

Pharmaceutical Guidelines Overview

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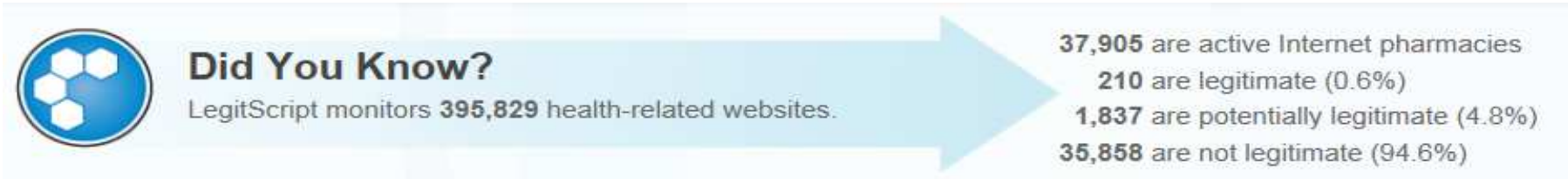
VISA

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Online Pharmaceuticals

Why the focus?



Did You Know?
LegitScript monitors **395,829** health-related websites.

37,905 are active Internet pharmacies
210 are legitimate (0.6%)
1,837 are potentially legitimate (4.8%)
35,858 are not legitimate (94.6%)



INTERPOL
CONNECTING POLICE FOR A SAFER WORLD

22 May 2014

Thousands of illicit online pharmacies shut down in the largest-ever global operation targeting fake medicines...Nearly 200 enforcement agencies across 111 countries have taken part in Operation Pangea VII. . . 237 arrests worldwide and the seizure of nearly \$365MM worth of [drugs]

The Washington Post 15 April 2014

*Google faces new pressure from states to crack down on illegal online drug sales
Several state attorneys general are pressing Google to make it harder for its users to find counterfeit prescription medicine and illegal drugs online, marking the second time in the past three years that the firm has drawn government scrutiny for its policies on rogue Internet pharmacies.*

THE WALL STREET JOURNAL. 29 March 2013

*UPS to Settle Web Pharmacy Case
United Parcel Service agreed to forfeit \$40 million to settle a probe into its shipments on behalf of illicit online pharmacies, federal prosecutors said. . .
The deal was the latest move in the U.S. government's [DOJ] expanding crackdown on illegal sales of prescription painkillers. More than 16,000 people died of opioid overdoses in 2010, according to the Centers for Disease Control and Prevention.*

- Increased Government focus on pharmaceutical merchants
- Visa has:
 - Joined the Center for Safe Internet Pharmacies (CSIP)
 - Engaged **LegitScript** to identify rogue pharmacy networks
 - Participated in Operation Pangea (I-VII)
 - Created the new Online Pharmacy Guide for Acquirers



What are the rules for Internet Pharmacy Merchants?

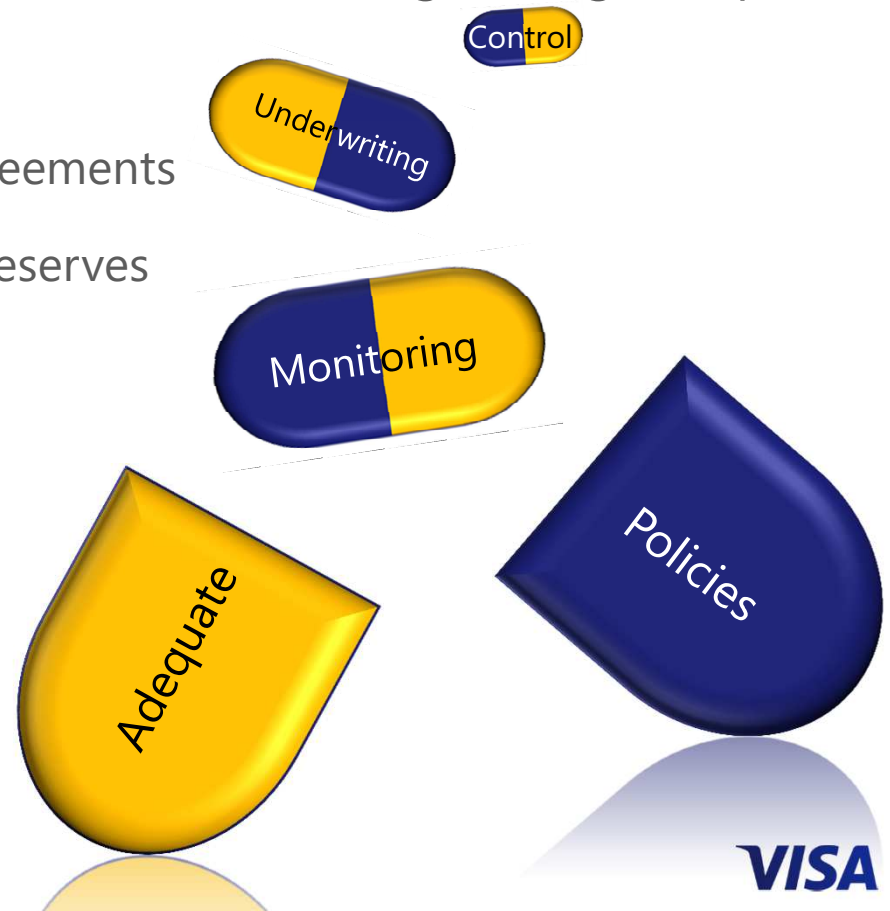
Visa International Operating Regulations

- Requirements
 - Clients must comply with applicable laws or regulations
 - Transactions must be legal in both the buyers and sellers jurisdiction
- Ineligible Payment Facilitator (PF) Merchant Type
 - PF are prohibited from providing payment services to an internet pharmacy
- High-Brand Risk (HBR) Acquirer Registration Requirement
 - Acquirers with merchants utilizing MCC **5912** “Drug Stores, Pharmacies” and **5122** “Drugs, Drug Proprieties, Druggist Sundries” must have a HRB license.
 - Acquirers not possessing a HRR acquiring license must apply for and be granted a license from Visa prior to submitting any High-Brand Risk Transactions into the Visa payment system.

Underwriting Internet Pharmacy Merchants

What is required?

- Acquirers must ensure all their operations comply with the *Visa International Operating Regulations* and the minimum standards described in the *Visa Global Acquirer Risk Standards Guide*, including having adequate policies as they relate to:
 - Merchant underwriting practices and agreements
 - Holding and controlling of funding and reserves
 - Merchant monitoring practices
 - Merchant education and training





Internet Pharmacy Merchants

Underwriting and Oversight
John Horton, President and Founder

A quick introduction

Merchant Monitoring

LegitScript maintains the world's largest list of online healthcare merchants, such as Internet pharmacies, supplement and other drug merchants organized by legitimacy and country.

We work in over a dozen languages.

Wide coverage

LegitScript works with numerous companies and government entities on a global basis.

We collect extensive data about rogue drug websites, networks and merchants...

Pharma-crime analysis.

...resulting in in-depth analyses.

LegitScript is endorsed by the National Association of Boards of Pharmacy and has formal or informal relationships with multiple regulatory agencies around the world.

Trusted by regulators



When is a merchant 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*.
- In some jurisdictions, but not all, websites selling OTC drugs are also regulated as Internet pharmacies.

* Source: LegitScript



Internet Pharmacies: A Market Overview

- About 25,000 – 42,500 Internet pharmacies active at any one time
- Worldwide, an average of 97% of Internet pharmacy websites are illicit; 3% of websites operate lawfully
- Measured by merchant, probably 2/3 are illicit; 1/3 are legitimate
- Counterfeit drug market estimated at \$75b annually

* Source: LegitScript data

What Makes an Internet Pharmacy Illegal?

A “rogue” Internet pharmacy sells prescription drugs in a way that violates drug and patient safety laws and regulations where the drugs are dispensed from or where they are offered to be shipped to. For example:

- Selling prescription-only medicines without a valid prescription.
- Selling unapproved, adulterated, misbranded or counterfeit drugs
- Lacking a required pharmacy licenses in the jurisdictions it ships drugs to.
- Engaging in fraudulent or deceptive business practices.

The screenshot shows a web browser window displaying the website 24medstore.com. The page features the logo for 'CANADIAN Health&Care Mall' and a navigation menu with links for 'ALL PRODUCTS', 'ABOUT US', 'HOW TO ORDER', 'TESTIMONIALS', 'FAQ', and 'CONTACTS'. A banner advertisement for 'CIALIS + VIAGRA MEN'S POWER CHARGE' is visible. The main content area displays a green-bordered license from the 'PROVINCE OF ONTARIO COLLEGE OF PHARMACISTS OF ONTARIO'. The license details include an issue date of 10/01/2011 and a license number of 02724941. The licensee is identified as 'Canadian Health & Care Mall, 186, Brock Street, Kingston, ON, Canada'. The license is signed by Bart Warren, the issuer, and expires on January 10, 2015. The license text states: 'The company named herein is licensed to resell drugs from the issue date and through the expiration date. This license is not transferable to any other person or company. The licensee is required by Law to notify immediately the College of Pharmacists of Ontario of any changes in the information reported in the Application.'



LegitScript

Fundamentally About Public Health



Medical student died after taking banned weight loss drug bought online



Tag: Leeds University medical student Sarah Houston

A medical student with bulimia and depression died after taking a banned weight loss drug bought on the internet.

Troubled Sarah Houston, 23, who was found dead in her bedroom by a flatmate, had been seeing a psychiatrist for three years.

She was prescribed anti-depressant Fluoxetine, but had been secretly taking fat-burning DNP in secret alongside her medication.

The drug, popular with bodybuilders, is a chemical pesticide and highly toxic.

It was first used to treat obesity around 80 years ago before being banned because of its dangerous side effects.

Following Sarah's death, 62 capsules of DNP were found in her bedroom and 38 capsules from the packet were missing.

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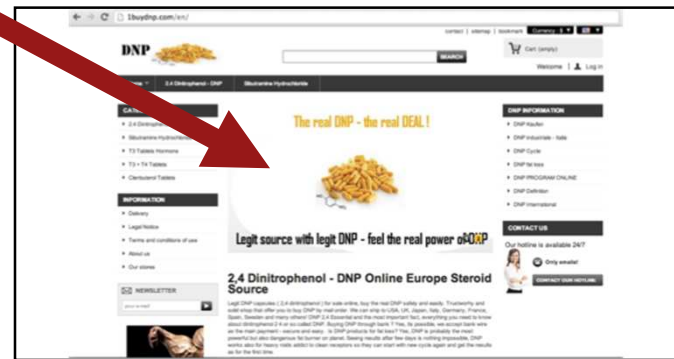
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"While the FSA has banned this drug from human consumption, its risks are not widely known and it does not seem to affect the ease at which it can be bought from the internet.

Accessible at ["1buydnp.com"](http://1buydnp.com)



How can we tell who is legitimate?

*Three primary (but not the only!) rules applicable globally**

1. An entity selling prescription drugs usually must be licensed as a pharmacy or otherwise recognized by the jurisdiction where they ship drugs to.
2. Shipping drugs from one country directly to an individual customer in another country is usually unlawful.
3. Simply filling out an online form in lieu of requiring a prescription based on a physical examination is usually unlawful.

* Every rule has exceptions. But these exceptions are minor and infrequent. A merchant whose business model is based on transactions that regularly violate one or more of the principles above is almost certainly non-compliant.



LegitScript

It's a Global Internet!

The Basic Rule:

Even 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, just as if the merchant were physically located in that country and subject to that jurisdiction's laws and regulations.

1. Prescription Requirement

Prescription-only: Medicines, treatments, medical devices or other healthcare products that the relevant healthcare authorities have determined require medical supervision to be used safely and effectively.

Pharmacy-only healthcare product: Do not necessarily require a prescription, but can only be sold at and by a licensed pharmacy.

Over-the-counter: 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 in the label.



2. Pharmacy Licensure

- If offering to ship drugs into a particular jurisdiction, a dispensing pharmacy must usually be licensed in that jurisdiction.
- Some jurisdictions have reciprocity or other recognition for a foreign pharmacy, but this an infrequent exception to the rule.
- Merely because a merchant can provide a pharmacy license does not mean that the drugs are really sourced from that location.

But hey, it's Canadian!

onlinepharmaciescanada.com

ONLINE PHARMACIES CANADA

HOME CHECKOUT PLACE AN ORDER

Check

Medication	Quantity	Price
Lipitor 20mg	16 Tablet	\$182.91
Lipitor 20mg	90 Tablet	\$71.85
Nexium 20mg	100 Delayed	\$53.27
Plavix 75mg	84 Tablet	\$84.42
... 0.025mg	90 Tablet	\$30.65
... mg	32 Tablet	\$325.62

3-in-1 GUARANTEE

Identity Theft Protection

Purchase Guarantee

Lowest Price Guarantee

SHOP WITH EASE

SHOP WITH CONFIDENCE

QUESTIONS?



3. Violating Drug Importation Rules

Prescription drugs imported from a supplier (including a pharmacy) in one country directly to a patient in another country are usually considered unapproved for sale.

Thus, Internet pharmacies shipping drugs from a supplier in one country to patients from another country usually operate illegally.



RECAP: Core Principles of Internet Pharmacy Legitimacy

1. Websites that allow customers to acquire a prescription drug based solely on an online form or questionnaire are usually illegal (even if the drug is not a controlled substance).
2. Pharmacies usually must be licensed or otherwise legally recognized in any jurisdiction where they offer to ship or dispense drugs.
3. It is typically 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.

Watch Out For:

Since there are high levels of profitability associated with illicit medicine sales online, rogue Internet pharmacy merchants are highly motivated to falsely appear legitimate to acquirers

Watch out for:

- Internet Pharmacy Affiliate Marketing Networks
- Geo-targeting
- “Comfort Letters” from Lawyers
- Bait and Switch
- Irrelevant or “International” Pharmacy Licenses
- False Customer Base
- Fake FAQs



Questions?

The following questions were submitted by webinar attendees

Q: I'm a US acquirer and I've registered all of my pharmacy merchants with Visa per the US requirement. Do I need to worry about those registered merchants potentially being rogue and if so what should I do or what can Visa do to help me identify these?

A: Yes, just because a merchant is registered as a High Brand Risk Merchant does not mean that the merchant is exempt from continual monitoring. All Card-not-present (CNP) pharmaceutical merchants should be regularly monitored for legitimacy. Validating merchants against the LegitScript database on a regular schedule is recommended.

Note: A \$500 per year fee is assessed for each registered HBR Merchant. The deadline for this yearly fee is September 12, 2014. Re-validating all current HRB merchants and prior to this date is recommended to avoid the charge for rouge merchants who may be subject to termination after Visa's HBRM yearly audit.

Q: Shouldn't the conditions you mentioned apply to any form of pharmacy sale - not just website but also phone orders?

A: Yes, these conditions apply to all CNP transactions

Q: We are a US acquirer and the majority of our merchants that operate as an internet pharmacy are tied to an existing Brick and Mortar (B&M) account. Since it's coupled with a B&M would you feel more comfortable with the merchant?

A: Not necessarily; we have seen instances where an Internet pharmacy network is operated, or directly tied, to a B&M pharmacy. After all, when a rogue Internet pharmacy ships drugs without a prescription, the drugs must come from somewhere, and sometimes, it is a real, licensed pharmacy engaged in illegal online distribution.

Q: What is a recommended source to know if a drug is prescription only or not?

A: For the US: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>. Several other countries' lists are provided in the acquirers' guide

Q: What about Closed Door Pharmacies?

A: They should still be measured under the same three principles. Again, we have seen examples of Closed Door Pharmacies having ties to illicit online sales.

Questions?

The following questions were submitted by webinar attendees

Q: If a pharmacy is taking orders through any channel, but processing via web terminal, is that an Online pharmacy?

A: Generally, yes. If a customer is advertised to in some method (email, phone call, etc.) but directed to a website to fill out billing information, than that would constitute an Internet pharmacy.

Q: Is a pharmacy license required in every state a merchant ships to, or just the state they ship from?

A: Generally, yes. In the US, there are only two exceptions that offer reciprocity with pharmacy licenses from other states: Pennsylvania and Massachusetts. Some states permit a very small number of shipments from licensed pharmacies in other states. However, as a general rule, if a merchant is offering to ship prescription drugs into a particular state, they are considered to be practicing pharmacy in that state and must be licensed there.

Q: If a merchant application shows a VIPPS or other type of certification? How do I know it is real?

A: Check the VIPPS list on NABP: <http://www.nabp.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy/>. Make sure to check that the domain is spelled correctly, as we have seen instances of an Internet pharmacy domain name with only one letter difference in an attempt to fool the acquirer.

Q: It seems that most online pharmacies are questionable or rogue. Should I be in this area at all?

A: While it is a risky area, legitimate online pharmacies serve a very valuable purpose for consumers. We estimate that roughly one-third of pharmacy merchants are legitimate. As this is, globally, nearly a trillion-dollar market (prescription drugs generally), we believe that there is a place for online healthcare, provided that it is safe and legal in the merchant's and cardholder's jurisdiction.

Questions?

The following questions were submitted by webinar attendees

Q: What are the guidelines for nutraceutical sales?

A: Please contact LegitScript for more details, but we do maintain a publicly available list of unproved and rogue products in this space. One core aspect is that a nutraceutical (dietary supplement) is illicit if it contains active pharmaceutical ingredients which are prescription only. There are also issues with false claims of curing, mitigating, or preventing diseases that need to be considered.

Q: Does LegitScript provide accreditation for online pharmacies that do not accept payment through their websites (ie: payment conducted over the phone)

A: Not at this time, although our program may be expanding to include these merchants.

Q: If a potential online pharmacy merchant provides a legal opinion letter from the pharmacy's attorney stating that the pharmacy is following all the necessary laws, can we rely on that legal opinion letter?

A: No. A lawyer may draft that letter under the assumption that the pharmacy is only distributing medications in the area it is licensed. Additionally, we have seen instances where lawyers are directly involved in the ownership or management of an illicit Internet pharmacy.

Q: What is your view on compounding manufacturers shipping to individuals based on a doctors prescriptions? or to doctors are they considered prescription/pharmacy?

A: At a minimum, all of the same guidelines apply. In the US, compounding pharmacies actually have increased regulations. But there are legitimate and illicit compounding pharmacies — it is a practice that is not inherently illegal or unsafe.

Q: Does LegitScript provide any information to Physicians? I had a Dr. suggest using Canadian pharmacy for expensive prescriptions.

A: This is a recurring problem. Yes: LegitScript is actively engaged in outreach to medical professionals, through processes such as continuing medical educational credits. Some physicians, presumably well-meaning, have recommended "Canadian" Internet pharmacies without actually realizing that the drugs are not really from Canada in most cases and are illegal.

Questions?

The following questions were submitted by webinar attendees

Q: Do the same core principles of internet Pharmacy Legitimacy apply to an animal pharmacy?

A: Yes, as pet medications have the same prescription guidelines as human medications.

Q: If I have a portfolio of merchants that I'm not sure contains pharmaceutical merchants how should I go about figuring that out. . Can you help?

A: We can absolutely help, and would be happy to do so. Drop us a note via our contact form at legitscript.com.

Q: What steps should I take if I get a legal letter that I'm not sure of?

A: In general, please be cautious of such letters, as LegitScript has observed multiple situations in which a legal letter is inaccurate or falsely claims that an online pharmacy operates legally, when it is not legal. LegitScript would be happy to review and offer a objective assessment.

Q: Are there websites I can reference that detail shipping laws?

A: We assume that your question pertains to prescription drug importation. Some information is available on the rules for each country in the acquirers' guide. However, there is no third-party website we are aware of that provides consolidated laws and rules for each country — you generally have to look at each country's laws.

Additional Questions?

If you have any additional questions please contact:

Elizabeth Scofield
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To validate a current or potential pharmacy merchant
www.legitscript.com

Thank you

