant.

Moreover, be cautious about the following arguments that registrants may make.

- “I have a pharmacy license (or export license) in _____, and therefore, I'm operating legally.” A pharmacy license only authorizes the practice of pharmacy in that jurisdiction. A

pharmacy or export license in India simply has no bearing in the United Kingdom, Japan or the United States.

- “I’m only the affiliate marketer (or website operator), not the drug supplier.” This doesn’t matter: the domain name is being used to facilitate unlawful activity.

Requesting a pharmacy license in any country where the registrant seeks to ship prescription drugs to is typically a reliable first step, followed by verification of the license. Despite what a registrant (or their attorney) might argue, a website shipping prescription drugs into a particular jurisdiction without a pharmacy license or registration there, or selling prescription drugs solely based on an online form without requiring an in-person doctor’s examination, will generally not be operating legally in those jurisdictions.

Conclusion: Four Things Registrars/Registries Can Do (and How LegitScript Can Help)

Registrars and registries play a critical role in the Internet ecosystem, and in the security and stability of the Internet generally. As a registrar or registry, here are four things that you can do to help fight the rogue Internet pharmacy problem.

1. Update Your Terms and Conditions. Be specific. Whether you use the model Terms and Conditions in Appendix A or something different, clearly let your users know that your services may not be used by rogue Internet pharmacies.
2. Develop Internal SOPs. If you are a registrar or registry and receive a Section 3.18 complaint, what will your process be? Internet pharmacy compliance isn't all that complicated, but you should develop standard operating procedures. The information in this guide (e.g., require production of a pharmacy license in the registrant's website's customers' jurisdictions) can serve as a starting point.
3. Maintain a "hot list" for review. As a registrar, you shouldn't be expected to actively monitor your customers' domain names. But some registrars maintain a "hot list" of terms that, when found in a domain name, flag the website for periodic review. Examples would be "pharmacy," "viagra," "no-prescription" or "tramadol."
4. Ask LegitScript. We're here to help. LegitScript is a for-profit business, but we currently work with registrars on a *pro bono* basis. Ask us for a free list of rogue Internet pharmacies registered with your company (if any): we'll provide the list; a short explanation of why each is egregiously illegal; and stand with you throughout the review and compliance process.

How to Contact LegitScript. LegitScript values our relationship with registrars and registries. Our multilingual staff hail from over 15 countries, and we work with registrars all over the world. At present, we do not charge registrars for assistance but provide assistance on a *pro bono* basis. (In the interests of full disclosure, we may offer enhanced paid services for registrars, registries and the hosting community at some point in the future.)

LegitScript can be reached at:

URL: legitscript.com

email: abuse.team@legitscript.com

Tel: 877 534 4879

Mail: 818 SW 3rd Ave. #353

Portland, Oregon 97204 USA

Appendix A(1): Model Abuse Policy — Option 1 (For Registrars Using LegitScript)

Definitions.

An “Online Pharmacy” means a website that sells or facilitates the sale of drugs (e.g., prescription medicines).

“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.

“Notices” means any and all notices as provided by LegitScript.

Abuse Policy.

Domain names registered with [REGISTRAR] may not be used to 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; operating without required pharmacy licenses; and the selling of unapproved drugs (e.g., falsified medicines, counterfeit drugs or drugs unapproved for sale). Where [REGISTRAR] is of the reasonable opinion, or receives notice from LegitScript that a domain is violating the applicable laws, then the domain will be suspended pending full investigation.

Domain Name Suspension.

[REGISTRAR] may SUSPEND and PERMANENTLY lock online pharmacy domains that appear in breach of our ONLINE PHARMACY POLICY without prior notification to you. Suspended online pharmacy domain names will remain locked and CANNOT be transferred away to another registrar until and unless [REGISTRAR] investigations are completed to their satisfaction and [REGISTRAR] is of the reasonable opinion that there is no breach, or where LegitScript notifies [REGISTRAR] that the domain name is no longer classified as operating in violation of this section.

Sole Responsibility.

It is your sole responsibility to be familiar with, and ensure that your website complies with, Applicable Laws. You agree that marketing prescription drugs to a jurisdiction despite not being appropriately licensed to dispense prescription drugs there, or selling drugs online in a way that does not comply with Applicable Laws, constitutes fraud and is a violation of this agreement.

Indemnification.

You hereby agree to indemnify and hold [REGISTRAR] harmless from any and all loss occasioned by you as a result of [REGISTRAR] suspending your domain name. You also agree to indemnify and hold [REGISTRAR] harmless from any complaints or claims made against you by third parties and any loss that occurs due to any third-party claims. Further, you hereby agree to indemnify and hold [REGISTRAR] harmless if LegitScript designates a domain name you have registered as operating in violation of this section.

Appendix A(2): Model Abuse Policy — Option 2 (General)

Definitions.

An “Online Pharmacy” means a website that sells or facilitates the sale of drugs (e.g., prescription medicines).

“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.

Domain names registered with [REGISTRAR] may not be used to 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; operating without legally required pharmacy licenses in the jurisdictions where drugs are offered to be shipped to; and the selling of unapproved drugs (e.g., falsified medicines, counterfeit drugs or drugs unapproved for sale). Where [REGISTRAR] is of the reasonable opinion that a domain is violating the applicable laws, then the domain will be suspended pending full investigation.

Domain Name Suspension.

[REGISTRAR] may SUSPEND and PERMANENTLY lock online pharmacy domains that appear in breach of our ONLINE PHARMACY POLICY without prior notification to you. Suspended online pharmacy domain names will remain locked and CANNOT be transferred away to another registrar until and unless [REGISTRAR] investigations are completed to their satisfaction and [REGISTRAR] is of the reasonable opinion that there is no breach.

Sole Responsibility.

It is your sole responsibility to be familiar with, and ensure that your website complies with, Applicable Laws. You agree that marketing prescription drugs to a jurisdiction despite not being appropriately licensed to dispense prescription drugs there, or selling drugs online in a way that does not comply with Applicable Laws, constitutes fraud and is a violation of this agreement.

Indemnification.

You hereby agree to indemnify and hold [REGISTRAR] harmless from any and all loss occasioned by you as a result of [REGISTRAR] suspending your domain name. You also agree to indemnify and hold [REGISTRAR] harmless from any complaints or claims made against you by third parties and any loss that occurs due to any third-party claims.

Appendix B: Commonly Marketed Unapproved Drugs (Sample List)

Drug Name	Unapproved	Notes
Anazole	US, Canada, EU, Japan, China, most other locations	This product is an unapproved drug and an unlawful form of anastrozole in most countries.
Bimat	US, Canada, EU, Japan, China, most other locations	This product is an unapproved drug and an unlawful form of Lumigan in most countries.
Black Cialis	US, Canada, EU, Japan, China, most other locations	“Cialis” is an approved drug in most locations, but “Black Cialis” is not an approved form of Cialis.
Boldebolin	US, Canada, EU, Japan, China, most other locations	This product is an unapproved drug and an unlawful form of boldenone in most countries. Boldenone is an anabolic steroid.
Careprost	US, Canada, EU, Japan, China, most other locations	This product is an unapproved drug and an unlawful form of Lumigan in most countries.
Filagra	US, Canada, EU, Japan, China, most other locations	This product is an unapproved drug and unlawful form of Viagra in most countries.
Finpecia	US, Canada, EU, Japan, China, most other locations	This product is an unapproved drug and an unlawful form of Propecia in most countries.
Kamagra	US, Canada, EU, Japan, China, most other locations	This product is an unapproved drug and an unlawful form of Viagra in most countries.
Nandrolin	US, Canada, EU, Japan, China, most other locations	This product is an unapproved drug and an unlawful form of nandrolone decanoate in most countries. Nandrolone is an anabolic steroid.
Reduce-15mg	US, Canada, EU, Japan, China, most other locations	This product is an unapproved drug and an unlawful form of sibutramine in most countries.
Reductil	US, Canada, EU, Japan, China, most other locations	Reductil is a brand name for sibutramine, a Schedule IV controlled substance that has been withdrawn from the market in several countries, including the United Kingdom and the US.
Retino-A	US, Canada, EU, Japan, China, most other locations	This product is an unapproved drug and an unlawful form of Retin-A in most countries.
Sibutril	US, Canada, EU, Japan, China, most other locations	This product is an unapproved drug and an unlawful form of sibutramine in most countries.
Silagra	US, Canada, EU, Japan, China, most other locations	This product is an unapproved drug and an unlawful form of Viagra in most countries.
Slimex 15mg	US, Canada, EU, Japan, China, most other locations	This product is an unapproved drug and an unlawful form of sibutramine in most countries.
Testobolin	US, Canada, EU, Japan, China, most other locations	This product is an unapproved drug and an unlawful form of testosterone enanthate in most countries. Testosterone is an anabolic steroid.
Viagra Professional Cialis Professional Levitra Professional	Everywhere.	“Viagra,” “Cialis” and “Levitra” are approved drugs in most locations, but not with “Professional” after their name.

¹ <http://sankei.jp.msn.com/life/news/110707/bdy11070720570002-n1.htm>
<http://www.irishexaminer.com/ireland/internet-drugs-linked-to-deaths-158146.html>
<http://www.dailymail.co.uk/news/article-1388795/>

² <http://online.wsj.com/news/articles/SB10001424052702303879604577410430607090226>

³ <http://www.businessweek.com/articles/2013-01-17/inside-pfizers-fight-against-counterfeit-drugs>

⁴ <http://www.dailymail.co.uk/news/article-1388795/>

⁵ There can be some complexity to the drug approval requirement. For example, in the US, many compounded prescription drugs are not technically FDA-approved but are nevertheless legal and exempted from the normal FDA-approval requirement. Consequently, LegitScript does not recommend that registrars base compliance decisions solely on a specific drug not being approved for sale, without expert input from a drug safety regulator, LegitScript or another source, or without violation of another one of the two principles above.

⁶ See, e.g., for the United States, <http://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm>.